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US Oncology

October 9, 2006

HAND DELIVERED

The Honorable Mark McClellan, M.D., Ph.D.
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **CMS-1321-P**

Dear Dr. McClellan:

US Oncology[1] would like to thank you for the opportunity to comment on Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule") published in the *Federal Register* on August 22, 2006.[2] Because we submitted detailed comments on CMS-1512-PN: "Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense (PE) Methodology" (the "Work/PE Proposed Notice"),[3] we will not repeat our recommendations for fine-tuning the proposed changes to the methodology for establishing the practice expense component of the 2007 fee schedule. We would, however, like to incorporate those recommendations by reference. We hope our earlier suggestions coupled with the comments that follow will facilitate the development of a Physician Fee Schedule Final Rule that will ensure continued access to quality care for the Medicare beneficiaries battling cancer in 2007 and beyond.

As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

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[1] US Oncology, headquartered in Houston, Texas, is one of the nation's largest cancer treatment and research networks. US Oncology provides extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced treatments and technologies, build integrated community-based cancer care centers, improve their therapeutic drug management programs and participate in many of the new cancer-related clinical research studies. US Oncology is affiliated with 977 physicians operating in 392 locations, including 90 radiation oncology facilities in 34 states. US Oncology also provides a broad range of services to pharmaceutical manufacturers, including product distribution and informational services such as data reporting and analysis.

[2] 71 *Fed. Reg.* 48980 (Aug. 22, 2006).

[3] 71 *Fed. Reg.* 37168 (June 29, 2006).

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IMPACT

CMS Should Implement Recommended Refinements to the PE Methodology to Improve Payment Levels for Chemotherapy Services in 2007

The impact analysis in the Proposed Rule projects an overall *reduction* in payments to hematology/oncology of 3% in 2007.[4] However, when the potentially disastrous effect of the 5.1% negative update factor on patient access to physician services is ignored for purposes of analysis,[5] CMS projects a 3% increase in payments for medical oncology in 2007 due to the proposed changes in work and PE RVUs.[6] This estimated aggregate impact fails to reflect adequately the significant economic challenges that will face oncologists under the Proposed Rule if they continue providing chemotherapy services in their offices next year. Because of rounding, it also hides the small, but unexplained, reductions from the Work/PE Proposed Notice to the Proposed Rule in the RVUs assigned to most chemotherapy services.[7]

When the offset provided by the increases in payments flowing from the five-year work review for mid- and high-level evaluation and management (E&M) services that constitute a significant proportion of the typical medical oncologist's overall billings is ignored, the estimated aggregate impact of the PE changes incorporated in the Proposed Rule is a 1% *reduction* in aggregate payments to medical oncology. Even this projected decrease grossly underestimates the potential of the proposed changes in the PE methodology to severely undercut a payment policy central to the Medicare Prescription Drug, Modernization and Improvement Act (MMA) provision that revamped payment rates for Part B drugs from an AWP-based methodology to an ASP-based one. Prior to the MMA, oncologists used profits from Medicare drug payments to cover losses from inadequate payments for chemotherapy administration. MMA §303 mandated simultaneous implementation of the ASP methodology and revisions to the physician fee schedule (PFS) methodology specific to the drug administration codes billed by medical oncologists with the intent of matching reimbursement for both drugs and drug administration to the actual costs incurred for each service component by physicians who furnish chemotherapy in their offices.

Despite the need for refinements to the ASP calculation (discuss later in these comments), the ASP methodology appears, at least from CMS's perspective, to have been largely successful in achieving Congress' objective of better matching the Medicare allowable amounts for drugs to product costs in the marketplace.[8] The same cannot be said for the effectiveness of the changes made by the

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[4] 71 *Fed. Reg.* 49070.

[5] We encourage CMS to work with us and the physician community to ensure Congress takes steps to both reverse the projected cuts resulting from operation of the Sustainable Growth Rate formula in 2007 and correct the underlying problem with the current formula permanently.

[6] 71 *Fed. Reg.* 37255; 71 *Fed. Reg.* 49070.

[7] The 2007 transitional non-facility total RVUs assigned to all but three of the CPT codes for chemotherapy drug administration services billed by US Oncology affiliated practices (CPT codes 96401-96542) are slightly lower in the Proposed Rule than in the Work/PE Proposed Notice. The same is true for the code for an initial infusion of a non-chemotherapy drug (CPT code 90765), which also is commonly billed by oncologists in our network.

[8] *Comparison of Average Sales Prices to Widely Available Market Prices: 4Q 2005,* OEI-05-00430 (June 2006), Appendix A (letter from Mark McClellan, Administrator of CMS, to Daniel Levinson, Inspector General, stating "The ASP system, which is based on market prices, has lead to lower Medicare payment rates for many drugs and generated substantial savings for beneficiaries.").

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MMA to the payment methodology for drug administration services. Moreover, the fact that increases in work RVUs for E&M services will mitigate the effect of PE RVU decreases for chemotherapy administration in 2007 is not germane. The intent of the MMA was to match reimbursement for chemotherapy administration with the costs of delivering those services. Just because this year's five-year review produced increases in physician work for E&M codes performed by oncologists as well as other physician specialties does not mean the intent of the MMA or the general policy position espoused by CMS, that payment for services should reflect the cost of providing those services, should be subverted.

As Exhibit 1 illustrates, Medicare payments for drug administration services in 2006 will fail to cover approximately $549 million of the costs oncologists incur when they provide chemotherapy services. The drug administration payment shortfall faced by medical oncology grows to about $588 million when bad debt at the level of 25% of the beneficiary cost-sharing amount (the typical level of bad debt experienced by US Oncology affiliated practices) is taken into account. The proposed changes in the PE methodology will exacerbate greatly this shortfall.

Exhibit 2 shows the projected effect of the Proposed Rule on Medicare payments for drugs and drug administration services billed by medical oncology. Exhibit 3 presents the same analysis assuming Congress reverses the negative 5.1% update and instead freezes the 2007 update factor at the 2006 level. The size of the underpayments for drug administration would increase by almost 18% from $549 million to $646 million under the Proposed Rule and by almost 11% from $549 million to $607 million if Congress replaces the negative update with a freeze. Exhibit 4 illustrates the steady reduction from 2005 in Medicare payments for those drug administration codes billed by Oncologists. The aggregate weighted change, based on utilization from 2005 Notice of Proposed Rule Making (NPRM) Utilization Data including Oncology Specialties only Hematology (82), Hematology/Oncology (83) and Medical Oncology (90) from 2005 to 2006 was a reduction of 3%. The projected change from 2006 to 2007 will be an *additional* decrease of 8% if the –5.1% update is implemented and an additional decrease of 3% if Congress enacts an update freeze. The adverse impact of the revised PE methodology on drug administration services will grow from 2007 to 2010 as the new methodology is phased in.

Payment cuts for drug administration services of this magnitude, even assuming Congress takes steps to reverse or mitigate the negative update factor in the Proposed Rule are contrary to the intent of the MMA. If implemented, these cuts will make it financially untenable for many oncologists to continue administering chemotherapy in their offices. Oncologists who elect to enroll in the drug Competitive Acquisition Program in 2007 will be particularly disadvantaged because they will not even be able to earn the small profits available on some drugs under the ASP + 6% methodology like physicians working under the buy-and-bill system can.

The depth of the projected cuts for drug administration services makes it clear **something must be done this year** to preserve access to in-office chemotherapy for Medicare beneficiaries. Implementing the recommendations we made in our comments on the Work/PE Proposed Notice for fine-tuning the revamped PE methodology should be the first step.

Although it is too long-term of a solution to fix the inadequate reimbursement for 2007, CMS should initiate the development of management and pharmacy handling cost codes. We believe that

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this approach might offer a viable, permanent solution to the problem of chemotherapy service underpayments. On September 20, 2005, we submitted comments to CMS encouraging CMS to establish a payment that will appropriately reimburse physicians for the costs of safely handling and delivering cancer therapies to patients.

CMS also should establish a payment for a specified bundle of chemotherapy coordination services under the PFS akin to the monthly payment nephrologists receive when they treat patients receiving dialysis or the weekly payment radiation oncologists receive for managing radiation therapy. We would envision medical oncologists being paid weekly or monthly for chemotherapy management, with payments being made each period during which a patient is receiving active chemotherapy treatment.

Furthermore, CMS should establish a payment that will reflect the extensive pharmacy handling costs associated with cancer therapies, such as maintaining and managing drug inventories, drawing up and admixing drugs for administration, and operating quality assurance and drug safety programs. We encourage CMS to work with the oncology community to evaluate pharmacy services and handling costs and develop a new payment methodology that will appropriately reimburse physicians for these costs. We would be happy to talk about this concept with you in more detail.

CMS Should Implement One or More 2007 Cancer Care Demonstration Projects

Refinements to the PE methodology alone will not be enough to correct the serious reimbursement shortfall facing physicians who provide in-office chemotherapy services in 2007. Unfortunately, other approaches to remedying the situation that build on procedures currently used to develop and refine the PFS (e.g., collection and use of survey data more reflective of costs actually associated with in-office chemotherapy, reevaluation by the RUC of the RVUs assigned to drug administration codes, etc.) are too long-term. So too are more radical solutions that depart from the current approach to setting physician payment rates.

US Oncology strongly urges CMS to implement one or more demonstration projects in 2007 designed to facilitate the development of a physician payment system that supports the delivery of consistent, efficient cancer care in a manner that ensures continued improvements in outcomes, as judged by steadily increasing survival rates, while appropriately containing costs. Not only is this approach, in our view, the only viable option for ensuring reasonable payment levels for medical oncology in 2007, it appears to us to be the best option for moving toward a meaningful pay-for-performance program for oncology in a world of limited resources.

Adopting a 2007 Cancer Care Demonstration Project to help resolve potential access problems tied to the anticipated shortfall in payments for drug administration services under the Proposed Rule would be consistent with the recommendations of the Institutes of Medicine (IOM) in its recently issued report on pay-for-performance. The report notes one problem with moving toward pay-for-performance for physicians is a lack of good quality measures for specialists. Moreover, the report expressly recommends offering financial incentives to physicians to voluntarily report quality data for a three year period before Medicare decides whether pay-for-performance for physicians should be mandatory and how such a program should be structured. It also recognizes physician office

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practices face cost and logistical roadblocks to quality data reporting and quality improvement not applicable to other providers, none of whom are subject to cost controls equivalent to the SGR.[9]

US Oncology strongly supports the concept of using pay-for-performance programs to improve quality of care in all settings where Medicare beneficiaries receive healthcare services. If pay-for-performance programs are correctly implemented, they can generate quality improvements and needed efficiencies that will help sustain the Medicare program in the future. We appreciate the deliberative, incremental approach to the establishment of pay-for-performance measures CMS has followed to date. We are convinced collaboration between providers and CMS is essential to the success of pay-for-performance programs. That said, we firmly believe quality improvement must begin with clinical expert consensus on valid quality measures. Payer support throughout the quality improvement process is equally critical.

Building on the 2006 CMS Cancer Care Quality Demonstration Project for 2007

The 2005 Chemotherapy Demonstration Project involved paying $130 extra for each chemotherapy administration if beneficiaries were asked about the severity of nausea, pain and fatigue when they presented for chemotherapy and the collected information was coded and submitted to CMS on the claim for the drug administration services. That project has been much maligned because it involved tasks that already should have been part of routine cancer care, failed to collect information on the interventions used to manage patients' symptoms, paid physicians a demonstration allowance many considered disproportionate to the amount of effort involved, and resulted in the collection of inconsistent, incomplete and unreliable data.[10] We do not disagree with those criticisms.

The shortfalls of the 2005 Chemotherapy Demonstration should not be allowed to undermine the value of the retooled Cancer Care Quality Demonstration Project underway in 2006. This one-year demonstration project's purpose is to identify and assess, in office-based practices, certain oncology services that positively affect outcomes in the Medicare population. The 2006 project involves the use of G-codes (temporary national codes for items or services requiring uniform national coding) to gather specific information about patients with particular types of cancer. The 13 major diagnostic categories included in the 2006 Demonstration Project cover approximately 70% of cancer patients, based on incidence rates published by the American Cancer Society.

Under the 2006 Demonstration, payment ($23 per visit) and reporting are not linked to the provision of chemotherapy services. Rather, they are associated with physician E&M visits for established patients with cancer. The information collected includes the primary focus of the visit, the spectrum of care provided, and an assessment of whether each patient's care represents best practice as identified through guidelines issued by (1) the National Comprehensive Cancer Network (NCCN), an alliance of 20 National Cancer Institute (NCI) designated cancer centers; or (2) the American Society of Clinical Oncology (ASCO), the medical specialty society representing medical

[9] Rewarding Provider Performance: Aligning Incentives in Medicare, Institute of Medicine, National Academy of Sciences (2006) available at http://www.nap.edu/catalog/11723.html.

[10] *Cost and Performance of Medicare's 2005 Chemotherapy Demonstration Project*, OEI-09-05-00171 (Aug. 2005) available at http://oig.hhs.gov/oei/reports/oei-09-05-00171.pdf.

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oncologists. By emphasizing NCCN and ASCO clinical practice guidelines as the source for standards of care, the 2006 Demonstration Project permits CMS to monitor and encourage quality care to cancer patients and to identify and promote best cancer care practices that lead to improved patient outcomes.

US Oncology believes the collection of data on adherence to clinical guidelines is an important first step toward the creation and implementation of a realistic cancer care quality improvement program. We suspect, however, that a one-year demonstration project will not be long enough to collect meaningful data, particularly since many community cancer care providers only began reporting data in the second quarter of this year. Accordingly, we encourage CMS to continue collecting additional information under a 2007 Demonstration Project designed both to explore potential avenues for quality improvement and to pay appropriately for the time and effort that must be expended by practices to submit the information CMS needs.

US Oncology would like to work cooperatively with CMS and the cancer care community to improve upon the 2006 Demonstration Project to create a 2007 Cancer Care Demonstration Project designed to generate meaningful data that can be used to develop an appropriate, effective quality improvement program for the benefit of Medicare beneficiaries with cancer.

US Oncology Network's Cancer Care Pathways

Cancer is among the most complicated and costly treatable diseases in medicine, involving a large number of specialties and services. Clinical outcomes are improving, as judged by steadily increasing survival rates, but costs continue to climb – in part because of high variability of care patterns across the nation, and even within single communities. With the aging "Baby Boomer" population entering peak risk years for a cancer diagnosis, spending for cancer treatment is increasing rapidly. In the year 2000, $37 billion was spent on cancer care services in the United States. By 2005, cancer care spending had doubled to $74 billion.

Although costs in many areas of healthcare spending are escalating rapidly, oncology is unique among healthcare specialties. Over 400 new drugs are currently in development. The success of current treatment protocols must be balanced against societal costs of incredibly expensive new therapies with dangerous side effects and virtually no therapeutically interchangeable drugs. Despite the high costs and side effects, the pressure to use the "greatest and latest" therapies is intense and from many fronts: patients and their families, the pharmaceutical industry, physicians, and patient advocacy groups.

In recent years, oncology has seen equally rapid advances in prevention, screening and imaging techniques which have changed the face of cancer care. Today's cancer patient requires continuous, integrated care consisting of diagnostic imaging, radiation therapy, chemotherapy and supportive measures.

US Oncology's affiliated physicians understand the current trends are unsustainable, particularly as Baby Boomers become eligible for Medicare, and recognize that all parties in cancer care have a role to play in improving quality and containing costs. US Oncology and its affiliated physicians believe, if providers and payers work collaboratively and thoughtfully in partnership, it will be

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possible to avoid ineffective and inappropriate treatments, lower cost per treatment, slow the rate of growth in treatment cost, achieve predictability and most importantly, measure and improve patient outcomes.

To begin such a collaborative effort with CMS, we would like to share some information about the work the leadership of our affiliated physician network has undertaken over the last two years to develop a consensus on appropriate clinical pathways among over 900 US Oncology affiliated physicians. For our network, the next step in this process will involve formal adoption of treatment protocols which our physicians now call simply "Pathways" by US Oncology affiliated practices, a process that began in earnest earlier this year.

The cancer care Pathways developed by US Oncology affiliated physicians reflect an evidence-based approach that involves defining sets of treatment options designed to deliver high-quality, high-value cancer care supported by clinical research findings. The Pathways were developed initially after a review of the available science by the physicians on the US Oncology Pharmacy & Therapeutics Committee (P&T Committee). They have been and will continue to be updated through review of new evidence as it becomes available.

The Pathways development process is managed by consensus panels of oncologists, each focusing on a specific cancer disease state. The panels use an evidence review process that grades the strength of literature support for, and the relative demonstrable benefits of, each of the available therapies. The process separates therapies proven superior for patient outcomes from those for which superiority is not clearly established. In many instances, the panels found the data pointed only to one regimen's clinical superiority. However, in those cases where the data did not show one regimen to be clearly superior, the panels analyzed the most frequently used alternatives based on patient convenience, toxicity and cost to patient/payer. The panels' consensus process results in clinical treatment Pathways that offer therapies with scientifically proven efficacy intersected with cost effectiveness.

Importantly, the first option on each Pathway is an appropriate clinical trial. US Oncology strongly believes in cancer research and our affiliated physicians enroll more patients in cancer clinical trials than any other network in the United States. Our physicians expect adherence to Pathways to increase the rate of accrual to clinical trials, thus hastening the pace of research outcomes.

Just as importantly, our affiliated physicians recognize that Pathways are not right for all patients. As a result, the Pathways allow the treating physician to make off-Pathways treatment decisions ("exceptions") where he or she determines it is warranted. However, each such exception is documented, peer-reviewed, and tracked as part of the continual Pathways updating process to determine if the relevant Pathway requires modification.

The implementation of Pathways is supported through US Oncology's oncology-specific Electronic Medical Record (EMR), iKnowMed. iKnowMed is a wholly owned software company of US Oncology, and US Oncology affiliated oncologists drive iKnowMed development. iKnowMed has been modified to support Pathways through:

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- Front-end point-of-care decision support. Pathways therapies are presented at the point of care for THAT patient's condition at THAT time, based upon
    - Diagnosis
    - Stage
    - Performance Status
    - Line of Therapy
    - Receptors
    - Other clinical factors as appropriate

- Back-end relational database support for data capture, reporting and outcomes measurement.

Currently, the network's affiliated physicians who have adopted clinical pathways have Pathway treatment options available to them for chemotherapy choices in the following cancers:

- Breast:
    - Neoadjuvant
    - Adjuvant
    - Metastatic
- Non Small Cell Lung:
    - Adjuvant
    - Metastatic
- Small Cell Lung
- Colon:
    - Adjuvant
    - Metastatic
- Prostate:
    - Hormone Refractory
- Ovarian
- Multiple Myeloma

By the end of 2006, the Pathways will be expanded to include:

- Supportive Care Drugs
    - Colony Stimulating Growth Factors
        - Neulasta/Neupogen/Leukine
    - Red Cell Stimulating Growth Factors
        - AraNesp/Procrit
    - Bisphosphonates
        - Zometa/Pamidronate
    - Antiemetics
        - Aloxi/Emend/Kytril
- Chemotherapy
    - Lymphomas

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During 2007, the goal is to expand the Pathways to include:

- Radiation Treatment
- Diagnostic Imaging
    - CT
    - PET
- Nursing Support Protocols
- Follow Up Care
- End of Life Care
    - Hospice
    - Palliation
- Chemotherapy for Other Cancers
    - Head and Neck, Renal, Gastric, etc.

With a dedicated group of over 900 physicians who have embraced evidence-based clinical pathways, an oncology-specific EMR for both front-end and back-end support, an outcomes research team, Phase I-IV clinical research capabilities, as well as extensive clinical and financial analysis team capability, the US Oncology network will be uniquely able to evaluate key issues in cancer care following the network's implementation of Pathways.

US Oncology believes that programs like our clinical Pathways initiative have the potential to benefit cancer patients, oncology practices and payers alike.

Patient benefits include:

- Care based on the best scientific evidence available
- Access to technologically effective and clinically proven therapeutic regimens
- Consideration for the latest clinical trials
- Treatment shaped by knowledge, the collective experience of our affiliated practices and the nation's largest network of community-based cancer centers.

Practice and physician benefits include:

- Increased accruals to clinical trials, advancing standards of practice
- Reduced errors through treatment standardization
- Improved cost-effectiveness of treatment for patients and third-party payers
- Collaborative relationships with payers
- Ability to track and report clinical data, with a focus on improved patient outcomes through science.

Payer benefits include:

- Predictability and consistency in treatment of insureds with similar cancers
- Contained and more predictable costs, modeled by their insureds' experience
- Reduction of unnecessary healthcare services and medical errors

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- Performance and outcomes measurements.

We hope CMS can build on our ideas and the Pathways work our affiliated physicians have done to establish a second cancer care demonstration project for 2007. We would envision a demonstration project providing appropriate incentives to oncologists willing to take a responsible approach to patient care, quality improvement and cost accountability and reporting the type of data CMS will need to develop and fine-tune for an effective oncology pay-for-performance program that will lead to consistent high-quality, high-value outcomes for Medicare beneficiaries. We would welcome the opportunity to make key members of the US Oncology Pathways team available for further, more detailed discussion with CMS about our approach to the war on cancer and the potential applicability of the approach to the Medicare program in 2007 and beyond.

DRA PROPOSALS

Section 5102 of the Deficit Reduction Act of 2005 (DRA) includes two provisions that affect payments for imaging services under the PFS. DRA § 5102(a) requires CMS to exempt any savings attributable to multiple imaging procedure payment reductions implemented initially in the 2006 Physician Fee Schedule final rule[11] from the budget neutrality provision, effectively pulling those savings out of the pool of money available for physician reimbursement. DRA § 5102(b) limits payment amounts for the technical component of imaging services provided in a physician's office to the technical component rates available to hospital outpatient departments for the same services under the hospital outpatient prospective payment system (OPPS), (the "DRA Cap").

The CMS impact analysis suggests DRA § 5102 will have essentially no impact on payment rates for radiation oncology.[12] As is the case with drug administration services discussed above, this aggregate analysis fails to illustrate the potentially devastating effect of the DRA, as CMS has chosen to interpret it in the Proposed Rule, on certain imaging and radiology guidance procedures crucial to cancer diagnosis, staging, and treatment by both medical and radiation oncologists.

Exhibit 5 presents a more granular impact analysis. It shows that payments for PET and PET/CT services collectively will be reduced an astounding 61% under the Proposed Rule, with the bulk of the reduction coming at the expense of the newer PET/CT technology. Physician practices simply do not have the financial wherewithal to absorb payment cuts of this magnitude in one year. US Oncology urges CMS to mitigate the magnitude of changes in PET/CT payment rates for 2007 by making revisions to the "Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule (the "2007 OPPS Proposed Rule") published in the *Federal Register* on August 23, 2006,[13] and to phase in the DRA Cap in a more responsible fashion.

US Oncology also is concerned because CMS has inappropriately elected to apply the DRA § 5102(b) imaging cap to radiologic guidance procedures that help radiation oncologists better target treatment in ways that improve patient outcomes. CMS should recognize that guidance services are integral to treatment and, as such, should not be subject to the DRA Cap. Finally, we

[11] 70 *Fed. Reg.* 70114 (Nov. 21, 2005).
[12] 71 *Fed. Reg.* 49071.
[13] 71 *Fed. Reg.* 49504 (Aug. 23, 2006).

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urge CMS to rescind the proposed 25% multiple-procedure reductions because it will result in duplicative cuts under the DRA Cap.

CMS Should Assign PET/CTs to APC 1514 for 2007 and 2008

Although this recommendation echoes a discussion in our comments on the 2007 OPPS Outpatient Proposed Rule, we will reiterate it here because the DRA § 5102(b) provision capping payments for the technical component of imaging services in physicians office at the rates paid under OPPS have inextricably linked the two rulemaking for CY 2007. US Oncology strongly urges CMS to follow the recommendation of its APC Technical Panel and keep PET/CT scans in APC 1514 for a minimum of two years.

This recommendation reflects our deep concern about the impact the DRA Cap on payment for PET/CT scans will have on beneficiary access to that service. PET/CT is a critically important service that is part of the treatment plan for many cancer patients. Currently PET/CT is Carrier priced. The proposed OPPS payment amount of $862.29 represents, in many Carrier jurisdictions, a payment cut of over 50%. To better serve our patients, a number of US Oncology affiliated practices have clinically deployed PET/CT scanners within the last two years, costing over $2 million each. Additionally, we had planned to convert our installed base of over 30 PET units to PET/CT over the next two years to better serve the diagnostic and treatment planning needs of patients. As numerous studies have shown, PET/CT yields numerous clinical and patient benefits because of the shorter scan times (less patient movement) and the ability to see both a metabolic and anatomical image set acquired in the same setting. The basis for our investment decision into these scanners was with the expectation that revenue would remain stable and allow us to recover the cost of the scanner within its useful lifecycle.

We note that hospitals allocate the costs of expensive capital equipment over all procedures with costs attributable to a specific revenue center. In the case of PET/CT, the cost of a $2 million PET/CT scanner is allocated over all procedures in the diagnostic radiology (or nuclear medicine) revenue center. Under the PFS methodology, the cost of a PET/CT scanner is attributed to only PET/CT scans and more accurately reflects the actual cost of providing a PET/CT scan. The hospital "cost" of providing a PET/CT scan is underestimated because the cost of the scanner is spread out over all radiologic services. In essence, hospital cost reporting results in the cost of non-PET/CT services being overestimated and the cost of PET/CT underestimated.

On a number of occasions, CMS has mitigated significant decreases in reimbursement by transitioning payment reductions over several years to allow providers to take steps to minimize the effect of reduced reimbursement on their ability to provide care to Medicare beneficiaries. In fact, CMS is doing precisely that with regard to transitioning payments under the new practice expense methodology from 2007 to 2010.

There are a number of compelling reasons why CMS should mitigate the payment reduction for PET/CT in the Proposed Rule by keeping PET/CT in APC 1514 for the next two years. They include:

- The APC technical panel recommended keeping PET/CT in APC 1514.

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- The cost of performing PET/CT is underestimated in the OPPS fee schedule because the capital equipment cost is spread out over all procedures in the diagnostic radiology revenue center. The PFS cost more accurately reflects the cost of performing a PET/CT because the cost of a PET/CT scanner is allocated to only PET/CT scans.
- Hospitals have not yet established unique charges for PET/CT scans (e.g., they have just rolled over their charges for PET scans) resulting in flawed claims data.
- Keeping PET/CT in APC 1514 for two more years will allow hospitals to establish PET/CT-specific charges and hospitals and physicians more time to adapt to lower payments.
- The cost of PET/CT under the PFS using refined direct cost inputs would result in payments significantly higher than under OPPS, meaning that it costs more to provide PET/CT in an office than a hospital.
- The inability of physicians to perform PET/CT in their offices will have a direct and immediate effect on the quality of care for cancer patients.

Lastly, we note that if CMS would blend its own external data (from the refined direct cost inputs used to establish practice expense RVUs under the PFS) with OPPS claims data to establish a payment rate for PET/CT, the payment rate would be significantly higher than the payment rate in the Proposed Rule and the 2007 OPPS Proposed Rule. Such a result lends additional support to placing PET/CT in APC 1514.

CMS Should Exclude all Radiology Guidance Procedures from the DRA Cap

The CMS proposal to subject many radiologic guidance procedures to the DRA Cap, including those used for the administration of radiation therapy, should not be finalized. It was not the intent of Congress to include those procedures under the DRA Cap.

DRA § 5102(b) requires that payment for certain imaging services under the PFS be capped at the payment amount for the same service under the OPPS. The extensive discussion in the Conference Report emphasizes:

- MedPAC's recommendations to "expand its coding edit policy to help the program pay more accurately for multiple imaging services performed during the same encounter,"[14] and
- CMS payment reductions for certain "subsequent"[15] imaging procedures performed on contiguous body parts and how "the multiple procedure TC payment reduction" applied "only to procedures involving contiguous body parts within a family of codes, not across families."[16]

The Conference Report discussion clearly indicates the intent of Congress was to cap payments for only "diagnostic" imaging services because both the MedPAC recommendations and the CMS multiple procedure payment reductions apply only to diagnostic imaging services. Further, the increased utilization of imaging procedures that has been of concern to CMS over the past several

[14] H.R. Rep. No. 109-362 at 217 (2005).
[15] *Id.*
[16] *Id.*

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years is related to diagnostic imaging procedures, not imaging used in conjunction with therapeutic procedures to improve outcomes.

CMS itself recognized this fact when it excluded from the DRA Cap all imaging guidance procedures where the guidance was included in the code for the procedure itself (e.g., diagnostic bronchoscopy). CMS should not base such an important policy decision on CPT coding descriptors. Whether guidance happens to be included in the coding descriptor for a procedure is not relevant for determining whether it should be included under the DRA Cap. Guidance associated with a procedure, whether for radiation therapy delivery or for invasive surgery, is never diagnostic and was never meant by Congress to be included under the DRA Cap.

Applying the DRA Cap to radiologic guidance procedures, including guidance for radiation therapy, will have a direct effect on the quality of patient care. We cite two CPT codes as examples: 76370, Computed tomography guidance for placement of radiation therapy fields and 77421, Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy. Each of these procedures would see dramatic payment cuts under the Proposed Rule.

Procedure Code	Proposed PFS Payment for CY 2007 ($) – Technical Component (using the current conversion factor)	Proposed OPPS Payment for CY 2007 ($)
76370	129.61	95.72
77421	116.35	60.14

Other radiation guidance codes impacted are 76370 (CT Field Placement) and 76965 (Ultrasonic guidance for interstitial radioelement application (Prostate Seed Implant)). Since these four codes pertain to Radiation Therapy, instead of diagnostic imaging, the DRA Cap should not apply.

Use of imaging to guide radiation therapy has dramatically improved treatment for cancer patients. Recent technologic advancement in guidance allows external beam radiation to be more highly focused which results in the delivery of higher doses of radiation to tumors and lower doses of radiation to normal tissues. Not only is efficacy improved, but the complication rate is also decreased.

The direct cost inputs which CMS uses to determine reimbursement for practice expenses in the office setting more accurately reflect the cost of those services than the OPPS APC payment amounts. For services such as radiation therapy guidance, much of the cost of the procedure is due to capital equipment expense. As we explained above in our discussion of PET/CT payment rates, hospitals are able to spread the cost of that equipment over all procedures in a revenue center, which results in underpayment for such services. Under the current and the proposed revised PFS methodology for 2007, capital equipment costs are allocated only to the procedures involving the equipment, meaning the cost of performing those procedures is more accurately reflected.

If CMS finalizes its proposal to cap guidance payments in the physician office at the OPPS rate, many physician offices likely will no longer be able to provide guidance for radiation therapy. Patients will be forced to seek care from hospitals. Such a result could cause some patients in rural areas to forego treatment and it clearly will result in longer wait times and care disruptions for all patients who do receive care.

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CMS Should Rescind the Proposed 25% Multiple-Procedure Reduction

In 2006, CMS implemented a 25% multiple-procedure reduction for the technical component of certain procedures when they were performed on contiguous body parts. The reduction was established because CMS thought it was making duplicate payment for some elements of practice expense (e.g., staff time, certain supplies) when certain ultrasound, CT, or MRI procedures were performed on contiguous body parts during the same session.

In the Proposed Rule, CMS stated:

> the ACR (American College of Radiology) provided information for 25 code combinations supporting a reduction between 21 and 44 percent. Given the expected interaction between the multiple procedures imaging policy and the further imaging payment reductions mandated by section 5102(b) of the DRA . . . along with the new information we have received from the ACR . . . we believe it would be prudent to maintain the multiple imaging payment reduction at its current 25% level. . . . "[17]

Further, in the OPPS final rule for CY 2006 CMS stated:

> In calculating median costs for outpatient imaging procedures in the radiology families we proposed for discounting, for most hospitals' claims, we used a hospital-specific diagnostic radiology CCR for the conversion of charges to costs. Some hospitals reported costs and charges in nonstandard cost centers for ultrasound, CT, or MRI services, and, in general, those modality-specific CCRs were lower than their CCRs for diagnostic radiology. Those lower CCRs were not inconsistent with hospitals' experiences of particular efficiencies in providing multiple ultrasound, CT, or MRI services in a single setting, without reductions in charges for those multiple procedure sessions. . .. . . We found that the imaging procedures we identified as eligible for the proposed payment reductions accounted for approximately half of the total OPPS charges attributed by the OPPS to hospitals' diagnostic radiology cost centers. This result suggests that costs and charges related to ultrasound, CT, and MRI services in the 11 proposed families are significant contributors from the OPPS to hospitals' diagnostic radiology cost centers; . . . . Thus, it may be correct that our median costs for imaging services in the 11 families proposed for the reduction policy reflect a reduced median based, in part, on hospitals' provision of multiple scans in one session. . . . [O]ur analyses do not disprove the commenters' contentions that there are efficiencies already reflected in their hospital costs, and therefore, their CCRs and the median costs for the procedures. Further, the results of our initial analyses do support the recommendation that we should defer implementation of the proposed multiple imaging procedure reduction policy to perform additional analyses.[18]

OPPS costs are calculated in the aggregate over revenue centers so they already reflect efficiencies achieved from the performance of multiple procedures. Hospitals also are able to spread the cost of expensive capital equipment such as MRI, PET/CT, and CT scanners over all procedures with costs attributable to the diagnostic radiology revenue center. Hospitals then determine charges for

[17] 71 *Fed. Reg.* 48996.
[18] 70 *Fed. Reg.* 68708.

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procedures within a cost center based on aggregate costs for that cost center, expected utilization, and other factors. Costs are not determined on a "per procedure" basis. For these reasons, when charges are reduced to costs for hospital procedures where capital equipment accounts for a large portion of the cost, the actual cost will exceed the cost as calculated by CMS.

Costs for procedures performed under the PFS are calculated on a "per procedure" basis using direct cost inputs for clinical labor, supplies, and capital equipment. The cost of expensive capital equipment is not allocated over other procedures within a revenue center. The physician methodology results in a more accurate determination of the cost of a specific procedure. It also reflects the reality that physician offices do not spread costs over a large number of unrelated procedures because most physician offices do not perform a wide variety of procedures.

Given the methodological difference, it is not surprising the "costs" of an imaging procedure (e.g., a CT, PET or MRI scan) as calculated using the PFS methodology is larger than the "cost" of the same procedure as calculated using the OPPS methodology.

Not only does making payment at the OPPS rate take the efficiencies of performing similar procedures on contiguous body parts into account, the table below shows that the payment reduction is actually greater in a number of actual scenarios.

Comparison of Cost Savings

CPT	Description	Proposed CY 2007 PFS Payment*	Proposed CY 2007 PFS Payment with 25% Reduction Only	Percentage Decrease in CY 2007 Payment if 25% Reduction Only	Proposed CY 2007 Payment applying the OPPS Cap Only without the Multiple Procedure Reduction	Percentage Decrease in CY 2007 Payment if OPPS Cap Only
71250	Ct chest w/o dye	$237.62	$237.62	0%	$194.69	-18%
74150	Ct abdomen w/o dye	$226.25	$169.69	-25%	$194.69	-14%
	TOTAL	**$463.87**	**$407.30**	-12%	$389.38	-16%
71551	Mri chest w/dye	$568.46	$568.46	0%	$385.24	-32%
74182	Mri abdomen w/dye	$563.16	$422.37	-25%	$385.24	-32%
	TOTAL	**$1,131.62**	**$990.83**	-12%	$770.48	-32%
72142	Mri neck spine w/dye	$552.92	$414.69	-25%	$385.24	-30%
72147	Mri chest spine w/dye	$532.46	$399.34	-25%	$385.24	-28%
72149	Mri lumbar spine w/dye	$552.92	$552.92	0%	$385.24	-30%
	TOTAL	**$1,638.31**	**$1,366.96**	-17%	$1,155.72	-29%

*Payment amount is calculated based on the current CY 2006 conversion factor.

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We would also note that the DRA Cap applies to single procedures as well as multiple procedures. This means that Medicare is paying less for almost all CT and MRI scans than it would if it were using its more accurate per procedure cost data under the PFS. We would also note that to the extent physicians will attempt to make up for loss of "per procedure" income due to the DRA Cap and the CMS multiple procedure reduction, utilization will actually increase, thereby negating any cost savings and exacerbating any inappropriate utilization of diagnostic imaging services.

In summary, the conditions under which the multiple procedure reduction was created no longer exist. Moreover, the payment reductions mandated by the DRA in most cases exceed the reductions under the multiple procedure reduction. Accordingly, and it is unnecessary to continue the multiple procedure reduction in CY 2007.

ASP ISSUES

US Oncology applauds the decision to reopen the comment period on the regulations at 42 C.F.R. 414.800 *et seq.* We agree stakeholders, including CMS, lacked real-world experience with ASP when the rulemakings that underlie those regulations were finalized. It is, therefore, appropriate to consider issues that were vetted during earlier rulemakings as well as new issues that have surfaced since ASP-based reimbursement became a reality in January 2005. We welcome the opportunity to provide input. As requested, we have limited our discussion to ASP reporting issues.

CMS Should Exclude Customary Prompt Pay Discounts Extended to Wholesalers from the ASP Calculation

The DRA Eliminates the Deduction of Wholesaler Prompt Pay Discounts in the AMP Calculation

Congress adopted a policy approach to reforming Medicaid payments to retail pharmacies in the DRA reminiscent of the approach it took in the MMA to reforming reimbursement for drugs covered by Part B of Medicare. Under the MMA, manufacturers report the ASP of Part B products to CMS so Medicare can pay physicians and other Part B suppliers for those drugs using a reimbursement metric reflective of drug prices available to them in the market. Similarly, under the DRA, CMS will provide State Medicaid programs with pricing data representative of drug costs incurred by retail pharmacies in the market so the States can better match pharmacy payments for drugs and for dispensing services to the actual costs of each service component. The reimbursement metric Congress adopted for Medicaid is the Average Manufacturer Price (AMP), which is intended to capture pricing on sales to the retail pharmacy class of trade. Although ASP is similar to AMP, it is intended to capture pricing on sales to all classes of trade, including sales to hospitals and health maintenance organizations that are carved out of the AMP calculation.

Manufacturers have been reporting AMP, as that term is currently defined at Social Security Act § 1927(k)(1)[19], to CMS since 1991.[20] CMS and the States have then used AMP in conjunction with

[19] 42 U.S.C. § 1396r-8(k)(1).

[20] "Average Manufacturer Price. – The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States

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other pricing data reported by manufacturers to collect rebates from manufacturers on each unit of drug dispensed to Medicaid beneficiaries. In this way, the State Medicaid programs – collectively the single largest purchaser of prescription drugs in the country until Medicare Part D was implemented – were able to obtain volume discounts commensurate with their buying power even though they purchased script by script rather than in bulk.

Congress made a critical change to the definition of AMP that will be in effect when the States first have the opportunity to adopt the AMP metric for reimbursement purposes. Specifically, DRA § 6001(c)(1) revised the definition of AMP to delete the instruction requiring the deduction of customary wholesaler prompt pay discounts when manufacturers calculate AMP. This change was made to support the DRA policy objective of better matching drug reimbursement with pricing actually available to retail pharmacies in the marketplace. As a check on potential abuse of the change involving the funneling of a portion of inappropriately large wholesaler prompt pay discounts to a wholesaler's pharmacy customers as a form of disguised price concession, DRA § 6001(c)(2) also requires manufacturers to report to CMS on the "customary prompt pay discounts extended to wholesalers."

Policy Argument Support Eliminating the Deduction of Wholesaler Prompt Pay Discounts in the ASP Calculation

Many stakeholders affected by the MMA provision establishing the ASP-based reimbursement system for Part B drugs have argued that customary prompt pay discounts extended to wholesalers should be ignored when ASP is calculated. They point out that, prompt pay discounts are not routinely passed on by wholesalers to their customers that bill Part B. Accordingly, netting the discounts out of ASP is inconsistent with Congressional intent. It undercuts the objective of matching Part B drug reimbursement with prices actually available in the market.

These stakeholders repeatedly have urged CMS to use its discretionary authority to exclude customary wholesaler prompt pay discounts from the ASP calculation, but CMS has consistently refused. Even in the Proposed Rule, CMS notes "prompt pay discounts will continue to be a type of price concession that manufacturers must include in their ASP calculations."[21] CMS bases its refusal on the definition of ASP in MMA §303(c).

The MMA definition of ASP directs manufacturers to calculate a drug's ASP as the selling price per unit of product distributed in the United States net of "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than [Medicaid drug rebates])" and exclusive of sales made at nominal price and sales exempt from inclusion in the determination of Best Price under Social Security Act §1927(c)(1)(C)(ii)(III). CMS claims because the statute includes the words "prompt pay discount," the agency has no choice but to require the deduction of wholesaler prompt pay discounts when ASP is determined.

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by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-98(k)(1).

[21] 71 *Fed. Reg.* 49002.

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US Oncology disagrees with CMS on the prompt pay issue. We strongly urge CMS to reverse its position in the final ASP rule and to instruct manufacturers to ignore customary prompt pay discounts extended to wholesalers when they calculate ASP even while they continue deducting any prompt pay discounts extended directly to end customers, such as physicians, hospitals, or chain drug stores, on sales that do not go through a wholesaler.

The change recently enacted as part of the DRA to eliminate the deduction of customary prompt pay discounts extended to wholesales from AMP when Congress retooled AMP to serve as the retail pharmacy reimbursement metric of choice for State Medicaid programs supports our position on the ASP side from a policy perspective. After all, physicians stand in the same position in the market as retail pharmacies *vis a vis* wholesaler pricing practices. Customary wholesaler prompt pay discounts should be handled similarly when ASP and AMP are calculated. Congress intended for each of these reimbursement metrics to reflect prices actually available in the market to providers that will be billing Medicare and Medicaid for drugs, regardless of whether those providers are physicians or pharmacies.

The CMS position on *bona fide* service fees in the Proposed Rule also supports excluding customary prompt pay discounts extended to wholesalers from ASP. Prompt pay discounts compensate wholesalers for the time value of money and for taking on the credit risks that manufacturers would otherwise have to assume if they sold their products directly to the end customer. It is illogical to propose treating wholesaler prompt pay discounts as price concessions which must be deducted when ASP calculated while at the same time asserting that *bona fide* service fees are payments for services rendered, not price concessions, and should, therefore, be disregarded in the ASP calculation.

MedPAC also recently concluded that CMS should refine its ASP methodology because it includes discounts that are not passed on to physicians, such as the prompt pay discounts extended to wholesalers.[22] This discrepancy creates a payment gap between the reported ASP and the average purchase price.

CMS Has the Legal Authority to Exclude Wholesaler Prompt Pay Discounts from ASP

Despite its position to the contrary, CMS has the legal authority to tell manufacturers not to deduct customary prompt pay discounts to wholesalers from ASP. "The meaning of statutory language, plain or not, depends on context."[23] The presence of a specific term, such as *prompt pay discount*, in a statutory list of payment adjustments that can occur between manufacturers and dispensing organizations, manufacturers and wholesalers, or manufacturers and both levels of the distribution channel, does not in itself require CMS to consider every instance of a prompt pay discount in its ASP rulemaking. For purposes of statutory interpretation, "context" relates to "the design of the statute as a whole and to its object and policy."[24] Given the clear intent of Congress when it

[22] Study on impact of changes in Medicare payments for Part B drugs: *Statement at Medicare Payment Advisory Commission public meeting* (Oct. 6, 2006) (Statement of Joan Sokolovsky, Analyst, Medicare Payment Advisory Commission).
[23] *Holloway v. United States*, 526 U.S. 1, 7 (1999) (cites omitted).
[24] *Gozlon Peretz v. United States*, 498 U.S. 395, 407 (1991) (quoting *Crandon v. United States*, 494 U.S. 152, 158 (1990)).

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enacted the MMA to match Part B drug reimbursement with drug acquisition costs available to physician in the market, CMS has the statutory authority to instruct manufacturers to ignore customary prompt pay discounts paid to wholesalers when they calculate ASP.

By requiring manufacturers to report prompt pay discounts to CMS, the DRA creates a safeguard against unscrupulous manufacturers, wholesalers, and dispensing organizations conspiring to "game" both AMP- and ASP-based reimbursement systems by providing for extraordinarily high wholesaler prompt pay fees with the understanding that a portion of those fees would be passed on to the wholesaler's customer in the form of a price concession. CMS could even toughen this safeguard by capping the permitted wholesaler prompt pay carve out at the industry standard level of 2% in both the ASP final rule and the DRA-mandated AMP rule that is to be effective by July 1, 2007.

CMS obviously recognizes that it has the authority to add regulatory gloss to MMA's language when it is necessary to effectuate Congressional intent. After all, it promulgated a final rule on Sept. 16, 2004[25] changing the methodology for handling unavailable lagged data in the calculation of ASP from the 12-month rolling average approach specified in Social Security Act § 1847A[26] to a new methodology designed to result in less variability in reported ASP values. CMS made this change because the methodology Congress specified in statute leads to large quarter-to-quarter variations in ASP that undermine the value of the statistic as an acceptable reimbursement metric. Congress' estimation methodology was, therefore, inconsistent with the overarching intent of MMA § 303(c) – to use ASP-based reimbursement to match Medicare payments to practitioners for drugs with drug acquisition costs.

Now that CMS has demonstrated its belief that it has the authority to read this type of revision into the provisions at Social Security Act § 1847A(c)(5)(A), we are hard pressed to see how the agency could question its statutory authority to read limitations into the definition of "prompt pay discount" in § 1847A(c)(3) directing manufacturers to ignore customary prompt pay discounts extended to wholesalers when they calculate ASP. After all, such an instruction is necessary to ensure that ASP is as reflective as possible of acquisition costs actually available in the marketplace to physicians and other Part B suppliers.

CMS Should Work with Congress to Reduce the Lag Time between ASP Reports and Reimbursement Based on Those Reports

Given the timelines laid out in Social Security Act § 1847A, there is a two quarter (6 month) lag between ASP reporting and payment based on reported ASP values. At a recent MedPAC public meeting, Joan Sokolovsky, a MedPAC analyst, recognized that some drugs cost more than the Medicare allowable amount because of the time lag.[27] For a number of expensive single-source

[25] *Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals*, 69 *Fed. Reg.* 55763 (Sept. 16, 2004).
[26] 42 U.S.C. § 1395w-3a(c)(5(A).
[27] Study on impact of changes in Medicare payments for Part B drugs: *Statement at Medicare Payment Advisory Commission public meeting* (Oct. 6, 2006) (Statement of Joan Sokolovsky, Analyst, Medicare Payment Advisory Commission).

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cancer drugs considered the standard of care, ASP has been rising, frequently on a quarterly basis. For some of these drugs, quarter-over-quarter ASPs have shown price increases of 1% or more. For example, between the 2nd and 4th quarters of 2005, the price for Rituximab (Rituxan) 100 MG (J9310) increased 3.7% or $16.11, from $439.81 to $455.92 per unit. As a result, many physicians likely lost money in the 4th quarter when they treated patients with Rituximab because the ASP also understated physician acquisition costs by at least the 2% prompt pay discount extended to wholesalers and did not adequately account for the wholesaler mark-up to end customers or the sales taxes imposed on pharmaceuticals by a number of states. When drugs come off patent, the government could also benefit from the rapidly falling prices if it takes action to reduce the time lag problem. For example, between the 2nd and 4th quarters of 2005, the price for Cisplatin 50MG (J9062) decreased 39.8% or $7.85, from $19.72 to $11.87 per unit because of the introduction of generics.

The two-quarter lag between ASP reporting and HCPCS-specific ASP pricing based on reported ASPs means the effective reimbursement rate (without taking into account the prompt pay discount issue discussed above) for products with rapidly increasing prices can be as low as ASP + 3-4% relative to current market acquisition costs. Such payment rates are incompatible with the APS + 6% amount Congress intended to protect providers from the often higher costs of acquiring drugs in hard-to-serve rural areas and the inevitable product-by-product variability in the precision with which ASP can reflect actual pricing to just the physician class of trade. Not surprisingly, physicians report have difficulty accommodating the cash flow dislocations that result. We note too that physicians and other Part B suppliers can experience a windfall when prices are rapidly decreasing, as can happen when a competing therapeutic alternative is introduced or an innovator drug comes off patent and generic competitors enter the market.

US Oncology would like to work collaboratively with CMS to advocate with Congress for monthly ASP reporting and changes in the timing of the calculation of HCPCS-specific payment rates based on such reports. Such changes parallel, to the extent possible, the requirements in DRA § 6001(b) for monthly manufacturer reporting of AMP to CMS and monthly downloads of AMP data to State Medicaid agencies. We believe legislation could be crafted that would allow the phase-in of Part B reimbursement based on less lagged monthly ASP data without imposing an undue burden on CMS or manufacturers since both already must retool their price reporting systems and operations to accommodate monthly price reporting of AMP under the DRA. A move to monthly ASP reporting also would be consistent with the push for more transparency in the pricing of healthcare services generally and would allow for more public scrutiny of rising drug prices and enhanced public recognition of the generic value proposition. We would welcome the opportunity to meet with CMS to discuss our ideas for addressing the ASP lag problem that currently disadvantages physicians and suppliers when prices are rapidly rising and costs Medicare money when prices are rapidly falling.

CMS Should Refine the Proposed Definition of *Bona Fide* Service Fees and Codify the Instruction to Ignore Such Fees in the ASP Calculation

The Proposed Rule codifies the definition of *bona fide* service fee at 42 C.F.R. 414.802, defining such fees as "fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not

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passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug." The Proposed Rule also stipulates at 42 C.F.R. § 414.804(a)(2)(ii) that manufacturers may not treat *bona fide* service fees as price concessions when they calculate ASP.

US Oncology is in general agreement with this approach but we believe CMS would be well-advised to refine its proposed definition of *bona fide* service fees when it promulgated a final ASP rule either as part of the 2007 Physician Fee Schedule Final Rule or as a freestanding ASP Final Rule. A more detailed discussion of our recommendations keyed to particular issues follows:

CMS Should Codify Instructions for Handling Service Fees in the ASP Calculation

US Oncology applauds CMS's decision to codify both the definition of *bona fide* service fees and the instruction not to deduct those fees when ASP is determined. Our comments on the various issues surrounding *bona fide* service fees reflect our dual role as both a wholesaler and a physician practice management company representing the interests of oncologists affiliated with our network.

We recognize that CMS has posted a Frequently Asked Question on its website indicating *bona fide* service fees are not price concessions that must be deducted when ASP is calculated. The FAQ status of that advice as well as certain ambiguities associated with the definition of *bona fide* service fees in the posting reportedly have contributed to variability from manufacturer to manufacturer in the handling of service fees in both ASP and AMP calculations.

We understand certain manufacturers prefer to view service fees as price concessions regardless of the implications of that decision for the calculation of ASP. Treating the fees as discounts lowers AMP values and reduces Medicaid drug rebate liabilities. Other manufacturers, especially those with product lines that are heavily dependent on the sale of Part B drugs, are less concerned about rebates and more focused on ensuring their reported ASPs accurately reflect pricing available to physician in the market. These manufacturers likely are inclined to embrace the service fee FAQ and to apply the principle it articulates to both their ASP and AMP calculations.

Codifying the instruction not to treat *bona fide* service fees as price concessions that must be deducted when ASP is calculated and better defining what constitutes a *bona fide* fee should bring needed consistency to manufacturers' ASP calculation methodologies and ensure that Part B drug payments are as reflective as possible under the applicable reporting rules of actual market prices. For the same reason, we encourage CMS to include an identical instruction on the handling of *bona fide* service fees and an identical definition of the term in the DRA-mandated AMP rule scheduled to issue later this year or early next year.

CMS Should Not Distinguish between Fees Paid to Wholesalers and Third-Party Logistics Companies in the ASP Calculation

US Oncology endorses CMS's decision to structure the *bona fide* service fee definition in a way that ensures identical treatment of fees paid to wholesalers that take title to product and fees paid to third-party logistics companies (3PLs) that do not. It would be inappropriate and inequitable for the costs for very similar distribution services to be treated differently under any price reporting rule – whether it is the ASP or the AMP rule – based solely on the nature of the relationship between the

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product's manufacturer and the company the manufacturer selects to handle or assist with product distribution. Allowing disparate treatment of service fees depending on a manufacturer's selection of a wholesaler or a 3PL as its distributor of choice also could have the unintended consequence of increasing overall healthcare costs. If fees paid to 3PLs were not seen as price concessions for ASP purposes but fees to wholesalers were, the distinction could cause some manufacturers intent on maintaining their ASPs as high as possible to shift their distribution away from wholesalers that are better positioned to consolidate orders and provide just-in-time shipping to their physician and pharmacy customers at costs reflective of reduced transaction overhead and leverage of fixed assets over larger volumes.[28]

CMS Should Resolve the Pick, Pack and Ship Controversy

During our negotiations with manufacturers over distribution agreements, some manufacturers have argued pick, pack and ship services cannot be *bona fide* wholesaler services. These manufacturers typically take the position that a wholesaler performs pick, pack and ship services on its own behalf, not "on behalf of" the manufacturer, because the wholesaler holds title to its inventory and cannot profit from its inventory investment unless it distributes the products it owns. To us, the proposed definition of a *bona fide* service fee contradicts the position espoused by these manufacturers and supports, instead, the conclusion that a wholesaler's charges for pick, pack and ship can be considered *bona fide* service fees for price reporting purposes so long as other relevant definitional requirements for such treatment are met (e.g., fair market value, pass-through limitation).

Because 3PLs always provide pick, pack and ship services "on behalf of" their manufacturer clients, so long as their fees meet the other relevant requirements, they qualify as *bona fide* service fees. Moreover, any manufacturer that eschews both 3PLs and wholesalers in favor of direct distribution must pick, pack and ship its own products and bear those distribution costs. Thus, not treating a wholesaler's pick, pack and ship operations as being done "on behalf" of a manufacturer and entitled to *bona fide* service fee treatment for price reporting purposes would be inconsistent with the proposed *bona fide* service fee definition. Simply put, the definition explicitly prohibits treating fees paid to wholesalers and 3PLs for supply chain services differently based solely on who holds title to the products they distribute. To dispel future debate over the pick, pack and ship question, we urge CMS to expressly confirm in the preamble to the final ASP rule that pick, pack and ship are *bona fide* wholesaler services.

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[28] *The Role of Distributors in the U.S. Healthcare Industry: A Study Prepared by Booz Allen Hamilton.* Healthcare Distribution Management Association (2004) ("Replacement of distributors with direct distribution by manufacturers on a daily basis, assuming the current extensive services and exceptionally high service levels currently provided by distributors to their pharmacy customers, would add at least $10.5 billion per year to industry costs. This is the equivalent of an 11.6 percent increase in pharmaceutical manufacturers' total costs. This also represents 10.3 percent of the manufacturers' revenue that distributors handle.").

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CMS Should Not Include a List of *Bona Fide* Services in the ASP Final Rule

We understand the appeal of defining *bona fide* service fees, at least in part, by providing a list of services CMS considers legitimate services. Putting aside the pick, pack and ship question discussed above, we have not observed confusion in the industry about what constitutes *bona fide* services. More importantly, relying on a list for definitional purposes could freeze the development of supply chain technologies and hamper the evolution of distribution efficiencies.

Even a superficial look at service developments in the distribution industry over the last decade substantiates the legitimacy of our concerns. If CMS or wholesalers themselves had been called upon to develop a list of *bona fide* wholesaler services ten years ago, that list likely would not have included many of the special procedures used today to distribute biological products that need to be refrigerated or frozen and that are assuming an ever increasing role in cancer care. Nor would it have anticipated the volume or sophistication of the data that wholesalers now routinely transmit to manufacturers to facilitate operational management. Today, data from wholesalers now impacts the supply chain all the way back to the manufacturing process and the acquisition of raw materials.

Although we are strongly opposed to any attempt to define *bona fide* services through the use of a list, if CMS finds our objections to a list-based approach unavailing, the definitional list that CMS develops should include categories of services, not specific services. When the list is published, it should be prefaced by a statement declaring that it is a collection of examples, not an all-inclusive listing. The introductory statement should emphasis the definition of *bona fide* services is intended to be dynamic and flexible. New services categories may evolve as drug products and distribution technology evolve. Many specific services, including some not yet contemplated, may fit within each listed service category. To further mitigate concerns about freezing technology, CMS should commit to publishing of any definitional list of *bona fide* services it finds necessary only in program guidance that easily can be updated without going through notice and comment rulemaking. We recommend *The Role of Distributors in the U.S. Healthcare Industry: A Study Prepared by Booz Allen Hamilton*[29] as a source of information about the various services offered by wholesalers.

CMS Should Accommodate Percentage-Based Service Fee Payments in Any Definition of Fair Market Value

CMS has asked for input on how manufacturers should determine whether service fee payments are fair market value (FMV). We are of the view it is not necessary to precisely define FMV *per se* in the service fee context. Distribution agreements involving the payment of service fees routinely are vigorously negotiated at arms' length between sophisticated, knowledgeable parties acting in their own best interest in a competitive market for supply chain services. Both parties are positioned to use FMV criteria consistent with standard methods of valuation, including cost to serve and comparable services valuation. Distributors began shifting to the service fee model about two years ago when the industry's historical reliance on inventory arbitrage ceased to be a reliable source of revenue in the face of SEC concerns over "channel stuffing" and payer pressure to hold down drug prices. Manufacturers have come to the service fee bargaining table intent on buying only needed services and holding the fees for those services down to the extent possible now that distribution

[29] *Id.*

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costs have become a line-item on their balance sheets rather than an invisible, indirect cost from a financial perspective. For these reasons, we encourage CMS to acknowledge that, absent unusual circumstances that would not be the norm in ethical business dealing, virtually all distribution service agreements fit squarely within common definitions of FMV from such diverse places as U.S. tax law,[30] Black's Law Dictionary, and Wikipedia (a free on-line encyclopedia) and should be presumed to be FMV regardless of how the payment terms under the agreement are structured.

One FMV issue has vexed the parties to distribution agreements and that is the question of whether service fees structured as percentage payments can qualify as FMV fees eligible for exclusion from the calculation of ASP. US Oncology recognizes the OIG typically frowns on percentage-based payment methodologies, particularly when those arrangements are used in agreements involving healthcare providers that file claims with Medicare or Medicaid. Nonetheless, we believe percentage-based payments make sense in the context of *bona fide* agreements for distribution services.

Many of the cost drivers for wholesalers including building insurance, transportation insurance, security, damage risk, and cost of capital are based on the value of the products sold to wholesalers at wholesale acquisition cost (WAC). Fees charged as a percentage of goods handled simplify determining how to appropriately compensate wholesalers for these and other cost drivers. Further, wholesalers typically offer a multitude of services to manufacturers, the cost and value of which sometimes vary by the service and other times vary by the value of goods sold. Either may vary from customer to customer, from manufacturer to manufacturer, or from product to product within agreements typically covering a broad array of goods. Pricing each service that each manufacturer wishes to include in its distribution agreement individually using an itemized, flat fee or per good/activity rate would complicate contract negotiations and could be off-putting to customers. The approach would, without doubt, increase transaction costs because of the substantial data tracking required to support that type of pricing in a world where approximately seven million prescription drug products are handled and shipped *daily* by wholesalers.[31]

Retail stores, healthcare providers and manufacturers all want costs they can predict and count on. If there are variables, they prefer they be straightforward and easy to audit. Rolling up the costs for the long lists of services typically covered in any particular distribution agreement and setting a single price for those services based on a percentage of WAC for the goods handled addresses these needs. Not surprisingly, the majority of service fee agreements that have been negotiated to date use this payment model. It is crucial for CMS to recognize expressly that service fee arrangements, including fees paid as a percentage of the value of goods handled, can be FMV and eligible to be excluded from the calculation of ASP so long as the wholesaler and manufacturer negotiated the fee at arms' length and the arrangement meets the other requirements of the *bona fide* definition. CMS could easily accommodate this recommendation by revising the proposed *bona fide* service fee definition to read "fees paid by a manufacturer to an entity, that represent fair market value, regardless of how those fees are structured, . . ."

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[30] *U.S. v. Cartwrigth*, 411 U.S. 546.

[31] Oral discussions with Robert Falb of HDMA.

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Because we feel so strongly about the importance of permitting all forms of FMV payment methodologies, we also encourage you to substitute the word "supply chain" for the word "itemized" in the proposed definition of *bona fide* service fees because the word "itemized" could be read is requiring individualized pricing terms for each particular service covered by a distribution agreement.

CMS Should Retool the No Pass-Though Requirement to Accommodate the Realities of Manufacturer Reporting

The Proposed definition of *bona fide* service fees permits manufacturers to ignore such fees for purposes of the ASP calculation only if the fees "are not passed on in whole or in part to a client or customer" of the wholesaler or 3PL receiving the fee. We understand CMS and the OIG want to ensure that services fees are not converted into concessions to end-customers that ultimately reduce drug prices available to physicians or pharmacies in the market. However, the reality is that manufacturers are only in a position to know whether the net price they realize on a sale has been reduced by discounts they control. Furthermore, U.S. antitrust laws generally prohibit manufacturers from dictating their distributors' resale prices or price-related terms.[32]

Absent a contract between a manufacturer and a wholesaler's customer that generates chargeback sales, manufacturers usually have no way of knowing if or when their distributors offer goods to customers at discounts off wholesale acquisition cost. Given this limitation, US Oncology believes fairness requires CMS to narrow the provision currently included in the proposed *bona fide* service fee definition prohibiting fees from being passed through to the wholesaler's customer to a provision stipulating only that there be no implicit or explicit agreement between the manufacturer and the distributor requiring the fees to be passed on, in whole or in part. That way the information a manufacturer needs to calculate ASP in accordance with regulations will be available to, and within the control of, the manufacturer tasked with performing the calculation.

If CMS has any doubt about the problems caused by price reporting instructions that turn on the behavior of a manufacturer's customer instead of the manufacturer's own behavior, it need look no further than the confused situation surrounding the proper handling of PBM rebates under the Medicaid rebate program.[33] This confusion is responsible for significant manufacturer-to-manufacturer variability in AMP calculation methodologies[34] and likely too in ASP calculation methodologies. The confusion ties back to instructions in Medicaid Drug Rebate Program Manufacturer Releases that made the decision about whether to deduct PBM rebates in the AMP calculation turn on whether the PBM passed those rebates through.[35]

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[32] Sherman Act § 1 (15 U.S.C. § 1).

[33] *See Determining Average Manufacturer Price for Prescription Drugs under the Deficit Reduction Act of 2005,* A-06-06-00063 (May 2006) available at http://oig.hhs.gov/oas/reports/region6/60600063.pdf.

[34] *Id.*

[35] Medicaid Drug Rebate Manufacturer Releases Nos. 28, 29, and 30 (1997) available at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage

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CMS Should Acknowledge the Acceptability of Inconsistencies between Financial Accounting Rules and Pricing Reporting Rules for *Bona Fide* Service Fees

US Oncology understands some manufacturers have expressed concerns about the fraud and abuse risks associated with accounting for service fees differently for financial accounting and ASP purposes. They note GAAP-accounting principles mandate treating service fees as reductions to revenue when the fees are paid to a distributor that takes title to products. They argue that failing to treat wholesaler service fees as a price concession for ASP purposes would create an unacceptable disconnect between ASP reporting and financial reporting. Some also point out that accounting rules permit service fees to be treated as an expense on the balance sheet when a 3PL is retained to distribute drugs without taking title to the products. As a result, some of these manufacturers believe they have no choice but to deal with a 3PL instead of a wholesaler to safely avoid having to deduct distribution costs from ASP.

We are sympathetic to the concerns voiced about the accounting disconnect given the enforcement environment facing the pharmaceutical industry today. There is, however, already precedent for a similar disconnect between accounting and price reporting with respect to AMP. The IRS has ruled that Medicaid drug rebates should be treated as reductions to revenue even through the Rebate Agreement prohibits manufacturers from deducting the rebates (e.g., treating them as price concessions) when AMP is determined.[36] The proposed definition of *bona fide* service fees recognizes it would be inappropriate and inequitable for such fees to be treating differently in the ASP calculation depending on whether a wholesaler or 3PL is handling a product's distribution. Given this recognition, we encourage CMS to address manufacturers' accounting concerns in the ASP final regulation by amending proposed 42 C.F.R. 414.804(a)(2)((ii) to read "For purposes of paragraph (a)(2)(i), bona fide service fees are not considered price concessions regardless of how the fee are characterized for purposes of financial accounting." Failing to do so will inevitability lead to continued variability in the ASP methodologies adopted by different manufacturers.

MISCELLANEOUS CODING ISSUES

CMS Should Explain the Reasons Underlying the Proposed RVU Changes for Brachytherapy Codes

We are perplexed by the proposed changes in reimbursement for brachytherapy services. It seem counterintuitive that proposed 2007 RVUs for the two simpler brachytherapy procedures, CPT codes 77781 and 77782, decrease while RVUs for the two more complex procedures, CPT codes 77783 and 77784, increase from 2006 levels. It appears the change to CPT Codes 77781 and 77782 from 2006 to 2010 are dramatic decreases of 73% and 39% respectively. We are concerned that the reduced payments for the two lower level procedure codes could create an inappropriate financial incentive for the use of external beam radiation therapy in certain situations where brachytherapy would be more appropriate clinically. Because of this concern, we ask that you explain the reasons underlying the proposed RVU changes for the brachytherapy codes in the final rule.

[36] Rev. Ruling 2005-08, published in Internal Revenue bulletin 2005-19 (May 9, 2005).

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In closing and on behalf of US Oncology and our nationwide network of cancer care specialists, thank you for this opportunity to provide our comments on Proposed Rule CMS-1321-P. As you know, we are grateful for the opportunity to engage in substantive discussions and practice site visits with CMS officials, and we continue to stand ready should you have any questions about the issues, concerns, suggestions and data analyses discussed above. We also look forward to working collaboratively with CMS on initiatives supportive of the development of pay-for-performance approaches that will further the provision of high-quality, high-value cancer care to beneficiaries under a sustainable Medicare system.

Sincerely,

Dan Cohen
Senior Vice President
Government Relations & Public Policy

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Exhibit 1

2006 Actual

2006 Actual: Demo not Included	Allowable Cost	Reimbursement	Estimated Net	Net of Bad Debt
Oncology Sector	$ 6,214,205,428	$ 5,772,916,940	$ (441,288,488)	$ (729,934,335)
5-Physician Practice	$ 3,464,346	$ 3,218,333	$ (246,013)	$ (406,930)
Per Beneficiary	$ 9,238	$ 8,582	$ (656)	$ (1,085)
Estimated Percent Loss:			-7.1%	-11.7%

Oncology Sector

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 4,993,573,380	$ 3,994,858,704	$ 998,714,676	$ (249,678,669)	$ 4,743,894,711	$ 4,885,974,187	$ 107,599,193	$ (142,079,476)
Drug Admin	$ 779,343,560	$ 623,474,848	$ 155,868,712	$ (38,967,178)	$ 740,376,382	$ 1,328,231,241	$ (548,887,681)	$ (587,854,859)
Demo	$ -							$ -
Total	$ 5,772,916,940	$ 4,618,333,552	$ 1,154,583,388	$ (288,645,847)	$ 5,484,271,093	$ 6,214,205,428	$ (441,288,488)	$ (729,934,335)

Five Physician Practice

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 2,783,858	$ 2,227,087	$ 556,772	$ (139,193)	$ 2,644,665	$ 2,723,873	$ 59,985	$ (79,208)
Drug Admin	$ 434,475	$ 347,580	$ 86,895	$ (21,724)	$ 412,751	$ 740,473	$ (305,998)	$ (327,722)
Demo								$ -
Total	$ 3,218,333	$ 2,574,666	$ 643,667	$ (160,917)	$ 3,057,416	$ 3,464,346	$ (246,013)	$ (406,930)

Per Beneficiary

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 7,424	$ 5,939	$ 1,485	$ (371)	$ 7,052	$ 7,264	$ 160	$ (211)
Drug Admin	$ 1,159	$ 927	$ 232	$ (58)	$ 1,101	$ 1,975	$ (816)	$ (874)
Demo								$ -
Total	$ 8,582	$ 6,866	$ 1,716	$ (429)	$ 8,153	$ 9,238	$ (656)	$ (1,085)

1/ Utilization based on 2005 NPRM Utilization Data published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90), Facility and Non Facility.

3/ Relative Value Units based on Addendum B published in the FR Published in the November 21, 2005 Vol.70, No.223. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Drug Cost based on Average Sales Price (ASP) published by CMS quarterly without Prompt Pay Discount (2%) including the six month lag from cost to reimbursment.

5/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in July 2006 for the three Oncology Specialties Only; Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

Exhibit 2

2007 Conversion Factor $35.9647

2006 Actual: Demo not Included	Allowable Cost	Reimbursement	Estimated Net	Net of Bad Debt
Oncology Sector	$ 6,310,618,991	$ 5,805,733,325	$ (504,885,665)	$ (795,172,332)
5-Physician Practice	$ 3,518,096	$ 3,236,628	$ (281,468)	$ (443,299)
Per Beneficiary	$ 9,382	$ 8,631	$ (751)	$ (1,182)
Estimated Percent Loss:			-8.0%	-12.6%

Oncology Sector

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 5,088,815,091	$ 4,071,052,073	$ 1,017,763,018	$ (254,440,755)	$ 4,834,374,336	$ 4,947,853,737	$ 140,961,354	$ (113,479,401)
Drug Admin	$ 716,918,234	$ 573,534,587	$ 143,383,647	$ (35,845,912)	$ 681,072,323	$ 1,362,765,254	$ (645,847,019)	$ (681,692,931)
Demo	$ -							$ -
Total	$ 5,805,733,325	$ 4,644,586,660	$ 1,161,146,665	$ (290,286,666)	$ 5,515,446,659	$ 6,310,618,991	$ (504,885,665)	$ (795,172,332)

Five Physician Practice

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 2,836,954	$ 2,269,563	$ 567,391	$ (141,848)	$ 2,695,107	$ 2,758,370	$ 78,584	$ (63,263)
Drug Admin	$ 399,673	$ 319,739	$ 79,935	$ (19,984)	$ 379,690	$ 759,726	$ (360,052)	$ (380,036)
Demo								$ -
Total	$ 3,236,628	$ 2,589,302	$ 647,326	$ (161,831)	$ 3,074,796	$ 3,518,096	$ (281,468)	$ (443,299)

Per Beneficiary

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 7,565	$ 6,052	$ 1,513	$ (378)	$ 7,187	$ 7,356	$ 210	$ (169)
Drug Admin	$ 1,066	$ 853	$ 213	$ (53)	$ 1,013	$ 2,026	$ (960)	$ (1,013)
Demo								$ -
Total	$ 8,631	$ 6,905	$ 1,726	$ (432)	$ 8,199	$ 9,382	$ (751)	$ (1,182)

1/ Utilization based on 2005 NPRM Utilization Data published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90), Facility and Non Facility.

3/ Relative Value Units based on Addendum B published in the PR Published in the August 22, 2006 PR Vol.71, No.162. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Conversion Factor based on CY2006 and the expected CY2007 Conversion Factor Published in the August 22, 2006 PR Vol.71, No.162.

5/ Drug Cost based on Average Sales Price (ASP) published by CMS quarterly without Prompt Pay Discount (2%) including the six month lag from cost to reimbursment.

6/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in July 2006 for the three Oncology Specialties Only; Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

Exhibit 3

2007 Conversion Factor $37.8976

2006 Actual: Demo not Included	Allowable Cost	Reimbursement	Estimated Net	Net of Bad Debt
Oncology Sector	$ 6,310,618,991	$ 5,844,178,324	$ (466,440,666)	$ (758,649,583)
5-Physician Practice	$ 3,518,096	$ 3,258,060	$ (260,035)	$ (422,938)
Per Beneficiary	$ 9,382	$ 8,688	$ (693)	$ (1,126)
Estimated Percent Loss:			-7.4%	-12.0%

Oncology Sector

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 5,088,815,091	$ 4,071,052,073	$ 1,017,763,018	$ (254,440,755)	$ 4,834,374,336	$ 4,947,853,737	$ 140,961,354	$ (113,479,401)
Drug Admin	$ 755,363,233	$ 604,290,587	$ 151,072,647	$ (37,768,162)	$ 717,595,072	$ 1,362,765,254	$ (607,402,020)	$ (645,170,182)
Demo	$ -							$ -
Total	$ 5,844,178,324	$ 4,675,342,659	$ 1,168,835,665	$ (292,208,916)	$ 5,551,969,408	$ 6,310,618,991	$ (466,440,666)	$ (758,649,583)

Five Physician Practice

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 2,836,954	$ 2,269,563	$ 567,391	$ (141,848)	$ 2,695,107	$ 2,758,370	$ 78,584	$ (63,263)
Drug Admin	$ 421,106	$ 336,885	$ 84,221	$ (21,055)	$ 400,051	$ 759,726	$ (338,619)	$ (359,675)
Demo								$ -
Total	$ 3,258,060	$ 2,606,448	$ 651,612	$ (162,903)	$ 3,095,157	$ 3,518,096	$ (260,035)	$ (422,938)

Per Beneficiary

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 7,565	$ 6,052	$ 1,513	$ (378)	$ 7,187	$ 7,356	$ 210	$ (169)
Drug Admin	$ 1,123	$ 898	$ 225	$ (56)	$ 1,067	$ 2,026	$ (903)	$ (959)
Demo								$ -
Total	$ 8,688	$ 6,951	$ 1,738	$ (434)	$ 8,254	$ 9,382	$ (693)	$ (1,126)

1/ Utilization based on 2005 NPRM Utilization Data published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90), Facility and Non Facility.

3/ Relative Value Units based on Addendum B published in the PR Published in the August 22, 2006 PR Vol.71, No.162. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Conversion Factor based on CY2006 and the expected CY 2007 Conversion Factor Published in the August 22, 2006 PR Vol.71, No.162.

5/ Drug Cost based on Average Sales Price (ASP) published by CMS quarterly without Prompt Pay Discount (2%) including the six month lag from cost to reimbursment.

6/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in July 2006 for the three Oncology Specialties Only; Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

Drug Administration Reimbursement Changes based on New Practice Expense Methodology

Exhibit 4

Code	Description	MTUS	ALDHQ	MCR 2005	MCR 2006	MCR 2007 (CF $37.8975)	MCR 2007 (CF $35.9647)	MCR 2010 (CF $37.8975)	MCR 2010 (CF $35.9647)
90760	Hydration iv infusion, init	141,397	$ 8,983,662	$ 64.80	$ 63.29	$ 61.51	$ 58.37	$ 58.10	$ 55.13
90761	Hydrate iv infusion, add-on	452,934	$ 9,315,718	$ 20.69	$ 20.09	$ 18.99	$ 18.02	$ 16.71	$ 15.86
90765	Ther/proph/diag iv inf, init	623,997	$ 48,497,442	$ 79.24	$ 77.31	$ 75.00	$ 71.17	$ 71.21	$ 67.58
90766	Ther/proph/dg iv inf, add-on	516,167	$ 13,454,278	$ 26.54	$ 25.77	$ 24.33	$ 23.09	$ 21.68	$ 20.57
90767	Tx/proph/dg addl seq iv inf	1,881,226	$ 80,614,704	$ 43.72	$ 42.45	$ 39.83	$ 37.80	$ 34.15	$ 32.40
90768	Ther/diag concurrent inf	620,423	$ 15,269,730	$ 25.37	$ 24.63	$ 22.85	$ 21.69	$ 19.82	$ 18.81
90772	Ther/proph/diag inj, sc/im	3,155,631	$ 59,988,052	$ 19.13	$ 18.57	$ 19.44	$ 18.45	$ 23.23	$ 22.05
90773	Ther/proph/diag inj, ia	92	$ 1,909	$ 19.52	$ 18.95	$ 18.30	$ 17.37	$ 17.93	$ 17.01
90774	Ther/proph/diag inj, iv push	148,461	$ 8,500,652	$ 58.94	$ 57.60	$ 57.30	$ 54.38	$ 58.44	$ 55.46
90775	Ther/proph/diag inj add-on	1,288,058	$ 34,586,923	$ 27.71	$ 26.91	$ 26.15	$ 24.82	$ 24.25	$ 23.02
96401	Chemo, anti-neopl, sq/im	256,439	$ 13,519,706	$ 53.09	$ 52.68	$ 58.70	$ 55.71	$ 78.41	$ 74.41
96402	Chemo hormon antineopl sq/im	85,641	$ 3,105,921	$ 36.69	$ 45.86	$ 42.48	$ 40.32	$ 34.15	$ 32.40
96405	Chemo intralesional, up to 7	141	$ 13,484	$ 108.01	$ 113.31	$ 121.20	$ 115.02	$ 151.14	$ 143.43
96406	Chemo intralesional over 7	17	$ 2,364	$ 145.53	$ 145.91	$ 144.77	$ 137.39	$ 151.97	$ 144.22
96409	Chemo, iv push, sngl drug	229,918	$ 28,160,752	$ 125.69	$ 122.41	$ 119.98	$ 113.86	$ 115.81	$ 109.91
96411	Chemo, iv push, addl drug	359,181	$ 25,611,520	$ 72.99	$ 70.87	$ 68.97	$ 65.46	$ 65.94	$ 62.58
96413	Chemo, iv infusion, 1 hr	1,729,679	$ 298,598,873	$ 177.61	$ 172.81	$ 166.07	$ 157.60	$ 150.15	$ 142.49
96415	Chemo, iv infusion, addl hr	1,167,019	$ 46,171,402	$ 40.21	$ 39.03	$ 37.18	$ 35.28	$ 34.15	$ 32.40
96416	Chemo prolong infuse w/pump	99,780	$ 18,245,598	$ 190.88	$ 185.70	$ 179.60	$ 170.44	$ 164.82	$ 156.41
96417	Chemo iv infus each addl seq	594,331	$ 50,030,585	$ 88.66	$ 84.51	$ 81.44	$ 77.29	$ 75.00	$ 71.17
96420	Chemo, ia, push tecnique	109	$ 11,940	$ 113.20	$ 110.68	$ 110.02	$ 104.41	$ 111.15	$ 105.48
96422	Chemo ia infusion up to 1 hr	35	$ 5,506	$ 198.29	$ 192.90	$ 181.26	$ 172.02	$ 149.05	$ 141.45
96423	Chemo ia infuse each addl hr	25	$ 1,730	$ 80.80	$ 78.83	$ 78.18	$ 74.20	$ 79.70	$ 75.63
96425	Chemotherapy,infusion method	958	$ 178,486	$ 184.24	$ 179.26	$ 178.99	$ 169.86	$ 180.88	$ 171.66
96440	Chemotherapy, intracavitary	18	$ 6,233	$ 396.41	$ 405.12	$ 371.13	$ 352.20	$ 297.99	$ 282.79
96445	Chemotherapy, intracavitary	88	$ 30,486	$ 393.00	$ 393.76	$ 360.41	$ 342.02	$ 286.88	$ 272.25
96450	Chemotherapy, into CNS	1,199	$ 295,071	$ 338.05	$ 325.54	$ 300.79	$ 285.45	$ 245.84	$ 233.30
96521	Refill/maint, portable pump	50,762	$ 7,630,970	$ 152.73	$ 153.11	$ 146.25	$ 138.79	$ 128.43	$ 121.88
96522	Refill/maint pump/resvr syst	25,149	$ 2,980,479	$ 110.28	$ 110.66	$ 110.62	$ 104.98	$ 113.28	$ 107.50
96523	Irrig drug delivery device	189,990	$ 8,087,918	$ 28.89	$ 28.04	$ 27.51	$ 26.11	$ 26.00	$ 24.67
96542	Chemotherapy injection	2,092	$ 482,473	$ 216.77	$ 192.52	$ 182.86	$ 173.53	$ 162.77	$ 154.47
Weighted Change From 2005					-3%	-6%	-10%	-11%	-16%
Weighted Change From 2006					0%	-3%	-8%	-9%	-13%

Change From 2006

90760	Hydration iv infusion, init					-3%	-8%	-8%	-13%
90761	Hydrate iv infusion, add-on					-5%	-10%	-17%	-21%
90765	Ther/proph/diag iv inf, init					-3%	-8%	-8%	-13%
90766	Ther/proph/dg iv inf, add-on					-6%	-10%	-16%	-20%
90767	Tx/proph/dg addl seq iv inf					-6%	-11%	-20%	-24%
90768	Ther/diag concurrent inf					-7%	-12%	-20%	-24%
90772	Ther/proph/diag inj, sc/im					5%	-1%	25%	19%
90773	Ther/proph/diag inj, ia					-3%	-8%	-5%	-10%
90774	Ther/proph/diag inj, iv push					-1%	-6%	1%	-4%
90775	Ther/proph/diag inj add-on					-3%	-8%	-10%	-14%
96401	Chemo, anti-neopl, sq/im					11%	6%	49%	41%
96402	Chemo hormon antineopl sq/im					-7%	-12%	-26%	-29%
96405	Chemo intralesional, up to 7					7%	2%	33%	27%
96406	Chemo intralesional over 7					-1%	-6%	4%	-1%
96409	Chemo, iv push, sngl drug					-2%	-7%	-5%	-10%
96411	Chemo, iv push, addl drug					-3%	-8%	-7%	-12%
96413	Chemo, iv infusion, 1 hr					-4%	-9%	-13%	-18%
96415	Chemo, iv infusion, addl hr					-5%	-10%	-13%	-17%
96416	Chemo prolong infuse w/pump					-3%	-8%	-11%	-16%
96417	Chemo iv infus each addl seq					-4%	-9%	-11%	-16%
96420	Chemo, ia, push tecnique					-1%	-6%	0%	-5%
96422	Chemo ia infusion up to 1 hr					-6%	-11%	-23%	-27%
96423	Chemo ia infuse each addl hr					-1%	-6%	1%	-4%
96425	Chemotherapy,infusion method					0%	-5%	1%	-4%
96440	Chemotherapy, intracavitary					-8%	-13%	-26%	-30%
96445	Chemotherapy, intracavitary					-8%	-13%	-27%	-31%
96450	Chemotherapy, into CNS					-8%	-12%	-24%	-28%
96521	Refill/maint, portable pump					-4%	-9%	-15%	-20%
96522	Refill/maint pump/resvr syst					0%	-5%	2%	-3%
96523	Irrig drug delivery device					-2%	-7%	-7%	-12%
96542	Chemotherapy injection					-5%	-10%	-15%	-20%

1/ 2010 represents fully implemented Medicare Allowables; Conversion Factor $37.8975 and $35.9647 with a 10% reduction to the Work RVUs for Budget Neutrality.

2/ Utilization based on 2005 NPRM Utilization Data published at website www.cms.hhs.gov

3/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90)

4/ Relative Value Units based on Addendum B published in the PR Published in the August 22, 2006 PR Vol.71, No.162. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both CMS and Patient Portion.

5/ Conversion Factor based on CY2006 and the expected CY2007 Conversion Factor Published in the August 22, 2006 PR Vol.71, No.162.

Radiation Oncology Impact Analysis
Specialty 92

Exhibit 5

Service Category	MCR 2006	MCR 2007 (CF $37.8975)	MCR 2007 (CF $36.9647)	DRA (CF $37.8975)	DRA (CF $36.9647)	MCR 2010 (CF $37.8975)	MCR 2010 (CF $36.9647)
RADIATION-DOSIMETRY ISO CAL	$ 57,020,588	$ 52,557,226	$ 49,876,808	$ 52,557,226	$ 49,876,808	$ 44,578,551	$ 42,305,045
RADIATION-OTHER	$ 164,944,179	$ 146,042,484	$ 138,594,317	$ 146,042,484	$ 138,594,317	$ 98,573,310	$ 93,546,071
RADIATION-SIMULATION	$ 103,839,451	$ 99,708,575	$ 94,623,437	$ 99,708,575	$ 94,623,437	$ 92,703,875	$ 87,975,978
RADIATION-TREAT DELIVERY	$ 131,868,722	$ 188,991,812	$ 179,353,230	$ 188,991,812	$ 179,353,230	$ 361,795,423	$ 343,343,858
RADIATION-TREAT MGMT	$ 77,436,933	$ 71,957,025	$ 68,287,217	$ 71,957,025	$ 68,287,217	$ 72,112,342	$ 68,434,613
RADIATION-TREAT PLANNING	$ 15,229,557	$ 13,939,967	$ 13,229,029	$ 13,939,967	$ 13,229,029	$ 13,284,738	$ 12,607,216
IMRT	$ 435,092,401	$ 410,265,363	$ 389,341,829	$ 410,265,363	$ 389,341,829	$ 341,442,048	$ 324,028,503
IGRT	$ 511,050	$ 456,513	$ 433,231	$ 269,920	$ 266,337	$ 311,538	$ 295,650
RADIATION-IMAGE GUIDANCE	$ 21,349,594	$ 21,029,751	$ 19,957,233	$ 19,124,346	$ 18,423,601	$ 20,935,624	$ 19,867,907
RADIATION TOTAL	**$ 1,007,392,475**	**$ 1,004,948,716**	**$ 953,696,331**	**$ 1,002,856,718**	**$ 951,995,804**	**$ 1,045,737,449**	**$ 992,404,839**
IMAGING /X RAY -MRI	$ 5,021,628	$ 4,928,186	$ 4,677,042	$ 3,574,601	$ 3,531,838	$ 4,857,796	$ 4,610,242
IMAGING /X-R MAMMO	$ 1,995,928	$ 1,917,551	$ 1,819,756	$ 1,917,551	$ 1,819,756	$ 1,849,631	$ 1,755,300
IMAGING /X-RAY -XRAY	$ 1,377,160	$ 1,312,065	$ 1,248,788	$ 1,219,316	$ 1,164,702	$ 1,209,890	$ 1,151,823
IMAGING /X-RAY-CT	$ 11,816,394	$ 11,919,761	$ 11,318,880	$ 10,472,871	$ 10,343,735	$ 12,736,027	$ 12,093,515
ULTRASOUND	$ 1,986,060	$ 2,034,194	$ 1,930,451	$ 1,913,296	$ 1,828,436	$ 2,355,396	$ 2,235,270
PET	$ 10,768,761	$ 10,747,495	$ 10,734,480	$ 4,241,298	$ 4,228,164	$ 10,743,218	$ 10,730,421
DIAGNOSTIC and PET TOTAL	**$ 32,966,930**	**$ 32,859,254**	**$ 31,729,396**	**$ 23,338,933**	**$ 22,916,631**	**$ 33,751,957**	**$ 32,576,571**
OTHER	$ 55,028,922	$ 55,576,557	$ 52,984,169	$ 53,696,272	$ 51,107,117	$ 54,224,792	$ 51,701,344
TOTAL	$ 1,095,387,327	$ 1,093,384,527	$ 1,038,409,896	$ 1,079,891,923	$ 1,026,019,552	$ 1,133,714,199	$ 1,076,682,755

Percent Change From 2006

RADIATION-DOSIMETRY ISO CAL	-8%	-13%	-8%	-13%	-22%	-26%
RADIATION-OTHER	-11%	-16%	-11%	-16%	-40%	-43%
RADIATION-SIMULATION	-4%	-9%	-4%	-9%	-11%	-15%
RADIATION-TREAT DELIVERY	43%	36%	43%	36%	174%	160%
RADIATION-TREAT MGMT	-7%	-12%	-7%	-12%	-7%	-12%
RADIATION-TREAT PLANNING	-8%	-13%	-8%	-13%	-13%	-17%
IMRT	-6%	-11%	-6%	-11%	-22%	-26%
IGRT	-11%	-15%	-47%	-48%	-39%	-42%
RADIATION-IMAGE GUIDANCE	-1%	-7%	-10%	-14%	-2%	-7%
RADIATION TOTAL	**0%**	**-5%**	**0%**	**-5%**	**4%**	**-1%**
IMAGING /X RAY -MRI	-2%	-7%	-29%	-30%	-3%	-8%
IMAGING /X-R MAMMO	-4%	-9%	-4%	-9%	-7%	-12%
IMAGING /X-RAY -XRAY	-5%	-9%	-11%	-15%	-12%	-16%
IMAGING /X-RAY-CT	1%	-4%	-11%	-12%	8%	2%
ULTRASOUND	2%	-3%	-4%	-8%	19%	13%
PET	0%	0%	-61%	-61%	0%	0%
DIAGNOSTIC and PET TOTAL	**0%**	**-4%**	**-29%**	**-30%**	**2%**	**-1%**
OTHER	1%	-4%	-2%	-7%	-1%	-6%
TOTAL	0%	-5%	-1%	-6%	3%	-2%

1/ Utilization based on 2005 NPRM Utilization Data published at website www.cms.hhs.gov

2/ Specialty includes Radiation Oncology (92), Non Facility Only

3/ Non Facility represents 74% ($1,065,844,471) of 2005 MCR Allowables and Facility represents 26% ($374,527,448) of 2005 MCR Allowables.

4/ Relative Value Units based on Addendum B published in the PR Published in the August 22, 2006 PR Vol.71, No.162. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both CMS and Patient Portion.

5/ Conversion Factor based on CY2006 and the expected CY2007 Conversion Factor Published in the August 22, 2006 PR Vol.71, No.162.

6/ Deficit Reduction Act (DRA) 2006 codes included in this analysis are based on Addendum F--Proposed CPT/HCPCS Imaging Codes Defined by Section 5102(b) of the DRA

7/ Intensity-Modulated Radiation Therapy (IMRT) reflects codes 77301 (Global, Technical and Professional) and 77418

8/ Image-Guided Radiation Therapy (IGRT) reflects codes 77421 (Global, Technical and Professional)

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ZLB Behring

October 10, 2006

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8018

ATTN: (CMS-1321-P) Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics including intravenous immune globulin (IVIG), which is used in treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or through the development of recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the proposed rule regarding 2007 changes to Medicare Part B and the Physician Fee Schedule. Our comments will be focused on the section of the proposed rule entitled "ASP issues". ZLB Behring will not be providing comment specific to the calculation of ASP, but instead will comment on how the proposed rule would affect patient access to IVIG. Some of the provisions suggested in this rule would be contrary to positive policies CMS enacted in 2006 to address IVIG reimbursement. ZLB Behring asks CMS to consider changes to the proposed rule with regard to IVIG.

Our main points regarding the proposed rule are as follows:

- CMS does not address the basic cause of the current IVIG situation; providers simply cannot afford to purchase the therapy at existing reimbursement rates in many cases. Consideration of a payment rate adjustment (similar to the precedent of blood clotting factor) and the establishment of Healthcare Common Procedure Code System (HCPCS) codes for each individual brand of IVIG would substantially improve the

reimbursement environment and would allow the provider to recoup the costs of the therapy.

- Elimination of the $69 pre-administration code for IVIG (G 0332) is problematic given the shortfall that will occur in covering physician administration costs. This code provided assistance in addressing the IVIG administration payment shortfall but did not solve the issue. With further reductions proposed in administration reimbursement through a reduction of the relative value units, this pre-administration code is more important than ever to assure that patients will have access to IVIG. CMS should also consider recognizing IVIG as a biologic response modifier so that the complexity of the administration is recognized and properly reimbursed.

ASP ISSUES

Ensuring Adequate Payment Rates for Plasma Therapies

IVIG access concerns have been ongoing for nearly two years in Medicare Part B. Providers are unable purchase the product for Medicare Part B beneficiaries in many cases without a loss. Until CMS addresses this problem, patient access to IVIG will remain problematic. ZLB Behring continues to advocate for two specific measures that will improve access to IVIG, as providers would be able to recoup the cost of the therapy through its reimbursement.

Brand-specific reimbursement - Plasma therapeutics have several brands within a HCPCS code, although each brand has unique features that connect with different patient profiles. Access to all brands is essential so that individual patients may be treated properly. The weighted average calculation of multiple brands within the HCPCS code has resulted in the reimbursement level being too low for providers to purchase some of the brands within the class of therapy. This has in part contributed to the current IVIG patient access situation. Part of the remedy would be to have brand-specific (NDC based) reimbursement based on the statutory reimbursement rate, rather than a volume-weighted average calculated from multiple brands comprised within a single HCPCS code.

IVIG is unique in that it is one of a very few biologics, almost all of which are blood plasma therapies, that have multiple brands within a HCPCS code. Bundling these products together can distort provider selection of therapies by arbitrarily having some therapies below or above the calculated volume weighted ASP. We urge CMS to exercise its authority to create new HCPCS codes for each individual product.

Payment Adjustment –Another access remedy is for IVIG to have an add-on payment or payment adjustment similar to that which applies for another plasma derived therapy, blood

clotting factor. We believe that CMS has the ability to institute additional reimbursement measures for specific cases when used in conjunction with the statutory reimbursement formula of ASP plus 6%. To support this request with data, the Plasma Protein Therapeutics Association (PPTA), of which ZLB Behring is a member, contracted with The Lewin Group to survey hospitals regarding their overhead costs specific to IVIG. The Lewin Group determined that during the snapshot in time they examined (October – December 2005) there was a 14.6% shortfall between a provider's purchase price for IVIG and the reimbursement rate. ZLB Behring urges CMS to consider a payment adjustment for IVIG, in the form of an add-on payment based on independent data. We believe this will alleviate the patient access issues being driven by a product reimbursement shortfall. Please find attached a legal opinion from Hogan & Hartson illustrating CMS legal authority in addition to a copy of the Lewin Group analysis on the product reimbursement shortfall.

For blood clotting factor, the additional reimbursement is in the form of a furnishing fee, which CMS has wisely incorporated into the therapy's payment rate. This measure has averted any potential patient access difficulties for people with bleeding disorders. The same principles can and should apply for IVIG. ZLB Behring urges CMS to consider this option so that individuals can obtain their life-saving IVIG on a continual basis.

Continue the Payment for IVIG Pre-administration Related Services / Classify IVIG as a Biologic Response Modifier

Addendum B of the proposed rule indicates the pre-administration code is to be deleted for 2007. Doing so would result in unintended consequences for the treatment of patients who need IVIG therapy. Currently, Medicare allows a $69 payment for pre-administration related services under G 0332 to reimburse physicians for the additional resources that are associated with locating and acquiring adequate IVIG products in addition to preparing for an infusion of IVIG, monitoring and managing inventory, and rescheduling infusions. This pre-administration code helps providers recoup the cost for the administration of IVIG. Eliminating the pre-administration code, when combined with the reduction of reimbursement for physician services in 2007 will further displace patients.

CMS should also consider classifying IVIG as a biologic response modifier. Immunologists have testified to CMS and Congress about the higher level of complexity required to administer IVIG than is recognized under current administration payment rates. Classifying IVIG as a biologic response modifier would be of help in addressing the administrative reimbursement shortfall comprised within the proposed rule and would properly reimburse for the complexity of administering IVIG.

Conclusion

The proposed rule put forward by CMS for the Physician Fee Schedule and Medicare Part B covered therapies is problematic and will serve to exacerbate problems relating to the provision of IVIG. CMS implemented a third quarter payment rate adjustment that did have a positive impact on the situation. While that was helpful, it was not enough to assure adequate payment to cover provider acquisition costs in many cases. However, by further reducing reimbursement on the administration side, the proposed rule diminishes CMS' very own remedies from 2006.

The pre-administration code implemented in 2006 for IVIG was of help in covering administration reimbursement. The elimination of those codes will only intensify the IVIG access situation. Administrative reimbursement for IVIG must be improved, by maintaining the 2006 pre-administration code. CMS should also consider recognizing IVIG as a complex therapy by classifying it as a biologics response modifier (or establishing an administration rate similar to the BRM level). Without such actions, physicians will be not be reimbursed for their cost of administration.

With product reimbursement not meeting the costs of therapy and administrative reimbursement not meeting the cost of services, IVIG access problems continue. The proposed rule would, unfortunately, magnify the situation. ZLB Behring respectfully asks CMS to use its authority to implement innovative measures to solve IVIG access problems. These would include a payment adjustment for IVIG, using the precedent of blood clotting factors as the example, and creating HCPCS codes based on the individual brands of IVIG. These two measures, combined with continuing the 2006 pre-administration codes or the classification of IVIG as a biologic response modifier would greatly contribute to remedying ongoing patient access difficulties.

Finally, as described in previous comments, the plasma therapeutics industry supply chain differs from that of traditional pharmaceuticals. Plasma therapeutics are expensive products to manufacture, with high cost for starting materials and all of the related costs of manufacturing inherent in producing a biologic. These costs can only be recovered in limited populations of

use. Reimbursement policies that limit patient access to these therapies not only endanger patient care now, but also economically threaten the future of manufacturers and providers to viably provide these therapies. Given the critical nature of these therapies, that would be a terrible consequence and is not unlike the loss of vaccine suppliers and the resulting consequences that had occurred over time in the United States. Increased reimbursement for vaccines helped to both attract supply and assure providers adequate coverage to administer the vaccines.

Thank you for the opportunity to comment on this proposed rule. Should there be any questions or if we may be of assistance, please feel free to contact either myself or Patrick Collins (610-878-4311). Your consideration of these comments in the formulation of the final rule is greatly appreciated.

Sincerely,

Dennis Jackman
Senior Vice President, Public Affairs

Attachments

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MEMORANDUM

March 13, 2006

BY ELECTRONIC MAIL

TO: Julie Birkofer
PPTA

FROM: Stuart M. Langbein

RE: **Questions Related to Intravenous Immune Globulin**

This memorandum responds to questions that you raised relating to Medicare reimbursement for intravenous immune globulin ("IVIG"). Specifically, you have asked whether the Centers for Medicare and Medicaid Services ("CMS") would have the discretion to establish a payment adjustment for IVIG when provided in a hospital outpatient department and in a physician's office. You also asked if any such adjustments could be made without first undertaking a new notice and comment rulemaking process. After a brief background discussion, each of these questions is addressed in turn.

Background

The Plasma Protein Therapeutics Association ("PPTA") and other organizations have been working with CMS to ensure that the Medicare payment rates for IVIG and related services in various settings are sufficient to ensure patient access to the product. Currently, Medicare payments for IVIG and related services are similar in the physician office and hospital outpatient department settings. The product itself is reimbursed at 106 percent of the average sales price ("ASP"), and there is a separate payment made for preadministration-related services (although the amount of this payment differs for physicians and hospitals). Finally, a separate payment is made to reimburse the physician or hospital for the service of administering IVIG, with the

pertinent payment rate set under the physician fee schedule and hospital outpatient prospective payment system ("OPPS"), respectively. 1/

Discussion

I. CMS Has Discretion to Adjust OPPS Payments for IVIG

In considering the ability of CMS to adjust IVIG related payments to hospital outpatient departments, the inquiry begins with the Medicare statutory provisions governing payments for drugs and biologicals (hereinafter, "drugs") under OPPS. The statute provides that, in 2006 and beyond, payment rates for specified covered outpatient drugs, which includes IVIG, shall be equal, subject to a provision on overhead costs,

> "(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or (II) 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." 2/

The referenced provision on overhead costs allows CMS to "adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account" recommendations made by the Medicare Payment Advisory Commission ("MedPAC"). 3/ In addition to these drug specific provisions, the OPPS statute provides CMS with the authority to establish "adjustments as determined to be necessary to ensure equitable payments" under OPPS. 4/ As detailed below, within the OPPS statute, CMS has considerable discretion to adjust the payment rate for IVIG.

1/ My understanding is that the questions you have raised do not involve changes to the payment for the service of administering IVIG. Thus, such payment will not be considered here. In addition, this memorandum focuses solely on the agency's authority to adjust payment rates for IVIG and does not address the likelihood that CMS would utilize any identified authority.

2/ Social Security Act ("SSA") § 1833(t)(14)(A)(iii).

3/ SSA § 1833(t)(14)(E)(ii).

4/ SSA § 1833(t)(2)(E).

A. Payments for Specified Covered Outpatient Drugs

The OPPS statute, quoted above, offers two mechanisms for determining OPPS payment rates for specified covered outpatient drugs such as IVIG in 2006. Each mechanism contains authority for CMS to adjust payment for IVIG. In setting the 2006 OPPS payment rates for specified covered outpatient drugs, CMS opted to use the ASP plus six percent methodology under SSA § 1847A. This methodology is referenced in SSA § 1833(t)(14)(A)(iii)(II), quoted above, and this provision allows for payment rates to be "adjusted by the Secretary as necessary." Because the language of the statute uses the singular term "drug," any such adjustment could be made on a product-specific basis, provided it was found "necessary." Thus, for example, CMS could find that, based on information provided to the agency, it is necessary for CMS to adjust upward the ASP plus six percent rate for IVIG to ensure patient access to IVIG in the outpatient setting. 5/

The other statutory mechanism for paying for drugs in 2006 under OPPS, SSA § 1833(t)(14)(A)(iii)(I), also provides CMS with authority to change the payment rate for a specified covered outpatient drug such as IVIG. Under this provision, payment is to be set at the average acquisition cost of a drug. The agency could determine that it had not accurately captured the average acquisition cost when establishing the payment rate for such a drug. Such a determination might be the result of additional information that had come to the agency's attention regarding a product. Accordingly, if the agency concluded that the payment rates for IVIG did not reflect average acquisition cost for the product, it could make an adjustment to achieve such a result.

B. Overhead Cost Adjustment

The OPPS statute vests discretion in CMS to adjust payments for drugs to take into account MedPAC recommendations on overhead costs. 6/ As CMS has noted, MedPAC recommended that the agency establish separate payments to reflect such costs. 7/ Thus, CMS could exercise this discretion and adjust payments for IVIG to take into account hospital overhead costs related to the product, as there is nothing in the statutory language that prevents the agency from making a payment adjustment for a single specified covered outpatient drug

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5/ While the statute grants CMS the authority to adjust the payment rates for specified covered outpatient drugs in 2006, it cannot exercise this discretion arbitrarily and capriciously. *See* Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 414 (1971). With regard to IVIG, CMS has already been convinced of the need for a specific payment adjustment, as the agency decided to make a separate payment for preadministration-related services under OPPS uniquely for IVIG because of concerns about beneficiary access to the product. 70 Fed. Reg. 68516, 68649 (Nov. 10, 2005). Thus, adjusting the payment rates solely for IVIG would not constitute arbitrary and capricious agency action.

6/ SSA § 1833(t)(14)(E)(ii).

7/ 70 Fed. Reg. at 68658.

such as IVIG. As discussed earlier, there would have to be support for the need for an individualized adjustment to account for the overhead costs incurred by hospitals in connection with IVIG.

C. Equitable Adjustment

Aside from the OPPS statutory provisions specific to drugs, there is a more general statutory provision that can be used as the basis for the authority to adjust the OPPS payment for IVIG. As noted earlier, SSA § 1833(t)(2)(E) allows CMS to make adjustments to ensure equitable payments under OPPS. As a result, CMS could determine that an adjustment is needed to ensure equitable payments for IVIG under OPPS. 8/

II. CMS Has Discretion to Adjust Payments to Physicians for IVIG

Physicians are reimbursed for the IVIG that they provide to Medicare beneficiaries at the pertinent ASP plus six percent payment rate under SSA § 1847A. Under this statute, CMS determines the ASP plus six percent payment rate for drugs and biologicals on a Healthcare Common Procedure Coding System ("HCPCS") code basis. Much of the specifics of this payment methodology are set forth in the Medicare statute, giving CMS less discretion to adjust the payment for IVIG than the agency has under the OPPS statute. Nonetheless, the agency has options available to it to alter the payments to physicians for IVIG.

A. Creation of Product Specific HCPCS Codes

As noted, CMS computes the ASP plus six percent payment rates for all drugs payable to physicians under Medicare Part B by HCPCS code. Currently, there are two HCPCS codes for IVIG, J1566 (immune globulin, powder) and J1567 (immune globulin, liquid) that are distinguished based on whether the product is a liquid or a powder. This distinction among IVIG products generates different payment rates for IVIG products. When physicians were first paid for IVIG under the ASP methodology in the first calendar quarter of 2005, this distinction among IVIG products did not exist. The coding change, and thus the payment change, was first effective in the second calendar quarter of 2005. 9/ As a result, changes to HCPCS codes, which are within the agency's authority, can cause changes to the physician office reimbursement rates. Accordingly, CMS could alter the payment rates for IVIG, as it has done before, by revising the HCPCS codes for IVIG. 10/

8/ All of the authorities discussed in Section II below also could be used as a basis for a payment adjustment for hospital outpatient departments.

9/ *See* http://www.cms.hhs.gov/Transmittals/2005Trans/itemdetail.asp?filterType=none&filterByDID=-.

10/ The requirement to treat single source drugs within the same billing and payment cost as of October 1, 2003 as multiple source drugs for purposes of the ASP statute, SSA § 1847A(c)(6)(C)(ii), does not alter the agency's

[Footnote continued]

B. Demonstration Project

The agency also has the authority to alter Medicare payments to physicians for IVIG under the agency's demonstrations authority. Section 402(a)(1) of the Social Security Act Amendments of 1967 ("SSAA") authorizes the Secretary to conduct demonstration projects for various purposes set forth in that statute, including:

> "(A) to determine whether, and if so which, changes in methods of payment or reimbursement [] for health care and services under health programs established by the Social Security Act, including a change to methods based on negotiated rates, would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives without adversely affecting the quality of such services";
> "(B) to determine whether payments for services other than those for which payment may be made under such programs (and which are incidental to services for which payment may be made under such programs) would, in the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under such program . . . ."

In exercising this demonstration authority, "the Secretary may waive compliance with the requirements of titles XVIII and XIX of the Social Security Act insofar as such requirements relate to reimbursement or payment on the basis of reasonable cost, or (in the case of physicians) on the basis of reasonable charge, or to reimbursement or payment only for such services or items as may be specified in the experiment . . . ." 11

The agency has exercised this authority on numerous occasions, including some recently that included added Medicare payments to physicians. Effective for calendar year 2005, CMS established a demonstration project under SSAA § 402(a) "to identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population." 12 Under this demonstration, participating physicians were paid $130 per

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[Footnote continued]

ability to create unique product-specific HCPCS codes for IVIG. Under § 1847A, computing the payment rate for a multiple source drug differs from that for a single source drug in that wholesale acquisition cost ("WAC") is used in computing rates for single source drugs. Thus, creating product-specific HCPCS codes for IVIG but determining payment rates without consideration of WAC in the computations is consistent with SSA § 1847A(c)(6)(C)(ii).

11 SSAA § 402(b).

12 69 Fed. Reg. 66236, 66308 (Nov. 15, 2004).

encounter for submitting certain patient assessment data. 13 For 2006, CMS replaced this demonstration project with another demonstration project under SSAA § 402(a), which involves a payment of $23 for physicians that submit specific codes when certain evaluation and management services are billed. 14 The agency's most recent use of this demonstration authority was the establishment a few weeks ago of a demonstration project to allow "States to be fully reimbursed for their efforts to help ensure that their beneficiaries eligible for Medicare and Medicaid have access to their covered Medicare drugs as they move to their new Medicare Part D drug coverage." 15

CMS could establish a demonstration project that would increase payments to physicians for IVIG consistent with the statutory authority vested in it by SSAA § 402(a). For example, one purpose of such a demonstration could be to determine whether increased payments would result in more economical provision and effective utilization of services paid by Medicare, pursuant to SSAA § 402(a)(1)(B). As has been reported to CMS, there are concerns about continued beneficiary access to IVIG which could lead to greater health complications for beneficiaries that receive IVIG. Accordingly, a demonstration project could test whether the added payment for IVIG would ensure access in a way that would diminish the need for other Medicare expenditures for affected beneficiaries. This assessment also would fall within SSAA § 402(a)(1)(A), which authorizes demonstrations to determine whether a change in payments would increase the efficiency and economy of Medicare services.

C. Inherent Reasonableness

CMS or a Medicare carrier may reduce or increase the payment for an item or service if it determines that the otherwise applicable rate "is not inherently reasonable." 16/ If CMS were to utilize this authority to establish a new national rate, it must publish proposed and final notices before the revised rate could be effective. If a carrier were to utilize this authority, it must inform affected entities, evaluate comments it receives, notify CMS of a final limit it plans to establish, notify affected entities of the final limit, and provide for an effective date that is at least 60 days after affected parties have been notified of the final limit. Regardless of whether pursued by CMS or a carrier, an adjustment could not be made unless the difference between the current and the proposed rate is at least 15%. 17/ Although CMS has yet to exercise this authority since final, revised regulations were issued 2002, the agency nonetheless retains the authority to use this tool.

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13 69 Fed. Reg. at 66308-09.

14 . 70 Fed. Reg. 70116, 70272-73 (Nov. 21, 2005).

15 *See* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1761.

16/ SSA § 1842(b)(8)(A)(i)(I).

17/ 42 C.F.R. § 405.502(g)(1)(ii).

III. CMS Could Adjust Payments for IVIG Without Further Rulemaking

The prior sections of this memorandum address the authority of CMS to adjust the payment rate for IVIG in the hospital outpatient and physician office settings. Were CMS to decide to exercise any such authority, an important question becomes the manner in which CMS could take action. You have asked whether CMS could establish a payment adjustment for IVIG without going through new notice and comment rulemaking. As explained below, CMS would be able to exercise the above areas of authority to make such an adjustment without undertaking a new notice and comment rulemaking process, in all circumstances but one.

Both the OPPS final rule and the physician fee schedule final rule issued setting the 2006 rates for drugs were issued as final rules with comment periods. 18/ In the OPPS rule, as the agency has done with past OPPS final rules, CMS allows for "comments on the payment classification assigned to HCPCS codes identified in Addendum B with the NI comment code and other areas specified through the preamble." 19/ Among the codes that have the NI comment code are those to be used to bill for IVIG. 20/ The physician fee schedule rule did not contain any limitations on the issues for which the agency would accept comments. 21/

A "final rule with comment period" is not specifically recognized by the Administrative Procedure Act ("APA"). The courts likewise have not afforded any special status to final rules with comment. Nonetheless, by designating a payment rate or an issue for comment in a final rule, the agency affords itself the opportunity to respond to comments submitted on such issues without first reissuing a proposed rule on that topic. The purpose of the notice requirement in the APA is to ensure that interested parties are able to communicate information and views about proposed policies to the agency. 22 By specifying that certain aspects of a final rule are subject to comment, the agency can argue that it has provided the notice that an issue is under consideration that the APA requires. As a result, the agency would claim, a subsequent change could be in compliance with the APA.

18/ *See* 70 Fed. Reg. 70116 (Nov. 21, 2005) (physician fee schedule rule); 70 Fed. Reg. at 68516 (OPPS rule).

19/ 70 Fed. Reg. at 68516.

20/ 70 Fed. Reg. at 68899.

21/ *See* 70 Fed. Reg. at 70116.

22 See American Acad. of Pediatrics v. Heckler, 561 F.Supp. 395, 398 (D.D.C. 1983) ("The Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, was designed to curb bureaucratic actions taken without consultation and notice to persons affected. Broad delegations of rulemaking authority from the Congress were intended to be tempered by assuring a degree of due process for those to be governed by the rule") (citing United States v. Morton Salt Co., 338 U.S. 632, 644 (1950).

If the agency were to revise a policy or payment rate based upon a comment to a final rule with comment, any procedural vulnerability likely would result from a court finding that the revised policy is not a "logical outgrowth" of the rule that afforded notice. 23 Courts set rules aside for insufficient notice when the purposes of notice and comment "have not been adequately served" and "a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule." American Water Works Ass'n v. EPA, 40 F. 3d 1266, 1274 (D.C. Cir. 1994). If CMS were to make a change to the payments for IVIG, whether that change would satisfy the "logical outgrowth" standard would have to be assessed based on a review of the change in comparison to what the agency said in the rule and based on the comments submitted on the subject. Given that PPTA and others submitted comments to CMS on the payment rate for IVIG, an argument can be made that CMS' exercise of most of the above authorities would be a logical outgrowth of the final rule with comment period (and the comments submitted to it). For example, the agency could argue that a payment adjustment was a response to timely submitted comments on the recent final rules indicating that the payment rates for IVIG were insufficient to ensure access to IVIG. As a result, the agency could issue a Federal Register notice explaining and implementing an adjustment to the payment for IVIG under one of the aforementioned authorities (except for inherent reasonableness, as noted below) as soon as practicable.

Indeed, there is ample precedent to support such an approach. In the agency's implementation of the ASP payment methodology the agency issued a final rule with comment period and decided to issue a subsequent final rule that addressed a single issue in response to comments received. After issuing an interim final rule with comment on April 6, 2004 that related to the calculation and submission of ASP data, CMS issued a final rule to respond "to the public comments received on the interim final rule concerning the methodology for estimating price concessions associated with manufacturers' ASP reporting requirements. Other issues and comments will be addressed at a future time." 24 Consistent with the approach taken for this ASP final rule, CMS could issue a final rule addressing only the payment for IVIG.

Another alternative for CMS would be to include a payment adjustment for IVIG in a correction notice. CMS has made numerous changes to payment rates after the issuance of an OPPS final rule in a correction notice published in the Federal Register, which demonstrates that CMS believes it has the authority to make policy changes after the issuance of a final rule. For instance, in 2003, subsequent to the issuance of an OPPS final rule with comment period, CMS issued a correction notice that included a revised payment rate for a product based on information submitted by the manufacturer on the cost of the product. 25

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23 This discussion is not to suggest that the agency must act through notice and comment rulemaking, but assumes that the agency were to take the position to that it must act through such a process.

24 69 Fed. Reg. 55763 (Sept. 19, 2004).

25 68 Fed. Reg. 75442, 75444 (Dec. 31, 2003).

The agency has also made changes affecting payment rates through a Program Transmittal, without the subsequent issuance of a Federal Register notice. When first implementing the transitional OPPS payment rate methodology from the Medicare Modernization Act, the agency treated a number of biologicals as multiple source drugs for purposes of the average wholesale price based ceilings to payment rates in a final rule with comment period. 26 In a transmittal issued on February 27, 2004, 27/ the agency determined that all biologicals should be treated as sole source specified covered outpatient drugs, thus applying different payment rates to these products than had been set forth in the final rule. Similarly, as noted in Section II(A) above, the agency altered the payment rate for IVIG through a Program Transmittal when it announced the establishment of new HCPCS codes for IVIG.

CMS' actions also illustrate that the agency's exercise of its demonstrations authority need not be done through new notice and comment rulemaking. The most recent project involving payments to States in connection with the implementation of Part D was commenced with the release of a CMS Fact Sheet, without rulemaking. Thus, a demonstration on IVIG likewise could be accomplished without rulemaking.

Of all of the identified authorities in Sections I and II for altering payments for IVIG, only the use of inherent reasonableness would require a process akin to rulemaking. A proposal to apply inherent reasonableness to a product nationwide would have to be issued first, followed by a public comment period, followed by a final determination from CMS prior to the application of inherent reasonableness. Practically, this amounts to a new rulemaking process.

Conclusion

For the reasons stated above, there are a variety of authorities that CMS could rely on to make a payment adjustment for IVIG in the physician office and hospital outpatient settings. Almost all of the identified authorities for making such an adjustment could be made without engaging in a new round of rulemaking, whether through the issuance of a final rule, a correction notice, or a Program Transmittal.

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26 69 Fed. Reg. 820, 825 (Jan. 6, 2004).

27/ *See* http://www.cms.hhs.gov/manuals/pm_trans/R112CP.pdf.

Assessing the Cost of IVIG Infusion Services in Physician Offices & Hospital Pharmacy Departments

Developed by:
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March 23, 2006

The LEWIN GROUP

Presentation Overview

- Background of IVIG
- Presentation Purpose
- Study Methods
- Providing IVIG Infusion Services
- Comparison of CMS Payments to Reported Costs for IVIG Costs of Goods
- Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices
- Total Infusion Costs per Month: CMS Payments vs. Physician Office Cost Data
- Study Conclusions

The following presentation is based on report submitted to CMS (report dated 12/27/05), and revisions sent to CMS (Herb Kuhn letter, dated 2/3/06).

Background of IVIG

- IVIG is a complex biological product used to treat numerous chronic disorders (e.g., Chronic Variable Immune Deficiency, Hypogammaglobunemia, and Idiopathic Thrombocytopenic Purpura) and can be provided in various settings.
- Aggregate provider IVIG usage is difficult to estimate and predict due to varying patient needs and diagnoses.
- The IVIG market is complex:
  - Current IVIG market prices differ significantly between contracted and non-contracted purchases
  - As providers cannot easily predict patient need some IVIG products are purchased at higher off-contract rates (contract rates only apply to IVIG product amount contracted for in advance)

Background of IVIG (continued)

- Physicians and hospitals reported that reduced physician Medicare payments beginning in 2004 (a decrease from $4109.20 in 2003 to $2878.28 in 2004*) resulted in a migration of patients from physician offices to the outpatient hospital setting, complicating patient access and IVIG market allocation.

- In 2006 CMS provided a temporary add-on payment for physician offices of $69, and for hospitals of $75 to cover pre-service costs related to "temporary market instability".

*Total infusion cost based on a 5 hour infusion at 50 grams of lyophilized/non-lyophilized IVIG.

Presentation Purpose

- To identify the costs of providing IVIG infusion in physician offices.
- To provide the total and component costs, on average, for providing IVIG infusions in physician offices.
- To compare CMS IVIG physician office infusion payments to costs incurred to provide IVIG infusion therapy.
- To determine the impact of CMS physician payment policies on physicians' willingness to provide IVIG infusions in physician's offices.

Study Methods

- Review past and current Medicare IVIG reimbursement.
- Develop an understanding of the IVIG market as it affects providers.
- Collect distributor and manufacturer pricing.
- Survey 76 physician offices to compare CMS payments to current physician office, cost of goods and physician time costs.
- Survey 30 hospital pharmacy departments to compare CMS payments to current pharmacy department cost of goods, product and handling costs.
- Conduct data analyses and policy interpretation.

Methods: Components of IVIG Infusion Costs for Physicians (revised categories, 2/06)

- Pre-Service
  - Check inventory
  - Locate & procure product
  - Place order
  - Shelving and storing
  - Pre-certification/verification of insurance
  - Telephone patient assessment /confirm appointment
- Clinical Administration
  - Prepare and/or reconstitute IVIG product*
  - History*
  - Vital check*
  - Physical exam*
- Clinical Administration (continued)
  - IV start
  - Pre-medication administration
  - Physician coordination and monitoring
  - Adverse events intervention
  - Discontinue IVIG infusion
  - Immediate post-infusion assessment**
- Post-Service
  - Post-infusion assessment by telephone (w/in 24 hours)

* Tasks shifted from pre-service category
**Tasks shifted from post-service category
Revised categories documented in letter to CMS (Herb Kuhn, 2/3/06)

Providing IVIG Infusion Services

- IVIG infusion services are currently provided by an increasing number of hospitals and physician specialists.
- Treatment varies in amount of product provided over time, as well as speed, concentration and frequency of infusions.
- Special training is required due to the extra complexities of infusing any biological product.
- Physicians, hospital pharmacists and staff expend extra hours obtaining appropriate IVIG products.
- When lack of availability of specific IVIG products require that a patient switch products, additional clinical time is needed for evaluation and monitoring of potential adverse reactions.
- Patients' clinical indications, medical conditions and past reactions to various products determine recommendations for specific products.
- As a result of the above factors, IVIG pre-infusion services are more resource-intensive than other infusions.

Comparison of CMS Payments to Reported Costs for IVIG Costs of Goods

Acquisition costs tend to be above CMS ASPs because these costs include off contract prices with a wide variety of suppliers, and reflect real time prices as opposed to dated prices embodied in CMS ASPs.

	CMS Final Rule CY 2006 ASP + 6%	Acquisition Costs*		Distributor/Manufacturer Price	
		Contract	Total (Contract and Off Contract)	Contract	Total (Contract and Off Contract)
PHYSICANS					
Lyophilized					
Average	$42.57	$44.57	$50.27	$43.50	$47.47
Liquid					
Average	$56.30	$58.36	$62.64	$54.33	$56.86
HOSPITALS					
Lyophilized					
Average	$42.57	$45.54	**	$42.79	$46.98
Liquid					
Average	$56.30	$56.09	**	$56.59	$58.47

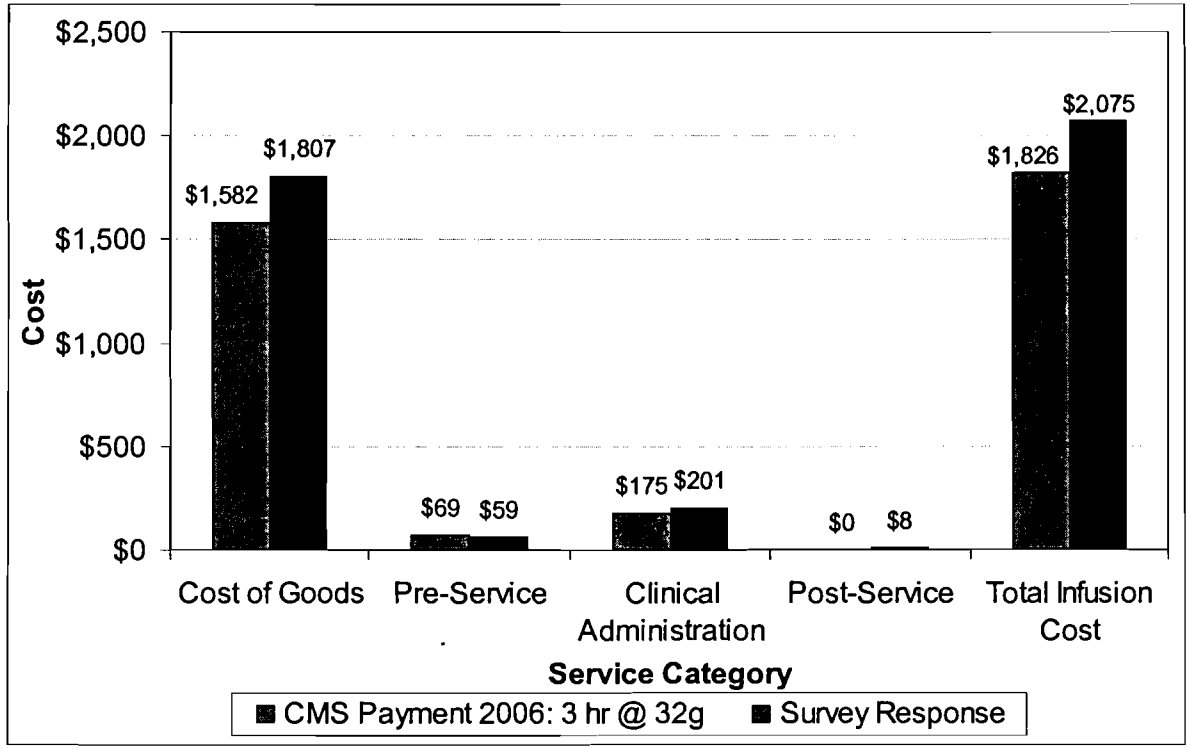
Data reflect reported distributor and manufacturer prices for "direct to physician" or "direct to hospital" sales. Reported distributor prices are estimated to represent over 55% of the physician market, while manufacturer prices include all reported manufacturer sales YTD through Q3 of 2005. All distributor ASPs reflect YTD totals as reported by distributors through November 2005.

*As reported by survey respondents.

** Hospitals reported paying between $45 and $156 per gram off-contract with widely varying amounts and products, depending on patient need and brand availability.

Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices

3 hr @ 32 g

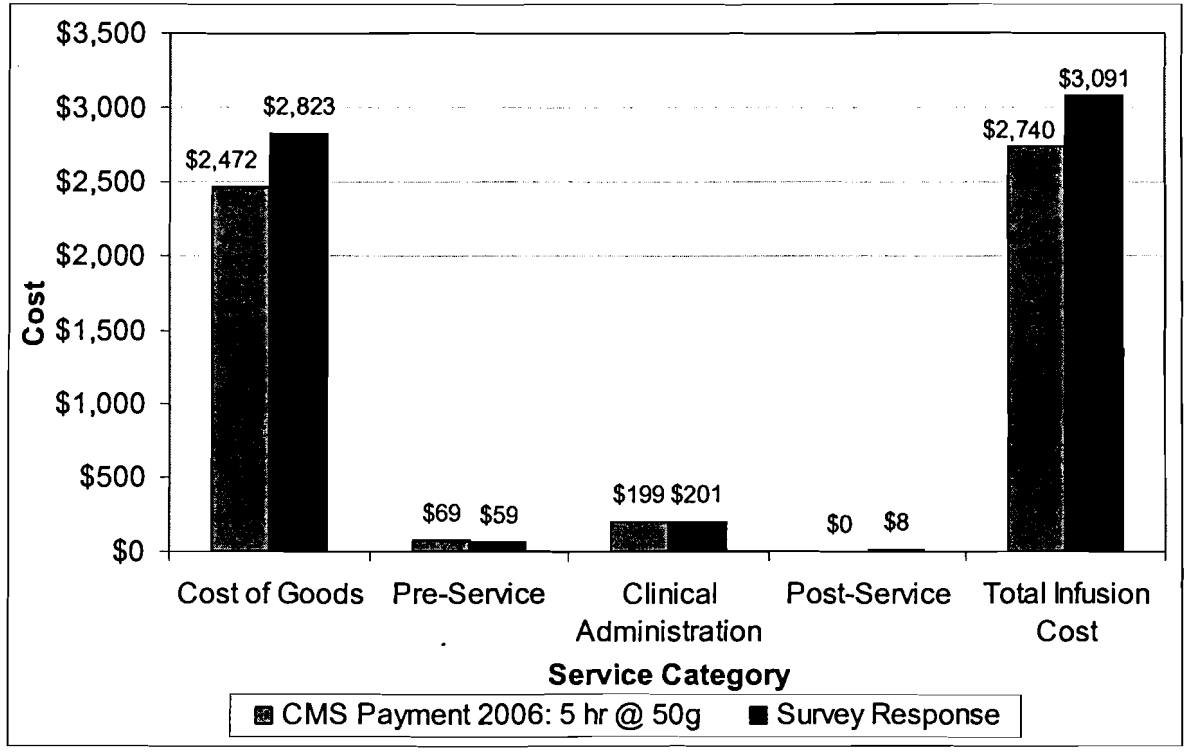


While CMS payments are based on a 3 hour infusion, survey data reflect each practices' reported average infusion costs.

Survey data represent the average of lyophilized and non-lyophilized data for intra-service time ($206.24 - lyophilized; $195.83 - non-lyophilized). Cost of Goods for CMS and Survey data are based on the average for lyophilized and non-lyophilized (CMS: $42.57 - lyophilized and $56.30 non-lyophilized; Survey $50.27 lyophilized and $62.64 non-lyophilized).

Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices

5 hr @ 50 g

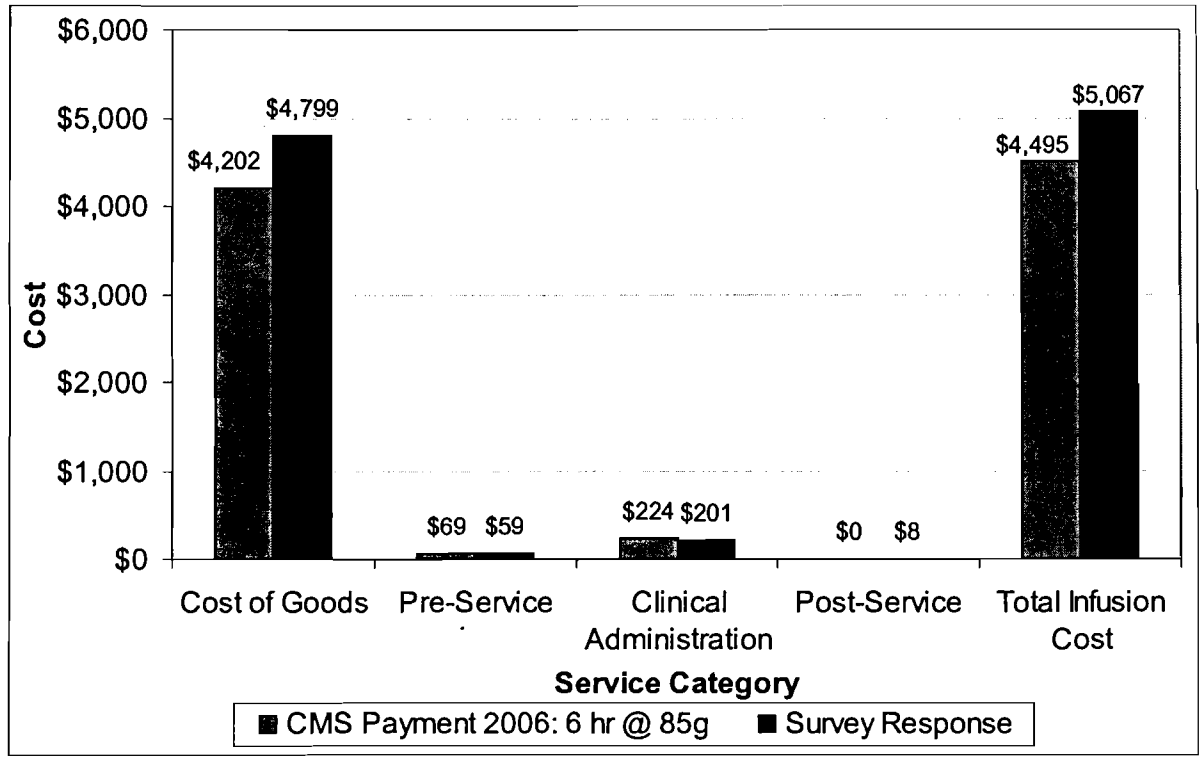


While CMS payments are based on a 5 hour infusion, survey data reflect each practices' reported average infusion costs.

Survey data represent the average of lyophilized and non-lyophilized data for intra-service time ($206.24 - lyophilized; $195.83 - non-lyophilized). Cost of Goods for CMS and Survey data are based on the average for lyophilized and non-lyophilized (CMS: $42.57 - lyophilized and $56.30 non-lyophilized; Survey $50.27 lyophilized and $62.64 non-lyophilized).

Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices

6 hr @ 85 g



While CMS payments are based on a 6 hour infusion, survey data reflect each practices' reported average infusion costs.

Survey data represent the average of lyophilized and non-lyophilized data for intra-service time ($206.24 - lyophilized; $195.83 - non-lyophilized). Cost of Goods for CMS and Survey data are based on the average for lyophilized and non-lyophilized (CMS: $42.57 - lyophilized and $56.30 non-lyophilized; Survey $50.27 lyophilized and $62.64 non-lyophilized).

More IVIG Physician Services Provided Result in Greater Losses

Total Infusion Cost per Month: CMS vs. Physician Office Cost Data

Physician Offices total estimated non-reimbursed **monthly costs** based on the number of infusions

3 hr @ 32 g			
	6 infusions	10 infusions (median)	25 infusions (average)
Lyophilized	-$1,802.76	-$3,004.60	-$7,511.51
Liquid	-$1,479.24	-$2,465.40	-$6,163.51

5 hr @ 50 g			
	6 infusions	10 infusions (median)	25 infusions (average)
Lyophilized	-$2,339.16	-$3,898.60	-$9,746.51
Liquid	-$1,868.76	-$3,114.60	-$7,786.51

6 hr @ 85 g			
	6 infusions	10 infusions (median)	25 infusions (average)
Lyophilized	-$3,808.56	-$6,347.60	-$15,869.01
Liquid	-$3,052.56	-$5,087.60	-$12,719.01

Study Conclusions

- The majority of costs associated with physician pre-service payments are constant, regardless of market conditions.
- Therefore, study findings suggest that the temporary add-on payments established by CMS accurately reflect pre-service costs and should be made permanent.
- CMS' Final Rule CY 2006 ASPs are below the prices paid by surveyed hospitals and physicians.
  - Providers pay widely varying prices depending on manufacturers, distributors, and suppliers involvement.
  - Survey prices reflect real time supplier prices, as opposed to dated quarterly manufacturer prices embodied in CMS ASPs.
- The more IVIG services physicians provide, the more money they lose, mostly attributable to the difference in ASP payments versus provider costs.

Study Conclusions (continued)

- Physicians and hospitals reported that reduced physician Medicare payments beginning in 2004 resulted in a migration of patients from physician offices to the outpatient hospital setting, complicating patient access and IVIG market allocation.
- It appears that CMS' attempt to correct for perceived overpayments of product in 2004 "overcorrected". This resulted in physicians being paid less than costs incurred for IVIG infusion services, primarily due to inadequate CMS ASPs that do not reflect what providers have to pay for product in the marketplace.
- The combination of product and market complexity and government administered prices is resulting in patient access issues in some markets.

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October 10, 2006

HAND DELIVERED

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1321-P

Dear Dr. McClellan:

CardioNet is pleased to have the opportunity to comment on the Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule") published in the *Federal Register* on August 22, 2006.[1] Because we submitted detailed comments on CMS-1512-PN: "Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense (PE) Methodology" (the "Work/PE Proposed Notice"),[2] we will not repeat our recommendations for fine-tuning the proposed changes to the PE methodology. We would, however, like to incorporate those recommendations by reference. We hope our earlier suggestions coupled with the comments that follow will facilitate the development of a Physician Fee Schedule Final Rule that will ensure continued access to cardiac monitoring services for Medicare beneficiaries in 2007 and beyond. As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

CardioNet is a provider of remote, real-time cardiac monitoring through wireless communications, and computerized arrhythmia detection technology called mobile cardiac outpatient telemetry ("MCOT"), an important breakthrough technology which is significantly improving physicians' ability to diagnose cardiac arrhythmias. MCOT is a technology that diagnoses clinically significant cardiac arrhythmias by monitoring, recording, and real-time wireless transmission of every heart beat while patients are at home, at work, traveling, or otherwise conducting their normal activities. MCOT is the first mobile outpatient telemetry system to provide real-time ECG monitoring, 24/7/365 analysis and immediate communication of life threatening symptomatic and asymptomatic arrhythmias to treating physicians via the

[1] 71 *Fed. Reg.* 48980 (Aug. 22, 2006).
[2] 71 *Fed. Reg.* 37168 (June 29, 2006).

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CardioNet monitoring station. A comparison of MCOT technology to cardiac loop event monitoring technology is attached as Appendix I. Twenty thousand Medicare beneficiaries in thirty states have already benefited from MCOT and the number of Medicare beneficiaries for whom MCOT is ordered continues to increase monthly.

CardioNet also is a member of the Remote Cardiac Services Provider Group, which is made up of nine companies that provide the majority of remote cardiac monitoring services for Medicare beneficiaries (the" Provider Group"). We submit these comments in addition to those offered by the Provider Group because CardioNet is the only member of the Provider Group that provides remote, real-time ECG monitoring of asymptomatic and symptomatic arrhythmias via built-in wireless technology and 24/7 attended analysis by specially trained electrodiagnostic technicians and nurses and is the only member of the Provider Group whose payments are based on CPT code 93236.

We would like to underscore the particularly devastating effect the proposed PE methodology will have on the reimbursement for CPT code 93236. Under CMS's proposed changes to the PE methodology, reimbursement for 93236 will be cut by 25% in 2007 and by a total of 100% by 2010. In other words, the payment rate for this important technology will be $0 in four years. Without adequate payment, there will be no further access to this technology or others like it in the future.

Accordingly, we are requesting CMS establish a temporary G code for MCOT until a new CPT Code can be established for this service.

PROVISIONS AND MISCELLEANOUS CODING ISSUES

I. CMS SHOULD ESTABLISH A G CODE TO DESCRIBE MCOT AND OTHER SIMILAR SERVICES UNTIL A NEW CPT CODE THAT ACCURATELY DESCRIBES THE TECHNOLOGY IS AVAILABLE IN 2009

CardioNet requests that CMS establish a G code with professional and technical components to describe MCOT and other similar technologies. We urge CMS to recognize the need for accurately reporting continuous real-time remote cardiac monitoring by establishing an appropriate G code for reporting both the professional and technical components of this service until CPT establishes a category 1 CPT code for this service. We propose the following descriptor for the G code which was the result of a joint effort among CardioNet, HRS and ACC:

> *Continuous electrocardiographic recording with concurrent computerized real-time data analysis and greater than 24 hours of accessible ECG data storage with automatic and patient triggered remote event transmission for continuously attended monitoring and data analysis with daily, emergent and one summary report(s); per 15 day period*

A. A G Code for MCOT is necessary to accurately describe this new technology

Current CPT codes do not describe MCOT and other similar technologies. The current CPT codes for cardiac monitoring were developed years ago and are limited to describing old technologies, such as Holter monitoring and cardiac event recording. Holter monitoring is performed over a 24 hour period and the codes used to report it are "per 24 hour" codes. Cardiac event recording is a 30 day service and its code descriptor is "per 30 days." MCOT is an entirely new technology because unlike other technologies which are only able to detect arrhythmias that cause symptoms, MCOT also able to identify symptomatic arrhythmias and transmit that information in real-time to a monitoring station which in turn notifies the treating physician immediately. No patient intervention is necessary to transmit data because the MCOT uses automatic wireless communication to transmit data to the CardioNet monitoring station unlike the Holter monitors and event recorders that require the data to be downloaded manually after use or require patients activate a land line to transmit the data. Also, because MCOT monitors and records every heart beat, it recognizes non-compliant patients automatically unlike the Holter monitors and event recorders that are unable to recognize patients who disconnect the monitor when it should be hooked up. MCOT also stores, and allows access, to 96 hours of monitoring data so that physicians can get a complete understanding of a patient's cardiac rhythm. It is impossible to describe MCOT with current CPT codes. A side-by-side comparison of MCOT with Holter and cardiac event monitoring technologies is attached as Appendix I.

The American College of Cardiology (ACC) and the Heart Rhythm Society (HRS) agree that current CPT codes do not describe MCOT and they intend to submit a coding proposal to CPT for a new CPT code to describe MCOT (and other similar technologies) in time for inclusion in CPT 2009.

CardioNet has been working jointly with ACC and HRS to develop a new code that will describe MCOT (and other similar technologies). The new code will accurately describe the technology and it will accurately describe how the service is provided. Because the length of service is variable based on how long it takes to identify an arrhythmia, it is inappropriate to use a code that describes either a "24 hour" service (such as Holter monitoring) or a "30 day" service (such as Event Recording). The language of our proposed G code is identical to the language developed jointly by CardioNet, ACC, and HRS. In addition to proposing a CPT code to describe MCOT (and other similar technologies), ACC and HRS also have advised CardioNet that the entire family of cardiac monitoring codes will be revised and updated.

Because ACC and HRS will submit the new code describing MCOT (and other similar technologies) for inclusion in CPT 2009, a temporary G code is necessary to appropriately report MCOT (and similar technologies) until the CPT code is established. We urge CMS to recognize, just as ACC and HRS recognize, that MCOT is an important new technology which should be reported accurately under a code with a descriptor that accurately describes the technology and the service.

B. MCOT produces better diagnostic information which results in a higher rate of detection of arrhythmias

A 17 center, 266 patient, prospective, randomized clinical trial comparing MCOT to cardiac loop event monitoring, the current standard test for diagnosing clinically significant arrhythmias has been completed. The trial included patients with syncope, pre-syncope, and severe palpitations and compared the two technologies with regard to diagnostic yield and the ability to detect asymptomatic arrhythmias. The results of this trial are currently embargoed. We anticipate that the trial results will be published in the very near future. The trial results also will be presented at the 2006 Annual Meeting of the American Heart Association in November.

C. The establishment of a G Code for MCOT (and other similar technologies) is consistent with CMS policy

CMS has established G Codes in similar situations and on a number of occasions has established G codes in the final rule even though they were not in the proposed rule.

CMS has established G Codes for five primary reasons: (1) to restructure its reimbursement policy to align physician payments with clinical outcomes; (2) to describe, and provide for payment of, new technologies, services, and procedures; (3) to promote accurate reporting of services; (4) to create a temporary G Code until an identical CPT Code became available; and (5) to implement changes in legislation, regulation, coverage and payment policy. Despite receiving criticism from the American Medical Association, and other specialty medical professional organization, CMS has adopted, and continues to adopt G Codes, for these reasons.

We believe that MCOT meets CMS established criteria for creation of G codes:

- MCOT is a breakthrough technology that is revolutionizing the physicians' ability to diagnose potentially fatal and other clinically significant cardiac arrhythmias because it can detect asymptomatic arrhythmias whenever they occur.
- Current CPT codes do not describe this technology. Unless CMS creates a G code that properly describes the technology, it will be misreported and improperly paid.
- The G codes will be temporary because CardioNet has been working jointly with ACC and HRS to develop a new CPT code that accurately describes MCOT and other similar technologies. A new code will be submitted to the CPT editorial panel in the 2009 CPT cycle.

II. CMS SHOULD ACCEPT THE DIRECT EXPENSE INPUTS PREVIOUSLY SUBMITTED TO CMS STAFF FOR THE G CODE. SHOULD CMS CHOOSE NOT TO ESTABLISH A G CODE, IT SHOULD ACCEPT THE DIRECT EXPENSE INPUTS SUBMITTED FOR CPT CODE 93236.

A. Payment history for MCOT

CardioNet is enrolled in Medicare as an independent diagnostic testing facility (IDTF). Our monitoring station is in Pennsylvania and we submit all our claims to the local Medicare carrier, Highmark Medicare Services, formerly known as HGSA (HSA). The HSA Carrier Medical Director (CMD), Dr. Andrew Bloschichak, initially paid for MCOT using a daily rate but quickly realized that paying based on a daily rate was extremely burdensome for both CardioNet and HSA because the length of time patients are monitored using MCOT is variable with a median of 13 days, it required daily claims submission, it imposed onerous documentation requirements, and it facilitated overutilization. Therefore, he changed payment to a case rate based on the median number of days patients are actually monitored and required CardioNet to submit a single claim using the relevant unlisted code 93799 (unlisted cardiovascular service or procedure) because no CPT code was appropriate. Also, although Dr. Bloschichak based payment for MCOT on 93236, he has had to make adjustments over the last two years because the costs of providing MCOT are not related to the costs of providing 93236 (e.g. he changed payment for MCOT to accommodate changes in the delivery of patient education services).

While the case rate aspect of using CPT code 93799 has been beneficial, there are a number of other aspects to using 93799 that are not. First, without a national payment amount based on CMS PE methodology, payment for MCOT will be subject to change at any time based on the thinking of whoever is the local CMD. This is particularly concerning for CardioNet because the HSA service area is part of the region currently being bid under the new MAC Medicare contracting process. If a new contractor wins the bid then payment for MCOT will be uncertain. We are very worried that if HSA does not win the contract that payment for our service will be in jeopardy. Our payment is based on the willingness of Dr. Bloschichak to learn about MCOT, carefully research issues and provide for payment that reflects the cost of the service. Second, while CardioNet submits claims electronically, all of our claims are subject to manual adjudication, which at times has resulted in significant delays in payment. The manual adjudication process also requires HSA to expend significant resources to process the increasingly large volume of claims. Third, use of an unlisted code has made payment for the physician interpretation problematic, as shown on Appendix II. Payment for physicians varies widely through the country and there is no single methodology used by carriers to determine payment.

B. Payment for MCOT will be devastated if the changes to the PE Methodology are implemented because there are no direct expense inputs for CPT code 93236

As discussed in more detail above, MCOT is paid a case rate based on the reimbursement for CPT code 93236 for up to 21 days on service. However, future payment for this service is not only uncertain, it is non-existent. Under CMS's proposed changes to the PE methodology, reimbursement for 93236 will be cut by 25% in 2007 and by a total of 100% by 2010.

It appears that this devastating result is related to a number of issues, some are related to CMS's proposed changes for determining practice expense but the most important problem is that 93236 has no direct practice expense inputs. A copy of CardioNet's comment letter on the proposed PE methodology is attached as Appendix III.

C. A G code should help stabilize payment for this innovative technology and minimize coding confusion until a CPT Code is available. As requested by CMS staff, CardioNet submitted direct expense inputs for the G code and 93236.

CardioNet has had several conference calls with your staff and had an in-person meeting on July 31, 2006 to discuss its concerns. Through these discussions it became apparent that assigning direct practice expense inputs to MCOT will be difficult because the technology presents many issues of first impression. For example, how to assign per service costs for wireless communication services..

At the July 31st meeting, CardioNet discussed the difficulty in developing direct cost inputs for a multiple day service into a single day code like CPT code 93236. However, at the request of CMS staff, in addition to submitting practice expense inputs for a G code, we also submitted practice expense inputs for 93236 to your staff on September 18, 2006.

The inputs for the G code reflect the costs of clinical labor, supplies, and equipment for a "fifteen day" period as per the proposed code descriptor. Note that the G code descriptor "per 15 days" reflects the fact that the average length of service is 13 days. The range of days per service is 2 to 26.

The inputs for 93236 include the costs of clinical labor, supplies, and equipment for one day as per the code descriptor.

A detailed explanation of the practice expense inputs are attached as Appendix IV.

Given the uncertainty of the status of the reimbursement for CPT code 93236 and the likely change in CPT language to establish MCOT as a 15 day service, CardioNet feels it is imperative that CMS establish a G code for MCOT with a descriptor that matches the likely CPT descriptor. This is the only means to be sure that the reimbursement for this code is stabilized today. It also

makes sense to use case rate cost inputs and establish case rate PE RVUs now because CMS will need to do so anyway when a new CPT code for MCOT is established in 2009. Creating "per day" PE RVUs this year will mean that CMS will have to establish case rate PE RVUs in 2009. A G code would serve to decrease coding and reimbursement confusion by limiting the number of coding and reimbursement changes this service will face over the next two years.

Given the clinical benefits of this technology, it seems only fair that CMS use CardioNet's recommendations to address the reimbursement problems that are threatening the long-term viability of this technology.

D. Work RVU for the G Code

We request that CMS work with the ACC and HRS to establish a physician work RVU and direct cost inputs for the PC of this G code. CardioNet does not have the expertise to make recommendations for physician work or practice expense related to the PC. However, we would like to note that Dr. Bloschichak, the HSA CMD, who has more experience than any other CMD in paying for MCOT, has established a case-rate payment of $128 for physicians.

IDTF ISSUES

III. CMS Should Withdraw ALL of Its Performance Standards and Work With the Provider Community Over the Next Year to Develop Modality Specific Standards for CY 2008 Proposed Physician Fee Schedule

A. CMS did not solicit or obtain any IDTF provider input before proposing the performance standards and it inappropriately applied DME standards to the IDTF provider community. Accordingly, the proposed standards utilize a misguided one-size-fits-all approach that fails to recognize that remote cardiac monitoring services have an entirely different business model than IDTFs that provide on-site patient services.

We are disappointed that CMS did not solicit or obtain any input from the IDTF provider community prior to the issuance of the IDTF standards. Usually, CMS solicits stakeholder input before issuing regulations that will impose a significant burden on a provider community. In fact, when CMS was considering developing performance standards for DME suppliers, it consulted with DMEPOS suppliers, physicians and homecare associations prior to releasing the proposed standards. The IDTF provider community should be provided at least as an extensive opportunity to work collaboratively with CMS on performance standards that will have such a substantial affect on their business practices.

Provider input would have make it clear to CMS that a one size fits all approach simply does not work for IDTFs given the potential range and complexity of imaging services provided by an IDTF. Similar to the specific quality standards developed for DMEPOS suppliers, we believe

that modality specific approach will enhance the quality and safety of remote cardiac monitoring services furnished to Medicare beneficiaries.

CMS indicates that it modeled the performance standards on the DME standards.[3] We believe that it is inappropriate to apply DME standards to the IDTF community. Unlike DME companies that manage inventory, IDTFs provide patient care services. Fraud and abuse inherent to the DME industry is very different from alleged abuse in the IDTF industry. Unscrupulous DME suppliers have been known to use a variety of means to obtain Medicare beneficiaries' identification numbers. These schemes include calling beneficiaries under the guise of conducting a health survey and recruiting Medicare beneficiaries by hosting free clinics where Medicare beneficiaries receive a quick exam and then are sold DME that is not medically necessary. Moreover, many of the proposed IDTF standards exceed requirements applicable to DME suppliers. Specifically, even though fraudulent recruitment schemes are common to the DME industry, CMS has not imposed a non-solicitation prohibition on DME suppliers; nor are DME suppliers subject to unannounced inspections.

We ask that CMS withdraw its proposed performance standards and work with the provider community over the next year to create modality specific standards. Any standards for remote cardiac monitoring that are developed should be based on existing industry standards.

We recommend that CMS take the necessary amount of time to properly allow for the development of IDTF standards tailored to the IDTF community and allow providers to make the necessary operational changes. To that end, CardioNet is committed to working with CMS to develop standards for the remote cardiac monitoring community. We would welcome the opportunity to work collaboratively with CMS to develop standards designed to improve the quality and safety of remote cardiac monitoring services provided to Medicare beneficiaries.

B. The nature of the erroneous payments identified in the OIG Report (A-03-03-00002) do not appear to support the development of the CMS proposed IDTF standards

The development of the IDTF standards in response to the OIG Report Review of Claims Billed by Independent Diagnostic Testing Facilities for Services Provided to Medicare Beneficiaries During Calendar Year 2001 (A-03-03-00002) (the "OIG Report")[4] is misguided. While the OIG Report reports that Medicare overpaid IDTFs by $164,839 in 2001[5], it does not identify widespread abuse across the country that would warrant the development of industry wide standards. Rather, the report identifies erroneous payments linked to a small number of beneficiaries and a small number of IDTFs located in California and Florida. The total dollar

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[3] 71 *Fed. Reg.* 49061.

[4] OIG Report No. A-03-03-00002 *Review of Claims Billed by Independent Diagnostic Testing Facilities for Services Provided to Medicare Beneficiaries During Calendar Year 2001* (June 30, 2006).

[5] We object to the estimated overpayment amount of $71.5 million. The report identified alleged abuse that involved a small number of facilities and services. It is unlikely that the same level of fraud exists in the entire universe of IDTF providers and especially remote cardiac monitoring services.

amount of the overpayment is small—less than $200,000 and average payments were in the range of $100/procedure. None of this suggests that there is widespread abuse in the IDTF industry. It is unfair to impose burdensome standards on the entire industry to correct a very localized incidence of fraud.

Furthermore, no IDTFs performing remote cardiac monitoring services were involved. Nor does it appear that erroneous payments were for remote cardiac monitoring.

Finally, we fail to understand how many of the IDTF standards will address the fraud identified in the OIG Report. The OIG Report found that overpayments resulted from noncompliance with existing requirements and did not recommend establishment of new requirements. Accordingly, the report recommended that CMS conduct site visits to monitor compliance with existing standards. Nowhere in the report does the OIG suggest that new standards need to be developed for ITDFs. It appears that it was the lack of compliance with existing standards, not the absence of standards, that caused many of the overpayments.

IV. IF CMS CHOOSES TO FINALIZE ANY PROPOSED PERFORMANCE STANDARDS FOR 2007, CMS SHOULD MODIFY THEM TO RECOGNIZE THE UNIQUE NATURE OF REMOTE CARDIAC MONITORING

Following is a discussion of the proposed regulatory changes and our recommendations:

1. ***Supervising Physician Standard 410.33(b).*** The Proposed Rule proposes to make supervising physicians "responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations." This dramatic expansion of the roles and responsibilities of supervising physicians is unwarranted and it evidences a failure to understand the function of a supervising physician in a remote cardiac monitoring IDTF. Supervising physicians are responsible only for the clinical services provided by the IDTF. Remote cardiac monitoring IDTFs typically engage independent contractors to act as supervising physicians. These physicians have full time private practices and they provide general supervision (which is the required supervision level for remote cardiac monitoring) over cardiac monitoring services. They do not provide administrative or operational support, nor are they typically interested in performing those services. Requiring them to perform those services would essentially make them "CEO's" of the IDTF which is inappropriate. If this proposal is finalized IDTFs will have great difficulty finding supervising physicians.

Recommendation: Delete this provision

2. ***Multi-State Entities and definition of Point of Actual Delivery of Service 410.33(e) and (i).*** These provisions would require IDTFs that operate across state boundaries to maintain documentation that its supervising physicians and technicians are licensed and certified in each state where the IDTF operates and it would require that point of the actual delivery of services mean the place of service on the claim form. The provisions further require that when a

diagnostic test is performed at a beneficiary's residence that the beneficiary's residence be the point of service on the claim form.

This provision, if finalized, would place a substantial hardship on all entities providing remote cardiac monitoring services and would likely put them out of business. Entities that provide remote cardiac monitoring services typically have one monitoring center in one state that receives data from remote monitors worn by patients in all fifty states. The data received by the monitoring center is analyzed, formatted, and communicated to the ordering physician who are also in all fifty states. IDTFs typically submit claims to only one carrier and currently are only required to conform to the requirements of the carrier to which they submit claims. The proposed provision would require that remote cardiac monitoring IDTFs to enroll in all fifty states instead of only the states where they have physical facilities and it would require that their supervising physicians and technicians become licensed and certified in all fifty states. The costs of doing this would be prohibitive and remote cardiac monitoring IDTFs would close their doors. Moreover, there is no basis for such a requirement in either the OIG report or in the name of patient safety. Although remote cardiac monitoring involves data collection wherever the patient is located, the analysis, formatting, and communication of that data takes place at the service provider facility. The functions performed at the service provider facility are really the essence of remote cardiac monitoring and are what make it a useful diagnostic test.

We also wish to point out that we are unclear as to how carriers can inspect and enroll IDTFs who have physical facilities in other carrier jurisdictions.

Recommendation: CMS should delete this provision and work with the IDTF community to craft a provision which meets CMS needs, which reflects how remote cardiac monitoring services are delivered, and is not unduly burdensome. If CMS wishes to finalize a proposal in this area, at a minimum, it should clarify that the point of service for remote cardiac monitoring tests is at the physical facility of the service provider.

3. ***Testing Equipment Availability Requirement.*** This provision would require remote monitoring IDTFs to make available for CMS inspection, within two business days, a catalogue of portable equipment including equipment serial numbers. It would also require IDTFs to notify local contractors of "any equipment" changes within 90 days.

Given the nature of remote cardiac monitoring, portable cardiac monitors are sent out to the patient for use. In the case of MCOT this equipment is used for anywhere between two and twenty six days and remains out of possession of the IDTF for even longer due to the time necessary for equipment delivery and return. Therefore, this provision is impractical and unworkable for remote cardiac monitoring IDTFs. We request that CMS modify this provision for remote cardiac monitoring IDTFs to allow them to make "representative" equipment with serial numbers available for inspection.

The contractor notification requirement is burdensome and onerous for remote cardiac monitoring IDTFs. Remote cardiac monitors are frequently replaced due to loss (non-return) and damage. Additionally, MCOT monitors have a useful life of two years before they must be

replaced. This means, in the case of MCOT, that hundreds of monitors are replaced every year. We recommend that CMS allow remote cardiac monitoring IDTFs to comply with this requirement by maintaining, and making available to the local contractor, a list of equipment serial numbers and inventory upon request.

Recommendation: Allow remote monitoring IDTFs to comply with the equipment availability requirement by making "representative" equipment and serial numbers available for inspection. CMS also should remote cardiac monitoring IDTFs to comply with the local contractor reporting requirement by making available, upon request, a list of equipment serial numbers and inventory.

4. ***Medical Records Storage Provision.*** The proposals would require IDTFs to make medical records available within two business days of a request yet it also seems to require on-site storage of those records. In view of retrieval requirement we would request that CMS clarify that IDTFs can store medical records off-site. We would also like CMS to define "current medical records" so IDTFs will know what records must be stored. In particular we request that CMS clarify that remote monitoring IDTF's do not have to obtain or store medical records from their referring physicians. It is usually not possible for IDTF's to obtain those records not is it appropriate for a remote monitoring facility to ask for and store records that should be kept by the referring physician.

Recommendation: Clarify that medical records can be stored off-site; that IDTFs are only required to maintain records of the services provided by the IDTF, not the medical records of any referring physician; that off-site storage of medical records is permitted so long as there is adequate access to the records; and to define "current medical records."

5. ***Liability insurance standard.*** CMS should eliminate the liability insurance standard. It is inappropriate to tie the amount of liability coverage to Medicare billings as those billings change constantly. Additionally, CMS does not state whether its proposed standard is for insurance per claim or aggregate insurance. The standard in the IDTF community is to have a minimum liability insurance of $ 1 million per claim and $3 million aggregate. We see no reason for CMS to create a different standard and we see no reason for this proposal to be finalized as we are not aware of problems in this area. Each IDTF makes an individual business decision shaped on the provider's claim history and location regarding the amount of liability insurance for its facility. It is inappropriate for CMS to manage the terms of liability coverage. Moreover, it is irrelevant who is the insurance carrier. Lastly, we fail to understand the basis for requiring that the insurance carrier not be related to the IDTF.

We also fail to understand why CMS is proposing to require that the insurance policy list the serial numbers of "any and all equipment" used by the IDTF. We do not believe liability insurance carriers have such a requirement for small pieces of equipment like remote cardiac monitors. Further, such a requirement would be extremely burdensome for remote cardiac monitoring companies due to the high frequency with which monitors are not returned, damaged, and replaced.

Recommendation: Do not finalize this proposal.

6. ***Site inspections and beneficiary access standard.*** We do understand the basis for the proposed unannounced inspection standard. In its proposal, CMS did not discuss any evidence showing that such a requirement would address alleged fraud and abuse. Further the proposed standard goes beyond any similar standard for DME suppliers.

With regard to the beneficiary access proposal, patients do not come to remote cardiac monitoring facilities for their tests and typically do not have reason to ever enter a remote cardiac monitoring facility. Remote monitoring IDTFs do not hold themselves out as being open to the public and posting normal business hours would make little sense. If CMS finalizes this proposal, we request that CMS state that remote monitoring IDTFs can comply with the requirement by posting their hours of operation and instructions for contacting the facility on the internet. Further because remote monitoring facilities operate twenty four hours a day, seven days a week, we request clarification from CMS as to the meaning of "regular business hours."

Recommendation: Do not finalize the unannounced inspection requirement and clarify that remote cardiac monitoring IDTFs may post their business hours and instructions to beneficiaries for contacting the facility on their website.

7. ***30 days notice standard.*** The current standard of 90 days notice is appropriate and should be continued. The OIG report identified IDTFs that failed to comply with existing requirements to update their enrollment information. It is unclear how a shorter notice period will have the desired result of minimizing fraud and abuse. On-site visits seem to be a more appropriate way of addressing a small group of IDTF provider's failure to comply with existing requirements. Some changes in ownership are very complex and requiring them to be reported in 30 days would be unduly burdensome and would not serve any useful purpose. We would also like CMS to clarify that IDTFs will not be required to complete an entire application in order to report changes in their enrollment information (unless currently required to do so).

Recommendation: Do not finalize this proposal and continue the current 90 day reporting requirement.

8. ***Non-solicitation standard.*** CMS should eliminate the non-solicitation standard. This standard is vague and may have first amendment implications with regard to the right to free speech. Moreover, it is unclear how this standard will achieve the intended result of limiting utilization when IDTFs are already limited to performing diagnostic services pursuant to a written physician order. Should CMS proceed with implementing this proposed standard, it should be very limited in scope and only implemented after extensive discussions with the IDTF provider community. For example, IDTFs should be permitted to write letters to existing patients describing new services and to print advertising materials that are educational in nature.

Recommendation: Do not finalize the non-solicitation standard.

9. ***Calibration of testing equipment standard.*** CMS should refine this proposed standard. In the remote cardiac monitoring industry there is no national standard for calibrating equipment nor is there any need for such standards because calibration is based on manufacturer instructions. We know of no evidence that compliance with manufacturer instructions is insufficient to ensure that the equipment is functioning properly and assures patient safety.

Recommendation: Clarify that calibration in accordance with manufacturer instructions is adequate to comply with this requirement.

* * *

We would like to thank CMS for the opportunity to submit formal comments on the Proposed Rule. We are deeply concerned by the drastic reduction in reimbursement for remote cardiac monitoring services and urge CMS to create a G code so that Medicare beneficiaries continue to have access to MCOT. Should you have questions please do not hesitate to contact Philip Leone at 610-729-7010.

Respectfully submitted,

David Wood
President and COO

Appendix I

(Notable Differences Between CardioNET and RCSPG)

CARDIONET

Service Components	Mobile Cardiac Outpatient Telemetry	Holter Monitoring	Event Monitoring
Patient Education and Hook up	•Monitor configuration •Scheduling/welcome call •Hook-up education	•Physician's office required to provide hook-up and education	•Physician's office required to provide hook-up and education
Communication	•**Wireless capability** •Data enters Monitoring Center consolidated by buffer, regardless of whether via cell or land line	•Not available for patient	•Requires land line
Patient Monitoring	•13 days average duration •**Asymptomatic wireless automatic ECG transmission** •**Symptomatic wireless automatic ECG transmission** •**96 hours ECG Storage** •Immediate review •Physician urgent notification	•1 day average duration •Records every beat for 24 hours •2-3 day delay	•30 day duration •Symptomatic ECG manual transmission requiring land line •Immediate Review •Limited monitor memory
Clinical Reports	•Daily reports •**HR trend graph** •**AF burden graph** •Urgent reports •**Requested reports** •End of service summary reports	•Holter Report	•Urgent reports •End of service summary reports
Service Compliance Management	•**Recognizes non-compliant patients automatically** •Hospitalizations •Patient compliance •Electrode irritation •MD communication relative to length of service	•Unable to recognize non-compliance during monitoring	•Unable to recognize non-compliance during monitoring
Equipment	•Monitor •Sensor •Base (2)	•Monitor	•Monitor

Appendix II

(Physician Reimbursement)

CARDIONET

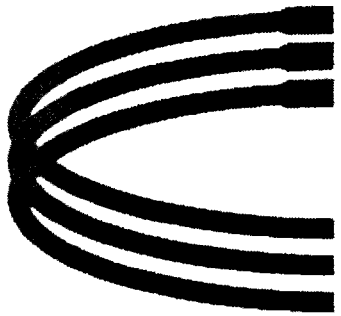
[redacted]

Carrier	States	CPT Code	MD Pmt/Case*	Comments
NHIC	MA, VT, NH, ME, CA	93799-26	$150	Case rate for up to 30 days of service
Trailblazer	DE,MD, DC, VA, TX	93799-26	$30	Case rate for up to 30 days of service
WPS	MI, IL, WI, MN	93799-26	$150	Case rate for up to 21 days of service
First Coast Option	CT, FL	93799-26	$40	Case Rate up to 30 days of service
Empire/GHI	NY, NJ	93799-26	$30	Case rate for up to 30 days of service
Palmetto GBA	OH, KY, SC	93237	$299	$23 rate per day in OH/KY/SC - $299/case assumes 13 days of service
HGSA	PA	93799-26	$128.27	Case rate for up to 21 days of service
BCBS of AR	AR, MO, RI	93799-26	$97	$7.48 per day - $97/case assumes 13 days of service
AdminaStar	IN, KY	93799-26	$43	$8.60 per day paid for up to five days of service
Health Now	Upstate NY	93799-26	$30	Case rate for up to 30 days of service
CIGNA	TN, NC, ID	93799-26	$30	Case rate for up to 30 days of service
BCBS of KS	KS, NE, NW, MO	93799-26	$30	Case rate for up to 30 days of service

*Payment per case can vary slightly due to local fee schedules

*** Average known physician reimbursement for commercial payors is $25.00/day, equating to roughly $300/case

[redacted]



CARDIONET

MOBILE CARDIAC OUTPATIENT TELEMETRY™

Appendix III

(CardioNET Comments In Response To Proposed Rule CMS-1512-PN)

August 21, 2006

VIA HAND DELIVERY

Mark B. McClellan, M.D. Ph.D.
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, N.W., Room 445-G
Washington, D.C. 20201

Re: Comments in Response to Proposed Rule CMS-1512-PN: Five-Year Review of Work Relative Value Unites Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

Dear Dr. McClellan:

CardioNet is pleased to have the opportunity to comment on the Proposed Rule related to changes in the physician fee schedule practice expense methodology (proposed PE methodology), as published in the June 29, 2006 Federal Register at 71 Fed. Reg. 37170 (the NPRM). CardioNet is a provider of remote, real-time cardiac monitoring through wireless communications, and computerized arrhythmia detection technology. The CardioNet mobile outpatient telemetry system is the first to provide real-time ECG monitoring and 24/7/365 analysis and response for patients with asymptomatic and symptomatic arrhythmias—while at home, at work, or traveling.

CardioNet also is a member of the Remote Cardiac Services Provider Group, which is made up of nine companies that provide the majority of remote cardiac monitoring services for Medicare patients (the Provider Group). We submit these comments in addition to those offered by the Provider Group because CardioNet is the only member of the Provider Group that provides remote, real-time ECG monitoring of asymptomatic (and symptomatic) arrhythmias via built-in wireless technology and 24/7/365 attended analysis by specially trained electrodiagnostic technicians and nurses and is the only member of the Provider Group to bill under CPT code 93236. We believe it is important to underscore the particularly devastating effect the proposed PE methodology will have on the reimbursement for the technical component (TC) of this service.

Our comments in this letter focus on the proposed changes to the methodology for determining indirect practice expenses. We will be submitting, in response to the August 3, 2006 notice of proposed rule making for the physician fee schedule, more detailed information regarding the direct-cost PE inputs specific to the CPT code currently used as the benchmark for establishing payment for CPT code 93236. Without intervention by the Center for Medicare and Medicaid

Services (CMS), payment for this service will be cut by 25% in 2007 and by a total of 100% by 2010.

We have identified several reasons for the reduction in payment for CPT code 93236. Some relate to the lack of accurate direct cost inputs for this code, which CardioNet is working to correct this problem with CMS and the relevant medical specialty societies. Nevertheless, extensive modeling of the proposed methodology leads us to believe that even if CMS were to use direct cost inputs which accurately reflect the unique costs associated with providing remote cardiac monitoring, the methodology for allocating indirect costs will prevent appropriate payment for these services.

In addition, CardioNet is working with the Moran Company to analyze the PE methodology on CPT code 93236. Our intent is to better understand why CPT code 93236 is so negatively affected and to determine what modifications to the proposed methodology could reasonably be made to address the problem. We identified three important modifications that CMS should make to its methodology:

- Discontinue use of physician work as an allocator of indirect costs,
- Use unscaled direct cost inputs to allocate indirect PE instead of scaled direct inputs, and
- Use clinical labor costs or clinical staff time to calculate specialty-specific pools of indirect practice expense

Given the magnitude of the proposed changes and the inequities in the current proposal, CardioNet urges CMS to defer implementation of the proposed changes while it works with CardioNet and the Provider Group to develop a fairer approach to allocation of indirect costs for remote monitoring technical component services.

A. Bottom-Up Methodology and Use of Physician Work to Allocate Indirect PE RVUs

CardioNet generally supports the move to a bottom-up methodology for calculating direct PE. Nonetheless, we are very concerned about the drastic reduction in the PE RVUs for CPT code 93236 under the proposed PE methodology. We realize CMS' proposed PE methodology includes steps, such as using clinical labor value in the indirect PE allocation when the clinical-labor value is greater than the physician work RVU, that are intended to mitigate the negative effects of the new methodology on services with zero (or very little) physician work. However, given the proposed reduction in payments for remote cardiac monitoring it is clear that these steps alone are inadequate.

1. Physician work should not be used to allocate indirect costs

Work RVUs are not an appropriate allocator for indirect costs. There is no rational correlation between physician work and the overhead costs incurred in providing a particular service. More specifically, many inpatient procedures such as open heart surgery and major abdominal procedures have high physician work RVUs but should have very little indirect PE allocated to them because the patients return for few, if any, post-operative visits and the service requires

very little office-based clinical staff, supplies, and equipment. Many "minor" office procedures which have low physician work RVUs and many TC services such as 24 hour attended remote cardiac monitoring require much more office-based clinical staff, supplies and equipment than inpatient surgical procedures with high physician work RVUs and should have a much higher indirect PE allocation. Further, because technical component services are not associated with work RVUs, approximately 40% of total indirect practice expense RVUs which are distributed on the basis of work RVUs are not available to technical component services at all. The playing field is not level and CMS should work with all stakeholders to determine an appropriate substitute for physician work to allocate indirect PE.

It is appropriate for indirect PE to be allocated based on direct PE because it makes intuitive sense and is transparent. Procedures that require a substantial amount of clinical staff time and are performed using expensive equipment (e.g., prolonged infusions, lengthy radiation treatment procedures, certain imaging procedures, surgical procedures requiring expensive single-use supplies) should have more administrative overhead, utilities, etc. assigned to them than services that last only 10 or 15 minutes and require minimal involvement of staff or equipment (e.g., chest x-rays, minor dermatologic procedures, ear wax removal).

Again, we urge CMS to reexamine the use of physician work as an allocator of indirect costs. For example, CMS could limit the allocation of indirect PE RVUs based on physician work to a specific percentage of total indirect PE RVUs. Or it could create a meaningful proxy for physician work that would give TC services a fair share of indirect PE RVUs.

2. Use unscaled direct cost inputs to allocate indirect PE

CMS has proposed using scaled (i.e., budget neutralized) direct cost inputs to allocate indirect PE. We believe that using adjusted direct cost inputs is inconsistent with the basic policy of allocating indirect costs at the service level in direct proportion to the amount of direct costs. While the proposed policy allocates indirect PE to services with high direct cost inputs it mitigates the full effect of that allocation by reducing the value of those direct costs through an adjustment factor of 0.667 (the budget neutrality factor).

Reducing the value of the direct cost inputs used to allocate indirect PE by a third creates unfair distortions in payment. Simply put, it reduces indirect PE for the very services the allocation policy was intended to protect – those services formerly in the non-physician work pool. The intent of using clinical labor value to allocate indirect PE for services with little or no physician work was to ensure that the PE methodology properly accounts for the costs of providing those services. Because lowering the value of that clinical labor (and of equipment and supplies) by a third is inconsistent with this intent, we recommend refining the proposed PE methodology to use unscaled direct cost inputs to allocate indirect PE.

Moreover, if direct costs are used to allocate indirect costs, the entire value of those direct costs should be used. The inevitable distortion in indirect PE allocation at the code level resulting from the use of budget-neutralized direct costs is not offset by any benefits. Services with high direct cost inputs are reduced by a much larger dollar amount than services with low direct cost

inputs even though they are reduced "relatively" the same. Table 53 of the proposed rule provides a good example of this policy problem. In that table, the budget neutrality adjustment to the direct cost inputs for 99213 causes the dollar value of those inputs to go from $16.50 to $11. It is noteworthy that PE RVUs for most outpatient E/M services remain unchanged with this methodological change. Consequently, while the effect of the proposed methodology on the ability for physicians to furnish office visits is insignificant, the effect of using scaled direct cost inputs to allocate indirect PE for TC services has a devastating financial impact on codes like 93236 which have high direct-cost inputs (e.g., staff time, supplies, and equipment) and makes it financially infeasible to provide those services.

CMS and the physician community have spent considerable time and effort to assemble a huge database with direct cost inputs for all services paid under the PFS. CMS has stated publicly that it knows of no other database as reliable as its own. Accordingly, CMS should demonstrate its confidence in that database by using its unadjusted data to allocate indirect expenses.

B. Creation of Specialty-Specific Indirect PE Pools.

1. A proxy for physician time should be used to create the indirect PE pools for Remote Cardiac Monitoring Services.

The use of only physician time to create the indirect PE cost pools unfairly impacts non-physician work services provided by independent diagnostic testing facilities (IDTFs). IDTFs do not fit the physician office model for determining practice expenses. IDTFs provide primarily technical component services and employ clinical staff to perform those services. In the case of remote cardiac monitoring, IDTFs are open 24 hours/day, 7 days/wk for 365 days/yr. Physicians, who may be independent contractors, are present for a small subset of that time to provide supervision and therefore any PE pool, if calculated based on physician time, would vastly understate the amount of PE that should be allocated to services performed by IDTFs that perform remote cardiac monitoring. Therefore, even though the PE per physician hour may be high, the total amount of PE available for TC services performed by IDTFs is low.

The impact of this is particularly profound in the case of the remote monitoring which is performed solely by IDTFs. IDTFs that provide these services have substantial indirect costs because of the need to maintain the facility on a 24/7/365 basis. However, these costs are discounted in the proposed methodology because the service does not involve physician time. The use of physician time to create cost pools combined with the use of physician work as an allocator doubly disadvantages services that do not have physician work.

2. Clinical labor costs or clinical staff time should be used to calculate specialty-specific pools of indirect PE

CMS very properly proposes to use clinical labor cost to allocate indirect PE when clinical labor costs exceed the physician RVU for a service. CardioNet is in agreement with this proposal because it appropriately acknowledges that many non-physician work services like remote cardiac monitoring and many services that require little physician work require a great deal of

staff time which should be more equitably recognized. This proposal also shows CMS recognizes the importance of allocating indirect PE proportionally to the amount of equipment and staff time used to provide a service.

However, the CMS methodology is not internally consistent in that it does not use clinical labor time to calculate specialty-specific aggregate indirect PE pools in step 13 of the methodology (as presented in the preamble to the proposed rule). Specifically, the proposed methodology, in step 13, adds the product of the indirect PE/HR for a specialty, the **physician time for the service** (emphasis added), and the specialty's utilization for the service but ignores clinical staff time or clinical labor costs in the calculation. To calculate IPCIs, CMS then compares the aggregate pools of specialty-specific adjusted indirect PE allocators (by adding the product of the adjusted indirect PE allocator for each service and the utilization for that service by a specialty) for each specialty (step 12) to the specialty-specific aggregate pools of indirect PE for each specialty determined in step 13 using survey data.

In other words, in the proposed methodology, clinical labor cost is included only in step 12, the denominator, and not in step 13, the numerator. This is not an apples-to-apples comparison and, in our view, will likely cause the IPCIs for specialties with services that were previously in the non-physician work pool (e.g., remote cardiac monitoring) to be improperly lowered. A more detailed discussion of how we reached this conclusion follows.

The calculation of aggregate pools of specialty-specific adjusted indirect PE allocators in step 12 includes PE that was allocated based on use of clinical labor costs for services where those costs were greater than the physician work value. This approach results in a larger pool than existed under the previous methodology where clinical labor costs were not used to allocate indirect PE. In contrast, the calculation of specialty- specific aggregate pools of indirect PE in step 13 using survey data does not contain the clinical labor value (or clinical staff time) for codes without physician work and will therefore, not only be smaller than the pools calculated in step 12, but also will not be comparable.

Because of the internal inconsistency between the step 12 and step 13 calculations, the PE scaling factors determined in step 14 will be inappropriately small for specialties who provide a large number of services that have little physician work or were formerly in the non-physician work pool. This distortion will be reflected in the IPCIs calculated in step 15 and used in step 16. As a result, the proposed methodology will lead to artificially low IPCIs for specialties with high volume non-physician work services, a result which means lower payments for many non-physician work services. This problem is compounded by the high indirect PE of independent diagnostic testing facilities (IDTFs) that perform remote cardiac monitoring services (as discussed below).

Using clinical labor cost or clinical staff time to create specialty-specific indirect PE pools and IPCIs is good payment policy, intuitive, and transparent. Not using clinical labor cost or clinical staff time to calculate the survey-based indirect PE pools is not internally consistent with CMS' own policy of using clinical labor cost to allocate indirect PE.

CMS should make its PE methodology internally consistent. The effect of this change is similar to the effect of using unadjusted direct cost to allocate indirect PE. Non-physician work services, especially complex non-physician work services, like remote cardiac monitoring, hopefully would see PE increases while E/M services are generally unchanged.

Although we believe that CMS could use either clinical labor cost or clinical staff time to calculate IPCIs, it is likely technically easier to use the clinical labor value. Using clinical labor values also may be technically more correct than using staff time because clinical labor value accounts for the cost of clinical staff time to the specialty (e.g., salaries for electrodiagnostic technicians are higher than salaries for radiology technicians).

C. Remote Cardiac Service Providers have costs that are very different from the IDTFs used in the CMS Methodology

Although CardioNet is enrolled in Medicare as an IDTF, our overhead costs are very different from the IDTFs that participated in the survey used by CMS to establish the IDTF PE/Hr and indirect practice cost index (IPCI). Those calculations are based on a practice expense supplemental survey of free-standing imaging providers. It does not include providers of remote cardiac services or, for that matter, any other IDTFs. As reported in the comment letter submitted by the Provider Group, the indirect costs for providers of remote cardiac services is about 60% of total costs as compared to only 50% for imaging IDTFs as reflected in the SMS and supplemental surveys. Treating all IDTFs as a single "specialty" under the physician fee schedule does not recognize the unique differences among various types of IDTFs. In particular, it does not recognize the high overhead costs associated with furnishing services on a 24/7/365 basis throughout the country.

It has been suggested that some of the problems resulting from the indirect allocation methodology might be remedied by assuming one hundred percent of these services are provided by the specialty of cardiology which has a higher IPCI than the IDTF specialty. We urge CMS to make this assumption, at least on an interim basis, however, the Provider Group engaged a consultant to model the effect of implementing this assumption and the simulations prepared by the consultant indicated that only modest increases (less than 5%) would result from this approach. Thus, while it may be helpful, as an interim one measure, it does not solve all the underlying problems resulting from the proposed methodology.

D. Multi-Specialty Survey

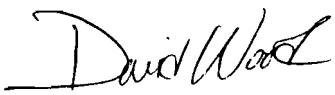
The AMA is coordinating a multi-specialty survey to develop updated practice expense data to replace current SMS data. Current information suggests that the survey would not include IDTFs that provide primarily technical component services. Therefore, we have serious concerns about this initiative. First, we note that because the SMS data did not include providers such as IDTFs, CMS decided, when it created resource-based PE RVUs, that it was necessary to create a separate "non-physician work pool" for technical component services. We would hope that this problem does not repeat itself. In that regard, we urge that CMS carefully consider ways in which accurate practice expense data for technical component providers can be collected

either as part of this survey or through a separate initiative. We are especially concerned with the continued use of any practice expense per hour approach which assumes a physician office model. The use of a PE/hour approach is meaningless when applied to IDTFs. We urge that CMS consider alternative models as it works with all members of the provider community to update practice expense data.

* * *

We would welcome the opportunity to discuss with you in person the basis for and the impact of our suggested refinements to the proposed PE methodology, particularly in the context of reimbursement for remote cardiac monitoring services. Should you have questions please do not hesitate to contact Philip Leone at 610-729-7010.

Respectfully submitted,



David Woods
Chief Operating Officer

Appendix IV

(Direct Practice Expense Inputs)

I. **PE INPUTS FOR PROPOSED G CODE,** G----- Continuous electrocardiographic recording with concurrent computerized real-time data analysis and greater than 24 hours of accessible ECG data storage with automatic and patient triggered remote event transmission for continuously attended monitoring and data analysis with daily, emergent and one summary reports; per 15 day period.

A. Clinical Labor

- Electrodiagnostic Technician – 505 minutes @ 0.37¢/min
- RN/LPN/MTA – 153 minutes @ 0.37¢/min
  - EP Tech time is based on (56 staff x 2080 hrs x 60 min)/~180,000) x 13 = 505
  - RN/LPN/MTA time is based on (17 staff x 2080 hrs x 60 min)/~180,000) x 13 = 153
  - 180,000 is the number of patient days per year
  - 13 is the average number of days patients are hooked up to the monitor
  - RN/LPN/MTA's perform different functions than the EP technicians. They are not providing quality assurance or oversight. Please see slide 13 of our presentation for more detail
  - These RN/LPN/MTA staff spend 100% of their time on individual patient care activities. They do not have nay other job responsibilities

B. Supplies

Item	Cost / item	Number of items/ day	Number of days	Total cost	Comment
AA Battery	**0.45¢**	**2**	**13**	**$11.70**	
Electrodes	**0.09¢**	**3**	**13**	**$3.51**	
Alcohol Pads	**0.013¢**	**3**	**13**	**$0.51**	
Adhesive Remover	**0.12¢**	**.5/ day** **7 used in total**	**13**	**$0.84**	
Wireless Communication	**0.33¢/min**	**20 min**	**13**	**$85.80**	**This amount reflects the fixed fee paid per month for each monitor – see below for more**

					details
Landline Communication	**0.27¢/min**	**4 min**	**13**	**$14.04**	**Dedicated 800 line for patient communication only – see below for more details**
Delivery	**$18.00**	**Ship to patient and ship back to CardioNet after use**		**$36.00**	**See details below**

- Delivery – CardioNet uses UPS as its carrier and the cost of shipping (delivery to the patient and return to CardioNet) is based on several factors including: (1) the distance the package is shipped, (2) the package size (1 cubic foot for MCOT), (3) the package weight (8 pounds for MCOT), (4) mode of delivery (next day air delivery which occurs 90% of the time vs. second day air delivery which occurs 10% of the time). The $18 one-way cost ($36 total for delivery and return) was calculated by factoring in the relative frequency of next day and second day air delivery, early morning delivery (which occurs 10% of the time and costs $2 extra), and CardioNet's negotiated discount. Examples: UPS divides the contiguous United States into eight zones. An eight pound package which is one cubic foot in size shipped from Pennsylvania to anywhere in Zone 2 costs CardioNet $24.60 if shipped by next day air and $12.70 if shipped by second day air. CardioNet's cost for shipment to Zone 8 is $55.70 if shipped by next day air and $29.10 if shipped by second day air. We note that packages greater than one cubic foot in size would cost significantly more to ship
- Wireless Communication – CardioNet pays a fixed monthly fee to its wireless provider irrespective of how many days its device is used. The rate was determined working backward from the fixed fee.
- Landline Communication – CardioNet maintains a separate 800 number 24/7 for patient calls. The amount was calculated based on the fixed fee CardioNet pays for this 800 number.

C. Equipment

1. Cost of Equipment

- Monitoring Device - $28,024 – Useful life 2 years, per IRS depreciation schedule for software and computers
- Phone Recording Device - $15,000 – Useful life 5 years

These prices are exclusive of maintenance contracts.

2. Time of Use of Monitoring Device

For purposes of the CMS methodology this can be calculated in one of two ways:

a. Total Number of Minutes of Actual Use

The total number of minutes of actual use per monitor is:

1440 minutes/day x 13 days x 12 uses per year = 224,640 minutes/yr

If this methodology is used then the utilization rate should be 1.0 (not 0.5 as per CMS usual methodology)

Total Number of minutes per service for the G code should be 1440 x 13 = 18,720

Therefore, the 3 numbers CMS requires to calculate the cost of the equipment per use are:

Minutes per service = 18,720
Total Minutes per year = 224,640
Utilization Rate = 1.0

b. Maximum Number of Minutes of Use

This methodology is more similar to CMS usual methodology where it assumes what maximal use is (150,000 min per year based on 8hr/d, 6d/wk) and then assumes that providers use equipment 50% of the time.
The maximum number of minutes a monitor can be used is:

1440 minutes/d x 26 days x 12 uses per year = 449,280 minutes

This assumes that every patient uses the monitor for 26 days which is the maximum the monitor is hooked up.

If this methodology is used then the utilization rate should be 0.5 per CMS usual methodology.

Total Number of minutes per service for the G code should be 1440 x 13 = 18,720

Therefore, the 3 numbers CMS requires to calculate the cost of the equipment per use are:

Minutes per service = 18,720
Total Minutes per year = 449,280
Utilization Rate = 0.5

3. Time of Use of Phone Recording Device

This device is used 24 hrs per day, 365 days per year.

Total Minutes = 525,600
Utilization = 1.0
Total Minutes per service = 18,720

II. PE INPUTS FOR 93236

A. Clinical Labor

- Electrodiagnostic Technician – 39 minutes @ 0.37¢/min
- RN/LPN/MTA – 12 minutes @ 0.37¢/min

  - EP Tech time is based on (56 staff x 2080 hrs x 60 min)/~180,000) = 39
  - RN/LPN/MTA time is based on (17 staff x 2080 hrs x 60 min)/~180,000) = 12
  - 180,000 is the number of patient days per year
  - 13 is the average number of days patients are hooked up to the monitor
  - RN/LPN/MTA's perform different functions than the EP technicians. They are not providing quality assurance or oversight. Please see slide 13 of our presentation for more detail.
  - These RN/LPN/MTA staff spend 100% of their time on individual patient care activities. They do not have nay other job responsibilities.

B. Supplies

Item	Cost / item	Number of items/day	Total cost	Comment
AA Battery	**0.45¢**	**2**	**$0.90**	
Electrodes	**0.09¢**	**3**	**$0.27**	
Alcohol Pads	**0.013¢**	**3**	**$0.04**	
Adhesive Remover	**0.06¢**	**1**	**$0.06**	
Wireless Communication	**0.33¢/min**	**20 min**	**$6.60**	**This amount reflects the fixed fee paid per month for each monitor – see below for more details**
Landline	**0.27¢/min**	**4 min**	**$1.08**	**Dedicated 800 line for**

Communication				**patient communication only – see below for more details**
Delivery	**$18.00**	**Ship to patient and ship back to CardioNet after use**	**$36.00**	**See details below.**

- Delivery – CardioNet uses UPS as its carrier and the cost of shipping (delivery to the patient and return to CardioNet) is based on several factors including: (1) the distance the package is shipped, (2) the package size (1 cubic foot for MCOT), (3) the package weight (8 pounds for MCOT), (4) mode of delivery (next day air delivery which occurs 90% of the time vs. second day air delivery which occurs 10% of the time). The $18 one-way cost ($36 total for delivery and return) was calculated by factoring in the relative frequency of next day and second day air delivery, early morning delivery (which occurs 10% of the time and costs $2 extra), and CardioNet's negotiated discount. Examples: UPS divides the contiguous United States into eight zones. An eight pound package which is one cubic foot in size shipped from Pennsylvania to anywhere in Zone 2 costs CardioNet $24.60 if shipped by next day air and $12.70 if shipped by second day air. CardioNet's cost for shipment to Zone 8 is $55.70 if shipped by next day air and $29.10 if shipped by second day air. We note that packages greater than one cubic foot in size would cost significantly more to ship

- Wireless Communication – CardioNet pays a fixed monthly fee to its wireless provider irrespective of how many days its device is used. The rate was determined working backward from the fixed fee.

- Landline Communication – CardioNet maintains a separate 800 number 24/7 for patient calls. The amount was calculated based on the fixed fee CardioNet pays for this 800 number.

C. Equipment

1. Cost of Equipment

- Monitoring Device - $28,024 – Useful life 2 years, per IRS depreciation schedule for software and computers
- Phone Recording Device - $15,000 – Useful life 5 years

These prices are exclusive of maintenance contracts.

2. Time of use of Monitoring Device

For purposes of the CMS methodology this can be calculated in one of two ways.

a. Total Number of Minutes of Actual Use.

The total number of minutes of actual use per monitor is:

1440 minutes/day x 13 days x 12 uses per year = 224,640 minutes/yr

If this methodology is used then the utilization rate should be 1.0 (not 0.5 as per CMS usual methodology)

Total Number of minutes per service should be = 1440

Therefore, the 3 numbers CMS requires to calculate the cost of the equipment per use are:

Minutes per service = 1440
Total Minutes per year = 224,640
Utilization Rate = 1.0

b. Maximum Number of Minutes of Use

This methodology is more similar to CMS usual methodology where it assumes what maximal use is (150,000 min per year based on 8hr/d, 6d/wk) and then assumes that providers use equipment 50% of the time.

The maximum number of minutes a monitor can be used is:

1440 minutes/d x 26 days x 12 uses per year = 449,280 minutes

This assumes that every patient uses the monitor for 26 days which is the maximum the monitor is hooked up.

If this methodology is used then the utilization rate should be 0.5 per CMS usual methodology.

Total Number of minutes for 93236 should be = 1440

Therefore, the 3 numbers CMS requires to calculate the cost of the equipment per use are:

Minutes per service = 1440
Total Minutes per year = 449,280
Utilization Rate = 0.5

Time of Use of Phone Recording Device

This device is used 24 hrs per day, 365 days per year.

Total Minutes = 525,600
Utilization = 1.0
Total Minutes per service = 18,720

We do not have a specific recommendation as to which methodology CMS should use to calculate the cost of the monitoring device.

CARDIOLOGY CONSULTANTS

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DIPLOMATES OF AMERICAN BOARD
OF INTERNAL MEDICINE
AND CARDIOVASCULAR DISEASES

October 9, 2006

Ms. Roberta Epps
Reg expert for Diagnostic Imaging Services
CMS
Central Building
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Ms. Epps:

Cardiovascular disease is the #1 killer in the United States. Given the magnitude of cardiovascular morbidity and mortality, a reasonable person would expect medicare to make it a priority to support cardiovascular specialists who lead the way in the battle against this dreaded disease. Instead, medicare plans to make crippling cuts in the reimbursement we receive for diagnostic procedures in our office practices. The current range of cuts is from 40%-62%, and involve essential diagnostic procedures including echocardiography, nuclear stress testing and outpatient diagnostic cardiac catheterization. Over the last several years, medicare reimbursements to physicians have failed to keep pace with medical inflation and cost of living increases. Nonetheless cardiologists have managed to maintain high levels of care for both medicare and non-medicare patients alike, including those patients who have no health insurance and receive care for free. Current medicare proposals that will take effect in January 2007 threaten our ability to deliver care to these patients. The net results of these cuts will be that the cost of providing cardiovascular services in the office setting will actually be greater than the reimbursement. Compounding the problem is the fact that private insurance companies use medicare as a guideline and this reduction in fees will impact our ability to deliver care to non-medicare patients as well. the magnitude and depth of these cuts will have a rippling catastrophic effect on cardiovascular care throughout Central Florida. It is unlikely that physicians will be able to afford to make new medical and information technologies available through their office practices. I anticipate many cardiologists will be forced to close their practices in the State of Florida and move to other states with a smaller medicare population. The remaining practices will have no choice but to reduce office staff substantially, and reduce or eliminate services in order to survive in this environment. Many cardiologists may find that they are unable to see new medicare patients, others will have no choice but stop seeing medicare patents at all.

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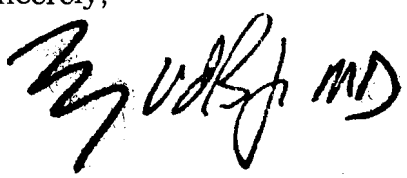
DIPLOMATES OF AMERICAN BOARD
OF INTERNAL MEDICINE
AND CARDIOVASCULAR DISEASES

In an effort to reverse these unfair cuts, the major cardiology groups in Central Florida have been meeting to discuss possible solutions. We have been meeting with our representatives who include Senator Bill Nelson and Congressmen Ric Keller and Thomas Feeney. In addition we have met without representatives from the Florida Medical Association and the Florida chapter of the American College of Cardiology. We are all in agreement that the proposed cuts will destroy our practices, and force many of us out of business. Therefore, we would ask that you freeze the reimbursement rates for the current office diagnostic procedures which include echocardiography, carotid ultrasound, Nuclear stress testing and diagnostic cardiac catheterization at the current levels.

We would ask that you develop a fair solution that addresses the issues of compensation for these services. Any solution that is fair should include the participation of clinical cardiologists like ourselves who have a vital stake in this process and actually take care of the patients.

Thank-you so much for considering these comments.

Sincerely,



Egerton K. van den Berg, Jr., M. D.

EKV/ms

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October 6, 2006

Via Email [David.Walczak@cms.hhs.gov; http:\\www.cms.hhs.gov/eRule] **Followed by Mail**

Mr. David Walczak
Centers for Medicare Medicaid Services
CMS 13-21
P.O. Box 8015
Baltimore, MD 21244 (3 copies)

Re: Proposed Reassignment and Self-Referral Rules

Dear David,

I am writing to provide my comments to the proposed changes to the reassignment and self-referral rules particularly as they relate to diagnostic tests. My primary concerns turn on what appears to be a confounding of the concept of purchased tests and reassignment. Although there has never been a clear definition published with regard to what qualifies as either a purchased technical component or a purchased professional component, in the proposals the primary issue is the definition of a purchased professional component.

From my analysis, a purchased professional component by definition is not a reassignment. As demonstrated in the other reassignment rules which have long been on the books, the purchased professional component that is permissible under the old Carrier's Manual 3060 provisions is specifically not a true reassignment.

The effect of a purchased service billing is relatively limited with regard to the impact on the physician practice. By contrast, reassignment is a different undertaking. In addition to joint and several liability for overpayments in the billing interrelationships that were clarified with the Medicare Modernization Act liberalizations, when a physician of a different specialty reassigns his right to payment to the billing group, the specialty of the practice for utilization profiling purposes converts to "multi-specialty group".

That critical distinction having been stated, the implications of the following statement would vitiate the effect of the Medicare Modernization Act provision.

> "We believe there are current rules on purchased diagnostic tests which generally should be applicable in both situations in which the billing entity is purchasing the test without a formal reassignment as well as situations in which the physician performing the test has reassigned his or her right to Medicare payment to the billing physician or medical group."

By this mechanism, a physician group which leases on a block time basis the use of technology, completely consistent with the shared facilities rules under Stark, would be treated as if they had merely purchased the technical component. Moreover, if they engaged in that activity, but did not themselves perform the professional component, which was read by an independently practicing radiologist, the arrangement would be prohibited. The approach stated in the quotation above would vitiate effectively the shared facility rules as they have been published extensively under Stark if an independent contractor physician either supervised or interpreted the service. This would fly in the face of the very explicit recognition in the Stark Phase I regulations of independent contractors as being "in the group" for Stark purposes.

In addition, the purported desired consistency of the rules with respect to purchased diagnostic tests, by expanding the definition of a professional component to include the reassignment by an independent contractor physician to a billing physician group, would create pragmatic problems as well inasmuch as the independent contractor who may be supervising the test under the Stark and diagnostic testing rules would not be able to interpret the same study that he supervised unless he were an employee, lest the group run afoul of the proposed purchased professional component provisions.

The fundamental problem is that there has never been an articulation of what constitutes a purchased service. Do block time leases under the Stark shared facilities rules create a purchased technical component? I would argue they do not. A purchased technical component is a single per use payment for a study including the use of the equipment and technician. Period. Nothing else is a purchased technical component.

My definition of a purchased professional component would be a per study payment for an interpretation <u>where the physician does not reassign</u> his payment to the group. Any other definition would disenfranchise independent contractor physicians from relationships with practices which include diagnostic testing interpretations.

The only statement that we have with regard to anything pertaining to purchased technical components let alone purchased professional components is that provided in the old Medicare Carrier's Manual provision section 15048 which talked about questionable payment arrangements. That language, in and of itself, is completely outdated since it does not take into account the right of the group to bill for independently contracted technicians.

Taken together, I think that the proposed changes which would turn all independent contractor reassignment in connection with diagnostic testing into purchased professional components is ill advised.

As always, I would welcome the opportunity to talk with you about these issues.

Sincerely yours,

Alice G. Gosfield

(AGG/eaf)

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MedCath®
Diagnostics, LLC

October 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

This letter is in response to the CMS Notice of Proposed Rulemaking referenced above which was published in the Federal Register on August 22, 2006. We are concerned about several provisions which will impact the ability of Medicare beneficiaries to access services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about two issues—the payment method proposed fro cardiac catheterization related procedures and the proposal to require standards for Independent Diagnostic Testing Facilities (IDTFs). Our concerns related to each of these issues are outlined below.

Payment Method

The proposed rule indicates that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. We believe that this approach is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. The change in the payment method appears only in Addendum B and no explanation is provided in the body of the proposed rule.

We suggest that CMS use the current relative value units for these procedures rather than relying on the Medicare carriers to price these services. The current relative value units result in a payment rate that is in relative parity with the amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification (APC) for cardiac catheterizations are 93 percent of the relevant

APC rate. The current fee schedule payment approximates the average cost of providing these services.

In response to the CMS Notice of June 29, 2006, we outlined our concerns about the proposed changes to a bottom-up methodology and the elimination of the non-physician work pool. The payment rates resulting from the use of the practice expense RVUs for these procedures reduce payment levels in 2007 by 16 percent and overall reductions of 53 percent by 2010. The flaws in the methodology, particularly as it relates to the cardiac catheterization procedure codes were described in general in our comment letter of August 18, 2006 and more specifically in the letter submitted by the Cardiovascular Outpatient Center Alliance (COCA), of which we are a member.

COCA has sponsored a study to estimate the costs of performing a cardiac catheterization (CPT code 93510 TC) in an outpatient center. The study results demonstrate that the 2006 payment level reflects the costs of performing the procedure while the payment level based on the relative value units (RVUs) proposed in the June 29th Notice do not cover the costs of the procedure.

IDTF Standards

IDTFs represent a diverse group of providers, including free standing diagnostic cardiac catheterization labs. In fact, IDTFs represent 65.1 percent of the utilization for CPT code 93510 TC, described as left heart catheterization. We commend CMS in proposing the application of standards for IDTFs, comparable to those that were developed for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The standards addressed in the proposed rule reflect the general standards related to operational and financial management issues. We believe that CMS needs to work with the various types of IDTFs to ensure that additional standards are developed, consistent with the approach taken with the DMEPOS standards where there are a set of specific requirements for each type of DME supplier. For example, these standards address the specific needs of oxygen suppliers compared to suppliers of monitors and supplies for diabetic patients.

We believe that unique standards for each type of IDTF will facilitate the development of a consistent Medicare policy regarding outpatient cardiac catheterization services. The standards will provide a solution to the situation which cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations (PROs).

The need to develop unique standards for each type of IDTF provider is consistent with the observation that CMS made in the NPRM regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to the observation that these types of IDTFs are different, we believe that cardiac catheterization centers are also different. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all

IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is not an adequate experience base to determine a national ate. In addition, carrier-based pricing has the potential to create disparities in beneficiary co-payment liability. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures and therefore request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Charles F. Furr, Jr. CHE
President
MedCath Diagnostics, LLC
10720 Sikes Place
Suite 300
Charlotte, NC 28277
704-708-6610 ext 1107