Submitter : Dr. Mark Kaminski **Date:** 10/10/2006

Organization : University of Michigan Cancer Center

Category : Physician

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

I have grave concerns over the impact of the proposed changes as they involve radioimmunotherapy of lymphoma with either Bexxar or Zevalin. I am one of the principal developers of this therapy and as an individual has the most experience in the U.S. (if not the world), having treated well over 300 patients over the last 16 years. This therapy, approved by the FDA in 2002 and 2003, is one of few treatments that can result in longterm complete remissions lasting over 10 years for patients with an incurable form of lymphoma, follicular lymphoma. This therapy is especially important for elderly patients (Medicare-eligible)who cannot tolerate more toxic forms of treatment, such as chemotherapy. It is gaining in its acceptance as the most effective treatment for this disease that is currently available. If, however, the current proposed changes are implemented, hospitals will have a disincentive to utilize this drug, and for all intents in purposes, this therapy will likely disappear from the treatment landscape. I am sure that if the public were aware of such a move they would be outraged.

As to the cost of this therapy compared to other treatments, it is similar to what would be expected from multi-cycle chemotherapy, with fewer side effects (that would need to be cared for and payed for), but with potentially better short-term and longterm outcome -- all delivered within a one to two-week period, instead of months.

Please reconsider the proposed changes as they would be devastating. I recommend retention of the present guidelines for reimbursement and drug acquisition costs.

Mark S. Kaminski, M.D.
Professor of Internal Medicine
Co-Director of Leukemia/Lymphoma/BMT Program
University of Michigan Comprehensive Cancer Center
Ann Arbor, Michigan

Submitter : **Dr. John Mulcahy** **Date: 10/10/2006**

Organization : **Coalition forthe Advancement of Prosthetic Urology**

Category : **Association**

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

Please see attached comment letter. Thank you for your consideration.

Policy and Payment Recommendations

Policy and Payment Recommendations

Please see attached comment letter. Thank you for your consideration.

CMS-1506-P-441-Attach-1.DOC

#441

The Coalition for the Advancement of Prosthetic Urology
1301 K Street, N.W. Suite 1100
Washington, D.C. 20005
(202) 414-9241

October 10, 2006

Filed Electronically and Via Hand Delivery

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

RE: CMS-1506-P - Proposed Changes to Medicare Hospital Outpatient PPS for CY 2007 Device-Dependent APCs, Prosthetic Urology – APCs 181, 385 and 386

Dear Administrator McClellan:

The Coalition for the Advancement of Prosthetic Urology ("CAPU") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital outpatient prospective payment system ("HOPPS") proposed rule for calendar year 2007 (the "Proposed Rule").[1] CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. CAPU has worked closely with CMS in the past in developing policies on adequate payment for prosthetic urology procedures under the HOPPS that support high quality care for Medicare patients. Our comments and recommendations are as follows:

1. CAPU appreciates the efforts CMS has made in the development of the proposed HOPPS rule. In particular, we are pleased that CMS has proposed to increase payment rates for several key prosthetic urology devices and procedures, including:
    - APC 385 Level I Prosthetic urology procedures –proposed payment $4,885,
    - APC 386 Level II Prosthetic urology procedures –proposed payment $8,354,
    - APC 181 Penile procedures–proposed payment $2,031.

    We strongly encourage CMS to adopt these proposed payment increases in the final 2007 HOPPS rule.
2. The Prosthetic Urology APCs are device-dependent APCs and CMS has created device coding edits to ensure that hospitals are reporting all the costs/charges for the devices.
3. **CAPU strongly supports CMS's proposal to use only claims that meet the device edits and contain actual charges for devices rather than "token" charges** for device-dependent APCs. Table 18 demonstrates that when CMS uses only hospital claims that meet the device edit and contain device charges, the median costs calculated for the procedures are several hundred dollars higher, as would be expected.
4. With regard to the offset adjustment in cases of replacement or full credit for failed or recalled device, we recommend that CMS change the proposed offset for APC 385 to 60%. The ratio of device costs to overall procedure costs is basically identical for APC 386 and APC 385. Therefore, offsets for both APC 385 and 386 should be 60%.

[1] See 71 Fed. Reg. 49506 (August 23, 2006).

Adequate payment levels for prosthetic urology procedures are critical to ensure that hospitals can continue to offer these important therapies to Medicare beneficiaries in the outpatient setting

As always, we thank CMS for the opportunity to provide comments on the proposed 2007 HOPPS rule.

If you have any questions about these comments, or if you would like additional information, feel free to contact me at 480.699.3378, or CAPU's counsel, Gail Daubert at 202.414.9241.

Sincerely,

John Mulcahy

John Mulcahy, M.D., Ph.D., F.A.C.S.
Diplomate, American Board of Urology
Chairman, CAPU

cc: Carol Bazell, M.D., CMS (vial email)
Robin Hudson, American Urological Association (via email)
CAPU Board (via email)
Gail Daubert, Esq. (via email)

Submitter : Mr. Todd Gillenwater **Date:** 10/10/2006

Organization : California Healthcare Institute

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please find attached the comments of the California Healthcare Institute (CHI) on the Calendar Year (CY) 2007 Hospital Outpatient Prospective Payment System (OPPS) proposed rule published on August 23, 2006.

CMS-1506-P-442-Attach-1.PDF

#442

C H I CALIFORNIA HEALTHCARE INSTITUTE
WWW.CHI.ORG

OCTOBER 10, 2006

BY ELECTRONIC DELIVERY

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates [CMS-1506-P]

Dear Dr. McClellan:

The California Healthcare Institute (CHI) welcomes this opportunity to comment on the Calendar Year (CY) 2007 Hospital Outpatient Prospective Payment System (OPPS) proposed rule published on August 23, 2006 (the Proposed Rule).[1] CHI represents the full biomedical sector of the California economy and unites more than 250 of California's leading biomedical firms, universities, and private research institutes in support of biomedical science, biotechnology, and pharmaceutical and medical device innovation. California is the global leader in biomedical R&D, with more than one-third of all U.S. biotechnology and medical device firms, turning scientific discoveries into medical products at an unprecedented rate. California companies lead the nation in bringing to market frontline therapies for diseases such as AIDS, breast cancer, stroke, and diabetes.

As the advocate for California's biomedical industry, CHI appreciates CMS' efforts to refine the OPPS to increase payment accuracy for outpatient procedures, technologies, and drugs and biologicals. CHI believes it is particularly important that CMS' reimbursement policies encourage new scientific breakthroughs that allow procedures to be performed faster, more accurately, and with less invasive approaches that minimize risk and recovery times. In this regard, we have the following concerns regarding CMS' proposed payment changes for devices:

- The rate-setting methodology for device-dependent ambulatory payment classifications (APCs) should require hospitals to use C-codes and ensure stable payment rates.
- CMS should establish greater consistency and transparency in the New Technology APC and Pass-Through application processes as well as the transition of technologies to clinical APCs.
- CMS should use external data to set rates for device-related APCs and should protect the confidentiality of those data.

[1] 71 Fed. Reg. 49506 (August 23, 2006).

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With respect to CMS proposed payment changes for drugs, biologicals, and radiopharmaceuticals, CHI is concerned that the proposed rates of average sales price (ASP) plus five percent for drugs and biological products without pass-through status are not adequate to reimburse hospitals for their acquisition costs, much less their pharmacy service costs. CHI believes CMS' proposal to reduce reimbursement for many separately paid drugs and biologicals will create obstacles to patient access and significantly affect hospitals' ability to provide these essential therapies to Medicare beneficiaries.

To ensure that hospitals are sufficiently reimbursed for providing advanced drugs and biologicals to Medicare beneficiaries, we recommend the following measures:

- Reimbursement for drugs and biological products under the OPPS should be no less than ASP plus six percent, the rate applicable in physicians' offices;
- CMS should eliminate the bundling threshold and pay separately for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting;
- CMS should continue to work with stakeholders to develop suitable methods of reimbursing hospitals for pharmacy service and handling costs;
- CMS should not apply an equitable adjustment to any drugs or biologicals;
- CMS should continue to use the payment methodology for radiopharmaceuticals implemented in 2006;
- CMS should finalize its proposed drug administration APCs to ensure that hospitals receive appropriate payment for the second and subsequent hours of infusion services;
- CMS should pay for a second or subsequent intravenous push of the same drug;
- CMS should provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions, regardless of the setting in which they are administered;
- CMS should allow hospitals to separately bill and receive payments for therapeutic infusions and hydration infusions provided in the same encounter; and
- CMS should continue to pay for preadministration-related services for intravenous immune globulin (IVIG).

We discuss our comments regarding the proposed OPPS payment changes for devices and for drugs, biologicals, and radiopharmaceuticals in more detail below.

I. PROPOSED OPPS CHANGES FOR DEVICES

A. The rate-setting methodology for device-dependent APCs should ensure stable payment rates and require hospitals to use C-codes. (Device-Dependent APCs)

CHI is concerned about the stability of OPPS rates for device-dependent APCs. We are disappointed that CMS does not propose to set a floor to moderate for any decreases in median costs from 2006 to 2007. In 2006, CMS adjusted median costs for device-dependent APCs to the greater of the median from claims data or 90 percent of the payment median that the agency used

to set the CY 2005 payment rate.[2] This payment floor helped to provide a stable transition from 2005 rates and to prevent large decreases in payments from year to year. Without such a floor, the median costs of six APCs will decline more than 10 percent from 2006 to 2007.[3] CHI is concerned that sizeable decreases in any individual device-dependent APC payment rate will lead to unpredictability in reimbursement and create obstacles to patient access to high-technology devices and procedures.

We particularly are concerned about the effects of the projected fluctuations on access to devices produced by small manufacturers. These companies often have only one device on the market and cannot rely on continued demand for other products to balance the effect of payment cuts for one product. If Medicare drastically reduces payment for these companies' products, these companies may cease production, denying beneficiaries appropriate and effective treatment options. We urge CMS to protect beneficiary access to innovative devices by preventing large decreases in payments for device-dependent APCs. CHI recommends that CMS establish a payment floor for CY 2007, and we ask that CMS exercise caution when making any cuts in payment for device-dependent APCs.

CMS can set accurate payment rates only if it has accurate data on hospitals' costs. For device-dependent APCs, CMS needs claims data that include the correct codes to identify the devices used. We support CMS' proposal to base the device-dependent APC medians the median costs calculated from calendar year 2005 claims with appropriate device codes that do not have token charges on the claim.[4] These claims will lead to better estimates of costs for device-dependent APCs than simply using all claims, including those that do not include correct coding for the device. To help CMS gather essential data for rate-setting, we recommend that CMS make payment for device-dependent APCs only when the hospital includes an appropriate HCPCS C-code identifying the device used.

Although CHI supports the use of only correctly coded claims in setting APC payment rates, we note that it often takes a few months for hospitals to implement new C-codes, particularly if the hospital has not reliably used those codes in the past. As a result, it may take a year or two after CMS issues a new C-code for the Medicare claims data to reflect use of and appropriate charge for the device accurately. CHI urges CMS to consider this data lag when determining whether claims data is available to calculate appropriate rates.

B. CMS should establish greater consistency and transparency in the New Technology APC and Pass-Through application processes and transition of technologies to clinical APCs. (Pass-Through Devices, New Technology APCs)

CHI believes that appropriate use of New Technology APCs and pass-through status are essential to protecting beneficiary access to advanced therapies. Congress created these provisions in the statute to ensure that hospitals would be paid appropriately while CMS collects data for use in future APC assignments and rate-setting. We remain concerned that that the

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[2] Id. at 49569.
[3] Id. at 49570.
[4] Id.

application processes for pass-through status and new technology APC assignments are not transparent or predictable. First, the CMS website does not provide information on the technologies for which New Technology APC assignments or pass-through status is sought, nor does it provide information regarding the number of applications received. In contrast, CMS provides this information regarding applications for new technology add-on payments under the inpatient prospective payment system (IPPS). Second, CMS's consideration of applications remains opaque. The agency does not provide information about the rationale for accepting or denying an application, does not accept public comment on its decisions, and provides no information about the timeliness of decision-making for completed applications. Because CMS considers these applications in private, stakeholders often do not understand the agency's decisions and cannot predict whether an application will be granted. We also cannot confirm whether CMS' decisions are correct. For example, if CMS assigns a new CPT code to a clinical APC instead of to a new technology APC, stakeholders will not know whether CMS considered all of the relevant evidence before making that decision. We cannot be confident that CMS is using all of the options under the statute to protect access to new technologies unless the agency makes its processes and decision-making more transparent.

CHI believes that sharing information about applications for New Technology APC assignments and pass-through status will help stakeholders understand the process better and ensure that these statutory protections for new technologies are used appropriately. Accordingly, CHI encourages CMS to provide opportunity for public discourse as it currently does with the new technology add-on process in the IPPS, explain its rationale for its decisions, and publish its timelines for decision-making.

CMS also could improve the predictability of New Technology APC assignments by implementing the Advisory Panel on APC Groups' ("APC Panel") recommendation "that when CMS assigns a new service to a New Technology APC, the service should remain there for at least two years until sufficient claims data are collected."[5] The purpose of new technology APCs is to protect beneficiary access to advanced treatment options while CMS collects sufficient data to set appropriate rates. CMS often moves services from new technology APCs to clinical APCs after less than two years. These moves may be premature and deny the agency the opportunity to gather sufficient data. Hospitals often cannot update their billing systems to use the new codes required for assignment to new technology APCs until several months after CMS issues the codes. This delay prevents CMS from beginning to collect accurate claims data until months into a technology's first year in a new technology APC. By leaving ensuring that all assignments to New Technology APCs last at least two years, CMS would improve its ability to collect a sufficient number of accurate claims to set appropriate rates in the future. We urge the agency to implement the APC Panel's recommendation.

[5] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

C. CMS should use external data to set rates for device-related APCs and should protect the confidentiality of those data. (Device-Dependent APCs)

CHI believes it is critical for CMS to use the best available data in setting rates. For many items and services, CMS' own data may be sufficient to calculate appropriate payment rates, but some items, particularly new technologies, are not adequately represented in claims data for CMS to accurately determine costs and set appropriate rates. CHI agrees with the APC Panel's recommendation that CMS should use readily available external data to validate costs determined by CMS' claims data.[6] Such external data can be used in three key areas: (1) to verify whether CMS' proposed rates are appropriate when the agency proposes to make a significant cut in reimbursement, (2) to identify and adjust payment for technologies that have been under-funded in the past, and (3) to remedy the effects of charge compression on reimbursement rates. Charge compression is the result of applying a constant cost-to-charge ratio (CCR) to all products when hospitals apply smaller markups to higher cost items than to lower cost items. Charge compression produces overestimates of the costs of lower cost items and underestimates of the costs of higher cost items. Manufacturers who believe that reimbursement for their products is inaccurate due to charge compression should be allowed to present confidential data to CMS in support of their case for more adequate payment. CMS should incorporate this supplemental data into the median cost calculations to set appropriate APC weights. Appropriate rates help ensure beneficiary access to these important therapies.

In addition to strongly recommending that CMS accept and use external data to ensure that its payments are appropriate, we urge the agency to establish protections for the confidentiality of such data. Manufacturers and hospitals will not provide the data CMS needs to set more accurate rates unless they are assured that the data will not be shared with others. These stakeholders also may be bound by non-disclosure agreements that prohibit them from sharing data with CMS if the agency does not agree to protect it. We ask CMS to maintain the confidentiality of external data submitted for rate-setting and to include this assurance in the final rule.

II PROPOSED OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

A. CMS' proposed reimbursement for drugs, biologicals, and radiopharmaceuticals will not sufficiently reimburse hospitals for the costs of providing these therapies, potentially harming patient access to them. [OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals]

1. Payment for Drugs and Biological Products

a) CMS' proposed rates are inadequate to reimburse hospitals for their pharmacy acquisition and service costs.

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[6] Id.

Presently, CMS reimburses drugs and biologicals at ASP plus six percent. For drugs and biological products without pass-through status, CMS has proposed to decrease that rate to ASP plus five percent.[7] CHI is troubled by this reduction because many hospitals already are struggling to provide care when drugs are reimbursed at ASP plus six percent. In the past few years, hospital outpatient departments have faced significant reductions in payment for drugs, with no adjustment for pharmacy service costs, and have experienced increasing patient loads. In particular, in addition to treating Medicaid patients and the uninsured, who often are not treated in physicians' offices, hospitals are taking on increasing numbers of patients without supplemental insurance. As recently noted by the Medicare Payment Advisory Commission (MedPAC) in its testimony to the House Ways and Means Subcommittee on Health, in some parts of the country, physicians are sending patients without supplemental insurance to hospital outpatient departments for care.[8] In this environment, CHI is concerned that the current reimbursement rate of ASP plus six percent may not be sufficient to guarantee the availability of appropriate therapies to beneficiaries and that a reduction in payment to ASP plus five percent will further encumber hospitals that currently are struggling to supply drugs and biologicals to patients. Patients will be left without providers for treatment unless hospitals receive sufficient payment for providing care. In addition, the access difficulties that currently affect IVIG under the ASP plus six percent payment methodology only will be heightened by the reduction of Medicare's reimbursement to hospitals .

In addition to not being adequate to cover hospitals' acquisition costs, CMS' proposed rates are not sufficient to cover hospitals' pharmacy handling costs. Pharmacy services cover a wide range of activities from basic mixings and reconstitutions to more advanced compounding that require a clean room, trained and certified personnel, and ancillary supplies. Pharmacists and pharmacy technicians perform a variety of services including conducting quality assurance measures to ensure therapies are correctly prepared, safely disposing of any unused medications, and consulting with physicians about the most suitable selection, dosage, and administration of drugs. These activities can require significant labor and resources, and, without them, the likelihood of error is substantial. The costs related to the provision of such services include pharmacist and pharmacy technician salary and benefits, supplies, equipment, and facility upgrades necessary required to satisfy changes in pharmacy regulations. Medicare payment for all aspects of providing drug and biological therapies, including preparing drugs, performing quality control, and administering drugs, must take into account all of these factors. Providing adequate reimbursement for drugs and biologicals will ensure that hospitals can provide quality care and continue to satisfy patients' needs.

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[7] 70 Fed. Reg. at 49585.

[8] Statement of Mark Miller, Executive Director, MedPAC, to the House Ways and Means Subcommittee on Health, July 13, 2006.

b) CMS should reimburse separately payable drugs at no less than ASP plus six percent in 2007 and should include all drugs and biologicals with HCPCS codes in its calculations of pharmacy costs.

Consistent with recommendations made by the APC Panel at its August meeting,[9] CHI urges CMS to set payment for drugs and biological products at no less than ASP plus six percent, the rate applicable in physician's offices. We are concerned that the proposed rates will not compensate hospitals for all of the costs of purchasing and preparing critical drugs for administration to Medicare beneficiaries. These rates may be below many hospitals' acquisition cost, and they clearly do not include hospitals' pharmacy service costs. In its June 2005 report, MedPAC stated that 26 to 28 percent of direct costs for pharmacy departments were comprised of pharmacy department wages, salaries, fringe benefits, and supplies.[10] Assuming that all hospitals could purchase covered drugs and biologicals at ASP, overhead costs of 28 percent would lead to hospital acquisition and handling costs of ASP plus 39 percent.

We believe CMS' calculations that led to the proposed rates are based on several incorrect assumptions and analyses. Specifically, because hospitals usually increase charges for high cost items by a smaller percentage than low cost items, CHI believes the imposition of a constant CCR to pharmacy incorrectly estimates the costs for specific drugs and biologicals. When a single CCR is applied to these items, the estimated cost of the low cost drug or biological could surpass its actual cost. In contrast, when a single CCR is applied to a higher cost item, the resulting charge may be below its actual cost.[11] Consequently, estimated unit costs and the Medicare payment rates based on such costs are unrelated to the actual costs of specific drugs and biologicals. Industry analysis of CMS' methodology for calculating average acquisition costs for drugs and biologicals concluded that these average costs, stated as a percentage of ASP, range dramatically. Such extreme variations clearly suggest that CMS' methods for calculating average acquisition cost lead to arbitrary, inaccurate, and irrational outcomes.[12]

CMS also underestimated the overhead costs when it used the mean unit costs for only separately paid drugs and biologicals in the estimate of the total costs for drugs compared to the total costs using ASP. In its June 2005 report, MedPAC noted that most hospitals do not set

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[9] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006.
[10] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.
[11] MJ Braid, KF Forbes, DW Moran. "Pharmaceutical Charge Compression under the Medicare Outpatient Prospective Payment System" *Journal of Health Care Finance* Spring 2004, p. 21-33.
[12] See also, Government Accountability Office (GAO), Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, September 2004, at 16 ("CMS's methodology does not recognize hospitals' variability in setting charges, and, therefore, the costs of services used to set payment rates may be under or overestimated.").

charges for handling costs and lack precise information about the magnitude of these expenses.[13] To the extent that hospitals include pharmacy service and overhead costs in their charges for drugs, a disproportionate amount of those costs are included in the charges for lower cost drugs due to hospitals' differential markups. Because the agency excluded from its calculations the lower cost drugs that are not separately paid under the OPPS, it also excluded a significant portion of hospitals' charges for pharmacy service and overhead costs. CMS could estimate overhead costs more accurately if it included all drugs and biological products with HCPCS codes in its calculations of mean unit cost. Although the exact share of total handling costs assigned to each therapy might not be accurate, including all HCPCS coded drugs would allow CMS to account for most of a hospital's handling charges. Industry analysis found that including -coded packaged drugs with reported ASPs in the calculations of mean unit cost greatly increased these estimates to well above ASP plus five percent. CMS could account for yet more pharmacy overhead if it included the numerous low cost drugs without HCPCS codes or ASPs that have charges reported under general pharmacy department revenue codes. Unless CMS includes, at a minimum, the packaged drugs with HCPCS codes with ASPs in its calculations, it will not accurately capture pharmacy service costs.

We note that CMS currently is studying how to address the effects of charge compression in the IPPS because it recognizes that charge compression could create inaccurate payment rates.[14] CHI hopes that any lessons learned from this study will be applied to the OPPS. While the study is ongoing, however, to ensure that all pharmacy overhead costs are included in the agency's calculation, CHI recommends that CMS recalculate the total costs of pharmacy services, including acquisition and overhead, using costs for all drugs and biologicals with HCPCS codes, not just the separately paid therapies. No matter what, CMS should set payment for separately paid drugs at no less than ASP plus six percent to protect continued access to care in hospital outpatient departments and minimize financial incentives to change patients' site of care.

c) CMS should continue to collaborate with stakeholders to establish the best procedures for the reimbursement of pharmacy service and handling costs.

As explained above, CHI believes that the claims and cost report data are insufficient to determine accurate payments for the acquisition and handling costs for each drug or biological. By providing hospitals with straightforward guidance regarding the reporting of pharmacy costs and establishment of charges for all pharmacy services, CMS can facilitate the improved accuracy of its cost data. We strongly encourage the continued cooperation by CMS with stakeholders in creating suitable systems under which hospitals will be paid for pharmacy service and handling costs. CMS should not adopt any payment reductions for drugs and biologicals until such a method is developed. We also urge CMS should to consider alternative means of providing more accurate payment for pharmacy service costs, including the employment of

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[13] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

[14] 71 Fed. Reg. 47870, 47897, (August 18, 2006).

codes for pharmacy handling services similar to those proposed for use in the OPPS in 2006 or payment for medication therapy management codes.

d) All drugs and biological products with HCPCS codes should be paid separately by CMS.

CMS proposes to increase the packaging threshold from $50 per day to $55.[15] CHI opposes this proposal and supports the APC Panel's recommendation to eliminate the packaging threshold for all drugs and biologicals with HCPCS codes.[16] To guarantee that hospitals are compensated appropriately for all of the therapies they provide, we encourage CMS to pay separately for all drugs and biological products with HCPCS codes. Currently, the OPPS packaging policy discourages hospitals from using packaged therapies even though they may be the most clinically suitable. Paying separately for these therapies will remove these incentives and would help provide hospitals with appropriate payment for drugs provided in their outpatient departments. Moreover, separate payment is comparable to physician reimbursement in the office setting. CMS has previously indicated its concern that differences in payment methodologies should not shift beneficiary care from one setting to another. These shifts are the natural result when only certain drugs are paid separately at ASP plus five percent in the hospital outpatient department, however, and all drugs and biological products with HCPCS codes are reimbursed at ASP plus six percent in the physician office.

In addition, eliminating the packaging threshold would help to improve the accuracy of payments under the OPPS. Although packaged drug costs are included in the OPPS, they are not included in charges for drug administration services. Industry analysis on this issue found that only four percent of packaged drug lines and five percent of packaged drug costs are on drug administration single claims. In contrast, 43 percent of packaged drug lines and 44 percent of costs were on single claims for other procedures and the remaining 53 percent of lines and 51 percent of costs were absent from CMS' analysis. Thus, unpackaging payment for these drugs and biologicals would improve the accuracy of OPPS rates for all services in which drugs and biologicals are used. It also would promote correct coding without increasing hospitals' administrative burdens because hospitals already are strongly urged to code for these drugs. We urge CMS to make separate payment for all drugs with HCPCS codes because it would be fairer for hospitals, is comparable to physician reimbursement in the office setting, and would improve the data upon which future rates are set.

e) CMS should not adopt an equitable adjustment for any drugs or biologicals for 2007.

We support the continuation of a market-based reimbursement policy using the ASP-based methodology for all therapies that CHI believes this is in line with Congress's intent in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). CMS' decision not to include a proposal to adjust payment for one drug or biological based on another drug or biological will let the market, not arbitrary government price setting, decide the most

[15] 71 Fed. Reg. at 49582.
[16] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006.

suitable payment for therapies. We commend CMS for this decision and encourage CMS to not impose an equitable adjustment to any drug or biological products in the final rule.

f) CMS should continue to use the 2006 methodology for the payment of radiopharmaceuticals.

CHI urges CMS to continue to use the methodology it implemented in 2006 to allow the agency to continue to collect data that incorporate all of the costs of supplying vital radiopharmaceutical therapies.[17] CHI believes that CMS' proposal to establish prospective payment rates for radiopharmaceuticals using mean costs derived from calendar year 2005 claims data through the application of hospital-specific departmental cost-to-charge ratios is deeply flawed. Specifically, this methodology will establish reimbursement rates that are below acquisition cost, impede CMS' ability to establish more suitable rates going forward, and ultimately undermine the availability of therapeutic radiopharmaceticals to patients .

For example, the proposed reimbursement method will result in significant reductions in payment for therapeutic radiopharmaceuticals, such as Zevalin®. The proposed 2007 rate for Y-90 Zevalin® is $12,130.20, a 42 percent reduction from the 2005 level of $20,948.25, and 38 percent less than the average purchase price reported by the Government Accountability Office in 2005. Similarly, the proposed movement of these therapies from new technology APCs to clinical APCs will decrease their reimbursement substantially. Taken together, these reductions will hamper hospitals' ability to continue to offer such therapies to beneficiaries.

CHI believes that CMS' proposed methodology for radiopharmaceuticals shares the same flaws as the proposed methodology for drugs and biologicals and would create inaccurate payments for the same reasons. We understand CMS' interest in using consistent methodologies across the OPPS, we urge the agency not to value consistency over accuracy. Rather than basing payments on mean charges reduced to cost, failing to include all of the costs of providing a therapy, CMS should continue to use the methodology it implemented in 2006 until it can collect more accurate claims data. The claims data CMS proposes to use to set the 2007 rates do not include the full costs of providing therapeutic radiopharmaceuticals using data from prior years because, as noted in the 2006 OPPS comments and in the June 2005 MedPAC report, hospitals did not accurately or uniformly report their overhead costs.[18] CMS issued instructions in the 2006 OPPS final rule for hospitals to include all charges associated with providing radiopharmaceuticals.[19] The agency should wait until hospitals have been able to implement this guidance and the agency has collected data for at least one year before using claims data to set payment rates. We agree with the APC Panel recommendation for CMS to continue to use the 2006 methodology.[20]

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[17] 70 Fed. Reg. at 68653.
[18] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.
[19] 70 Fed. Reg. at 68653.
[20] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006.

B. CMS should clarify the payment rates that will apply to drugs and biologicals with pass-through status that are covered under the Competitive Acquisition Program. [Pass-Through Drugs]

CMS proposes to continue to reimburse pass-through drugs and biological products at ASP plus six percent with one exception—drugs that also are included in the Competitive Acquisition Program (CAP) will be reimbursed at the CAP rate.[21] According to CMS, there are two drugs and biologicals covered under the CAP with pass-through status, and these drugs will be reimbursed at the "amounts determined under the competitive acquisition program."[22] We ask CMS to clarify that it will base payment for these therapies not the aggregate payment for all drugs covered under the CAP, but on their individual payment rates under the CAP, as required by the statute.

C. CMS should finalize its proposed new APCs for drug administration, implement the APC Panel's recommendations regarding drug administration services, and continue to make payments for preadministration-related services for IVIG. [OPPS Drug Administration]

CHI appreciates CMS' efforts to establish more appropriate payment for drug administration services. CMS proposes to create six new APCs for drug administration services and to make separate payment for additional hours of drug administration services. CHI believes that these changes, in addition to the new rates CMS has proposed based on more precise coding, will enhance the adequacy of Medicare's payments for administration of advanced drugs and biologicals.

In addition to CMS' proposed changes, we support the APC Panel's recommendation to make payment for a second or subsequent intravenous push of the same drug.[23] Under the current coding guidance and the proposed new drug administration APCs, CMS will make payment for a second or subsequent intravenous push only if it is used to administer a different drug. CHI believes this policy fails to recognize that the second push requires the same amount of work and resources as the first. Moreover, if payment for the drug is packaged, the hospital is not reimbursed for the second push nor is it reimbursed for the additional dose of the drug. CMS could ensure appropriate reimbursement for second and subsequent pushes by (1) implementing another methodology in CY 2007, (2) developing a new HCPCS code for the procedure, or (3) instituting a modifier. When combined with making separate payment for all drugs with HCPCS codes, implementing the APC Panel's recommendation also will promote appropriate hospital reimbursement for all drugs and biologicals and their administration services.

CHI also supports the APC Panel's recommendation that CMS provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions,

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[21] 71 Fed. Reg. at 49580.
[22] Id. at 49581.
[23] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006.

regardless of the setting. The Current Procedural Terminology's[24] (CPT's) instructions direct providers not to report injection or infusion codes with codes for which an IV push or infusion is an inherent part of the procedure, such as administration of contrast material for an imaging study. Because these instructions are not clear, hospitals might not report a drug administration code in many situations where it would be appropriate to do so. Allowing payment for drug administration services in all settings and clarifying the coding guidance will help hospitals code appropriately for all services and help to set more accurate payment rates in the future.

Additionally, CHI supports the APC Panel's recommendation to allow hospitals to be paid using first hour codes when both a hydration infusion and a non-chemotherapy infusion are provided in the same visit.[25] Under the OPPS, CMS currently has a single payment code assigned to the first hour of a therapeutic or diagnostic infusion. In 2006, CMS issued guidance to allow hospitals to report a first hour for each different type of infusion when the infusions can be reported using different codes, and they meet the requirements for billing an hour of each type of infusion.[26] Under the Proposed Rule, if a hospital provides an hour of therapeutic, non-chemotherapy infusion and an hour of hydration infusions, the first hour would be paid using code C8950, assigned to APC 440, and the second hour would be paid using code C8951, assigned to APC 437. To ensure that hospitals are properly reimbursed for therapeutic infusions and hydration infusions, we ask CMS allow hospitals to be paid using first hour codes when both a hydration infusion and a non-chemotherapy infusion are provided in the same visit.

In addition, we ask CMS clarify its guidance on coding and payment for drug administration services under the OPPS. Currently, guidance to hospitals indicates that "hospitals are to report chemotherapy drug administration HCPCS codes when providing non-radionuclide anti-neoplastic drugs to treat cancer and when administering non-radionuclide anti-neoplastic drugs, anti-neoplastic agents, monoclonal antibody agents, and biologic response modifiers for treatment of noncancer diagnoses."[27] We appreciate this instruction, which is consistent with the CPT's guidance for the chemotherapy codes used in physician offices. We recommend, however, that CMS clarify that it also applies to standard and specialty IVIG and DNA or RNA based therapies because these therapies are biologic response modifiers, and thus their administration should be billed using C8954, not C8950, the code for non-chemotherapy intravenous infusion for therapy or diagnosis.

Similarly, we urge CMS to continue to make payment for preadministration-related services for IVIG. As you know, recent changes to Medicare's payment methodologies for drugs and biologicals have raised concerns over beneficiary access to IVIG. CHI believes CMS recognized the unique aspects of this therapy and its importance to Medicare beneficiaries, by

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[24] Current Procedural Terminology, or CPT, is a trademark of the American Medical Association.

[25] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006.

[26] January 2006 Update of Hospital Outpatient Prospective Payment System Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, Dec. 16, 2005 (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

[27] Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2.2).

establishing a $75 payment for preadministration-related services for IVIG in last year's OPPS final rule. Regrettably, CMS proposes to eliminate this payment for 2007. CHI believes the elimination of this payment would be a major step backward. All of the costs that that hospitals incur related to IVIG that CMS identified last year will continue to be incurred next year, and CMS offers no evidence that these costs would not continue. Accordingly, CHI believes these costs should continue to be reimbursed.

III. CONCLUSION

CHI appreciates the opportunity to offer these comments. We look forward to working with CMS on these and other issues of concern in the future. If you have any questions or would like to discuss these ideas further, please contact Todd Gillenwater at 858-551-6677.

Respectfully submitted,

David L. Gollaher, Ph.D.
President and CEO

Submitter : **Hadley C. Ford** **Date: 10/10/2006**

Organization : **ProCure Treatment Center Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-443-Attach-1.PDF

#443

ProCure
TREATMENT CENTERS, INC.

October 9, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year. These positive clinical results also indicate a marked reduction in normal tissue damage and resulting co-morbidities thereby reducing short and long term complications and cost.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

444 Park Avenue South New York, NY 10016-7321 212-584-0960 - Tel

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	—	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules. This is of paramount concern to ProCure Treatment Centers as this company has invested significant resources to increase the availability of this important technology, and is actively preparing to expand to multiple states. It is very important that this technology is appropriately applied and equally important that the technology be properly and consistently reimbursed be it a freestanding and or hospital based facility.

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients. Over time Proton Therapy has been carefully evaluated and reviewed in the Academic setting, and now as is the classic free market approach, the technology is being embraced in the mainstream clinical setting and programs are developing bringing not only the clinical benefits, but significant economic benefits to the communities in the form of jobs, and investment.

We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

CONCLUSIONS

In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.

Also, we strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates are made in a consistent manner with those in effect for Hospital Outpatient Departments.

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

ProCure Treatment Centers has carefully approached this technology with an interest in making it available for appropriate use within the cancer treatment milieu. It is clearly a technology that has demonstrated clinical and financial efficacy, it is in demand by clinicians and patients, and it has reached the stage where free market principles will support the development of these important programs. It is very important that the CMS system not create undue penalties based upon organizational structure. Free standing and/or hospital-based programs have markedly similar cost and operational structures and as this letter has outlined fair and balanced reimbursement is important for the appropriate development of this technology and the clinical benefit it will have on patients.

Sincerely,

Hadley C Ford
Chief Executive Officer

444 Park Avenue South New York, NY 10016-7321 212-584-0960 - Tel

Submitter : Mr. Michael Hill **Date:** 10/10/2006

Organization : New Hampshire Hospital Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-444-Attach-1.DOC

#4411

New Hampshire Hospital Association

October 9, 2006

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

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

Dear Dr. McClellan:

On behalf of the New Hampshire Hospital Association (NHHA), with its 26 acute care hospital members, we appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (PPS) for calendar year (CY) 2007. The rule also includes proposals on inpatient quality reporting for fiscal year (FY) 2008, ambulatory surgical center (ASC) payments for 2007 and 2008 and Medicare Administrative Contractors.

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

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

125 Airport Road Concord, NH 03301-7300 603.225.0900 Fax: 603.225.4346 http://www.nhha.org

The proposed rule contains several significant policy changes in the outpatient PPS and in other areas of Medicare policy. We will address the 2008 policy and payment changes for ASCs in a separate comment letter that will be sent prior to CMS' November 6 deadline.

LINKING INPATIENT QUALITY DATA REPORTING TO OUTPATIENT PPS UPDATE

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

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

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

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

FY 2008 INPATIENT QUALITY MEASURES

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

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

HOSPITAL CLINIC AND ED VISIT CODING

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

The NHHA appreciates the opportunity to comment. The attached detailed comments expand on the points raised above and also on several other important proposals in the rule. If you have questions, please feel free to contact me or Paula Minnehan, VP, Finance and Rural Hospitals, at (603) 225-0900.

Sincerely,

Mike Hill

Michael Hill
President

Submitter : **Ms. Patricia Aiken-O'Neill** **Date: 10/10/2006**

Organization : **Eye Bank Association of America**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

October 10, 2006

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1506-P; CMS-4125-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Ambulatory Surgical Center List of Covered Procedures; Ambulatory Surgical Center Payments System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient PPS Annual Payment Update Program HCAHPS Survey, SCIP, and Mortality)

[Comment: Table of Contents Section XV: Proposed OPPS Payment Status and Comment Indicators.
A. Proposed CY 2007 Status Indicator Definitions, 2. Proposed Payment Status Indicators to Designate Services that Are Paid under a Payment System other than OPPS.]

Dear Administrator McClellan:

On behalf of our more than 83 member eye bank organizations, the Eye Bank Association of America (EBAA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule which addresses payment policy and rates for services performed pursuant to the hospital outpatient prospective payment system for calendar year 2007. The adoption and implementation of an appropriate payment policy for the acquisition of corneal tissue for procedures provided in a hospital outpatient department (HOPD) setting is absolutely vital to the eye banking system, a network that was established for the single purpose of procuring and providing donated human eye tissue for sight restoring transplantation procedures.

The 83 eye bank members of the EBAA represent 99% of the entire U.S. eye banking community and provide 97% of all corneal tissue for transplantation. All eye banks are 501 (c)(3) organizations. The community supports the CMS proposal to pay for the acquisition of corneal tissue as a separate payment at reasonable cost, not payable under the Outpatient Prospective Payment System as outlined in Section XV, Proposed OPPS Payment Status and Comment Indicator, A. (2). Proposed Payment Status Indicators to Designate Services that Are Paid Under a Payment System Other than OPPS. Addendum D1 defines the acquisition of corneal tissue as Status Indicator F as an item/service not paid under OPPS and paid at reasonable cost.

This payment policy remains unchanged from the previous years as set forth in the April 7, 2000 final rule with comment period, which implemented OPPS. The factors included in the development of the payment policy for the acquisition of corneal tissue remain unchanged. The current payment system recognizes significant charitable contributions and allows for a successful community-based donation network.

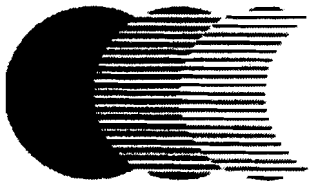
In sum, the EBAA appreciates CMS payment direction for this service and categorization. We seek consistency in the adoption and implementation of payment policy for the acquisition of corneal tissue between providers in a Hospital Outpatient Department setting and an Ambulatory Surgical Center setting. The EBAA will provide further comment on the Ambulatory Surgical Center provisions by the November 6, 2006 Comment Close date.

Again, thank you for your direction and consistency in payment policy for this important public health service.

Sincerely,

Patricia Aiken-O Neill
President

CMS-1506-P-445-Attach-1.DOC



EYE BANK ASSOCIATION of AMERICA

Via CMS Website

October 10, 2006

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1506-P; CMS-4125-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Ambulatory Surgical Center List of Covered Procedures; Ambulatory Surgical Center Payments System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient PPS Annual Payment Update Program—HCAHPS Survey, SCIP, and Mortality)

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In sum, the EBAA appreciates CMS' payment direction for this service and categorization. We seek consistency in the adoption and implementation of payment policy for the acquisition of corneal tissue between providers in a Hospital Outpatient Department setting and an Ambulatory Surgical Center setting. The EBAA will provide further comment on the Ambulatory Surgical Center provisions by the November 6, 2006 Comment Close date.

Again, thank you for your direction and consistency in payment policy for this important public health service.

Sincerely,

Patricia Aiken-O'Neill
President

Submitter : Mr. Daniel E. Smith **Date:** 10/10/2006

Organization : American Cancer Society

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-446-Attach-1.DOC

October 10, 2006

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

RE: CMS-1506-P: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of the American Cancer Society ("the Society") and its millions of volunteers and supporters, we respectfully submit the following comments for your consideration regarding the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Outpatient Prospective Payment System (HOPPS) and calendar year (CY) 2007 payment rates, CMS-1506-P, as published in the Federal Register on August 23, 2006.

As the nationwide voluntary health organization committed to eliminating cancer as a major health problem, the American Cancer Society has a particular interest in ensuring that our nation's seniors have access to high quality cancer prevention, early detection, and treatment tools through the Medicare program. As you may know, cancer is a disease that disproportionately affects the elderly-according to the Society's 2006 Facts & Figures, more than 60% of all new cancer diagnoses occur in this population. Given the importance of hospital outpatient services to cancer patients, the Society appreciates the opportunity to provide you with comments on the proposed HOPPS rule.

Proposed Hospital OPPS Changes

Radiology Procedures

The Society is pleased that CMS has decided to continue to defer for CY 2007 implementation of a multiple imaging procedure payment reduction policy. The Society expressed its concerns regarding CMS' previous proposal to make a 50% reduction in HOPPS payments for some second and subsequent imaging procedures during the comment period for the 2006 proposed HOPPS rule. Cancer patients frequently use imaging procedures both in terms of staging their disease but also to monitor the efficacy of cancer treatment. The Society believes CMS' decision

will preserve access for cancer patients for appropriate and necessary imaging services involving contiguous areas of the body.

Special Packaging Rule for Certain Anti-emetics

The Society is also pleased that CMS will continue the policy it adopted in 2005 of exempting the oral and injectible 5HT3 anti-emetic products from the packaging rule, thereby making separate payment for all of the 5HT3 anti-emetic products.

As CMS is aware, chemotherapy is difficult for many patients to tolerate because the side effects are often debilitating. Anti-emetic use is often an integral part of the treatment regimen, allowing cancer patients to achieve the maximum therapeutic benefit from chemotherapy while helping to control side effects such as nausea and vomiting. Separate payment for anti-emetic products helps ensure that these vital therapies are available for the beneficiaries who need them.

Proposed Payment for Specified Covered Outpatient Drugs

The Society is concerned that CMS is proposing to pay average sales price (ASP) + 5% for drugs and biologicals without pass-through status and that are not packaged. This is a reduction from CY 2006's payment rate of ASP + 6% for these drugs. While CMS has indicated that it believes this amount is sufficient to cover drug acquisition as well as overhead and handling costs, the Society is concerned that CMS is basing its conclusion on analysis of claims data, despite studies from both the GAO and MedPac which indicate that such data are inadequate as a basis for setting payment rates. If hospitals cannot in fact obtain their cancer drugs at or below these reimbursement rates for their cancer patients, they may be forced to reduce their services to cancer patients or incur substantial additional costs. Furthermore, the Society has concerns that the proposed reduction in drug reimbursement may set a precedent for a similar reduction in drug reimbursement for physicians and other providers. The Society asks that CMS carefully monitor the impact of this provision on cancer patients' access to care.

Proposed Payment Changes for Radiopharmaceuticals

Currently, CMS pays for radiopharmaceutical agents that are separately payable based on a hospital's charge for each radiopharmaceutical agent adjusted to cost using the hospital's cost-to-charge ratio (CCR). For CY 2007, CMS is proposing to base prospectively determined payment amounts on average costs for all hospitals as determined from 2005 claims data. The Society is concerned that reimbursement for some radiopharmaceuticals may be substantially reduced under this new methodology, thus creating a hardship for cancer patients who must be assured access to these life-saving treatments. In particular, radioimmunotherapy for non-Hodgkin's lymphoma utilizes two expensive radiopharmaceuticals, Bexxar and Zevalin. Reductions in reimbursement under CMS' proposed rule for these agents is projected to be as high as 50%. The Society urges CMS to consider whether a special payment methodology could be implemented to avoid drastic reductions in reimbursement for these radiopharmaceuticals.

Conclusion

The proposed HOPPS rule has the potential to affect millions of Medicare beneficiaries diagnosed and living with cancer. We appreciate the hard work that you and your agency have put into implementing the many provisions of this proposed rule. We want to take this opportunity to thank you for all your hard work and dedication in the implementation of the many regulations, demonstration programs, projects, and policies that had and will continue to have a tremendous impact on patients diagnosed and living with cancer. It was a pleasure working with you and the Society stands ready to work with the incoming Acting Administrator to meet our mutual goals of improving the health of and reducing the cancer burden among Medicare beneficiaries.

Sincerely,

Daniel E. Smith
National Vice President
Federal and State Government Relations

Wendy K. D. Selig
Vice President
Legislative Affairs

National Government Relations Office
901 E Street, NW, Suite 500 Washington, DC 20004 t) 202.661.5700 f) 202.661.5750

Submitter : **Mr. Ebbie Erzuah** **Date: 10/10/2006**

Organization : **Sparrow Health System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. William Flynn **Date:** 10/10/2006

Organization : Addition Technology, Inc.

Category : Device Industry

Issue Areas/Comments

OPPS

OPPS

See attachment under file name CMS 1506 P (Addition Technology)

CMS-1506-P-448-Attach-1.DOC

#446

Intacs®

By Electronic Submission

October 10, 2006

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-1506-P

Dear Dr. McClellan:

Addition Technology, Inc. ("ATI") would like to thank you for the opportunity to comment on the Proposed Rule CMS-1506-P, "The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule"[1] and the proposed payment of keratoprosthesis procedures performed using the AlphaCor™ prosthetic cornea. As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

At the outset we wish to commend and thank the members of the hospital outpatient PPS team with whom we have been working. Throughout this process we have felt that these individuals have given their time and attention to the problematic circumstances surrounding this procedure.

We are deeply concerned that CMS' proposal to reimburse hospitals at a payment rate of $3,116.62 for performing an integrated keratoprosthesis will impair Medicare Beneficiaries access to this last resort treatment. Hospitals will find it financially impossible to continue to offer the procedure at this grossly inadequate payment rate. In fact, we are aware of several hospitals who are no longer performing the procedures because the current Medicare reimbursement is insufficient to cover the costs.

At the August 2006 meeting of the Ambulatory Payment Classification Panel (the "Panel") it was recommended that CMS develop a separate payment methodology that will reimburse hospitals an appropriate amount for the AlphaCor. The Panel also expressed its desire to ensure this treatment is available to Medicare beneficiaries. We urge CMS to accept the recommendation of the Panel and appropriately pay for integrated keratoprosthesis so that access to this critical procedure can be preserved in 2007 and beyond.

Addition Technology, Inc.
A VMG LLC Investment Company

950 N. Lee Street, Suite 210, Des Plaines, IL 60016
Main: (847) 297-8419 - Fax: (847) 297-8678

155 Moffett Park Drive, Suite B-1, Sunnyvale, CA 94089
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[1] 71 *Fed. Reg.* 49504 (Aug. 23, 2006).

I. CMS should ensure that Medicare beneficiaries continue to have access to integrated keratoprosthesis

A. Integrated keratoprosthesis is a last resort treatment option for a limited patient population

AlphaCor was cleared by the FDA in 2002 and designed to replace a scarred or diseased native cornea. It is the only technology available today that is a flexible, bio-integratable, one piece synthetic cornea made of poly-HEMA, with a 7.0 mm diameter. AlphaCor is implanted directly into the corneal pocket dissected by a surgeon and the surgeon sutures the incision. No corneal donor tissue is used. The device bio-integrates over the three to six months following surgery and in some cases, the patient's cornea above the AlphaCor is removed once the AlphaCor device stabilizes.

While the majority of Medicare beneficiaries are successfully treated with a standard corneal transplant procedure, keratoprosthesis implantation using AlphaCor provides a critical treatment option for those patients who are not candidates for a corneal transplant procedure. Keratoprosthesis is a last resort procedure for those patients with corneal opacity not suitable for standard penetrating keratoplasty with donor tissue, who have rejected donor tissue or where adjunctive measures required to prevent graft rejection are medically contraindicated. Left untreated, these Medicare beneficiaries likely will become blind.

In 2005, only 78 procedures using AlphaCor were performed. The number of Medicare beneficiaries who received AlphaCor is a smaller patient sub-set of this total. Because this technology is intended for a very limited patient population, there is no risk of over-utilization.

B. Unless there is a fair and adequate reimbursement for this innovative treatment, hospitals will not be able to offer this procedure to Medicare beneficiaries

We are deeply concerned that CMS's proposal to reimburse providers at a payment rate of $3,116.62 will impair Medicare Beneficiaries access to this last resort treatment. This reimbursement rate is clearly inadequate when it does not even cover the cost of the device, which is approximately $7,000. In fact, we are aware of several hospitals who are no longer performing the procedure because the current Medicare reimbursement is insufficient. As a result, Medicare beneficiaries and physicians will have no choice but to turn to ASCs for this procedure. Furthermore, some ASCs are currently refusing to perform the procedure because some Carrier Medical Directors' gap-filling methodology results in a payment that is less than invoice cost for the device. Lastly,, access through ASCs will become essentially non-existent in 2008 if the new ASC payment methodology is implemented as proposed and the APC payment for this procedure is not corrected.

II. CMS should not use its unreliable 2005 claims data to set the payment rate for APC 0293

A. Coding Confusion

The claims data used to set the payment rate APC 0293 does not accurately reflect the costs of performing keratoprosthesis. ATI engaged The Moran Company to analyze the 2004 and 2005 OPPS data for APC 0293 and simulate the mean for the APC 0293 using only single claims that contained both CPT Codes 65770 and C1818. The following chart provides an overview of the payment history for CPT Code 65770:

	2005	2006	2007 Proposed
APC	0244	0244	0293
Payment Rate	$2,262.17	$2,275.16	$3,116.62
Median	$2,379.46	$3,617.49	$3,127.51
Mean	$2,388.72	$4,271.67	$4,331.44
Total Frequency	94	145	140
"Singles" Frequency	22	42	41

Only 41 single procedure claims listing CPT 65770 were used to determine the median cost for APC 0293. Of these 41 claims, only six claims also properly reported C1818. Thus, CMS included 35 claims in its rate-setting for APC 0293 that reported CPT 65770 without any other procedure code or C1818. CPT code 65770 describes a procedure that requires a prosthetic cornea, yet the overwhelming majority of the claims used to calculate payment for this procedure did not contain the code for the prosthetic device (C1818). Every integrated keratoprosthesis procedure using the AlphaCor device should be reported using both CPT Code 65770 (keratoprosthesis) to describe the procedure and C1818 (integrated keratoprosthesis) to report the AlphaCor device. While there is one other artificial cornea used today, it is not described by C1818 because it is not a single piece device, it is not bio-integratable, and it requires human donor tissue to attach to the recipient.

Hospital confusion regarding the appropriate use of C1818 is illustrated further by the fact that the 2005 claims data included claims with C1818 billed with CPT Code 66180 (implant eye shunt), CPT Code 65710 (corneal transplant) and CPT Code 66984 (cataract surgery) but without CPT Code 65770. These claims are clearly erroneous because none of these procedures require an artificial cornea. In other cases, hospitals are reporting CPT Code 65770 with other 6xxxx procedures without C1818. In the 2005 claims data, there are 69 claims that listed CPT Code 65770 but did not list C1818.

B. Median costs/charges understate the resources expended to perform keratoprosthesis

The 2005 claims data used to set the median cost for APC 0293 also does not accurately reflect all the costs to furnish keratoprosthesis. The Median cost of $3,127.51 does not cover the cost of the device (approximately $7,000).

The claims data shows that hospitals' billing practices are inconsistent and hospitals are not accurately reporting the cost of performing keratoprosthesis. This is illustrated by the fact that only two of the 17 hospitals known to have purchased AlphaCor in 2005 submitted claims to Medicare containing both C1818 and 65770. One hospital has a charge of $2,129 for the procedure, and the other claim had a charge of $8,182. Clearly the charges cannot be accurate when the device alone costs approximately $7,000 and neither ATI nor the predecessor company that sold AlphaCor has charged a rate for the device that was outside of this range. Given that so few devices are sold, they are not discounted in any way.

C. A programming error involving the rate setting methodology used to set the proposed payment rate for 2007 incorrectly excluded costs associated with C1818

An error in the data file used to calculate the median for integrated keratoprosthesis may also have added to the significantly low payment rate for keratoprosthesis with the AlphaCor. CMS's published median for APC 0293 was $3,127.51. Yet, when Moran simulated the median for the

single claims correctly coded with CPT Codes 65770 and C1818, it calculated a much higher median of $10,514.

During the course of Moran's analysis, they noticed a significant methodology problem in rate setting APC 0293. When Moran first attempted to run their simulation for the subset of correctly coded single claims including both CPT Codes 65770 and C1818, their replication program produced zero claims with both codes.

Upon investigation, Moran discovered because the C1818 had a status indicator of "H" in 2005, it was not counted in the packaged costs of the single claims using the 2007 single claim methodology which based selection of packaged items on status indicator "N". During the process of developing the Moran replication program for 2007 OPPS rates, Moran asked CMS staff which file of status indicators was used to identify single claims and packaged items. In response to this inquiry, CMS responded that the Moran should use a particular 2005 file—the file in which C1818 had status indicator "H". Accordingly, we believe that the costs associated with C1818 may have been excluded from the packaging. This error may be the cause, at least in part, for the extremely low median for APC 0293. We urge CMS to review their payment methodology for APC 0293 and the impact this potential error may have had on the proposed payment rate for this procedure.

III. CMS should accept the August 2006 APC Panel's recommendation to develop a payment methodology that would provide for an appropriate payment rate for keratoprosthesis

CMS has previously recognized that coding and billing errors can lead to significant variability in median calculations for low-incidence procedures. When this has occurred, CMS has created alternative methodologies to determine a fair payment for certain low-volume procedures. For example, CMS created a low-volume adjustment methodology for blood products because the claims data may have not captured the complete costs of the products due to coding and billing errors. This is precisely what has occurred for integrated keratoprosthesis. We urge CMS to make similar accommodations for keratoprosthesis. When the erroneous claims are excluded, the single claims that accurately report CPT Codes 65770 and C1818 have a median cost of $10,514. This simulated median more accurately captures the costs of keratoprosthesis procedure and the device.

Given the extensive coding errors associated with this procedure, the inconsistent cost and charge data, and the additional confusion created by the possible billing of an incorrect device under the C1818, there is a significant need to implement a process to ensure CMS is receiving accurate data about keratoprosthesis with the AlphaCor. Assuming the error identified by Moran is accurate, CMS could, in the short-term (i.e., for 2007), set the median based on the few claims with the procedure correctly coded and that seem to have reported realistic costs and charges. This median would be assigned to APC 0293. The problem with this methodology, however, is that it does not address the long-term coding problems created by the inappropriate use of C1818 by devices that are not described by the code.

Alternatively, CMS could take a longer-term approach aimed at collecting clean data about integrated keratoprosthesis procedures with the AlphaCor (and the devices similar to AlphaCor that are expected to marketed in the near future) as well as data regarding the procedures involving the other technology. The collection of meaningful data would require CMS to develop two G codes. One G code would describe the procedure when performed with an integrated cornea that does not require human tissue. The other G code would be reserved for

the other technology. We recommend that CMS consider creating the following two G Code descriptors:

- **G code #1 = Keratoprosthesis with implantation of integrated artificial cornea, no donor cornea tissue required**

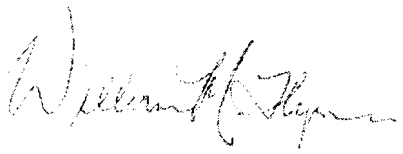
- **G code #2 = Keratoprosthesis with insertion of artificial cornea requiring use of donor cornea tissue**

Next, CMS would have to include an edit that required that C1818 always appear with G code #1. This code should be assigned to New Technology APC 1574 for 2007. G code #2 could be assigned to the newly created APC 0293. An edit could be created that did not accept claims containing this G code and C1818. Assuming that hospitals are educated regarding the coding differences, which ATI has agreed to do, then over the next 2 to 3 years CMS should have reliable data from which to set payment rates.

ATI would a gain like to thank CMS for the opportunity to submit formal comments on the Proposed Rule. We urge CMS to adopt the recommendation of the APC Panel to develop a payment methodology that will ensure that hospitals are adequately reimbursed for providing keratoprosthesis with the AlphaCor that Medicare beneficiaries continue to have access to this innovative, last resort treatment option.

Thank you for your careful consideration to this matter.

Sincerely,



William Flynn
President & CEO

Submitter : Mrs. Gayle Hughes **Date:** 10/10/2006

Organization : St. Vincent Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-449-Attach-1.DOC

#449

October 9, 2006

In Reply to: CMS 4125-P and 1506-P

Centers for Medicare & Medicaid Services

Proposed Changes to payments for Outpatient Services

St. Vincent Health System is committed to providing Quality outcomes for our patients and currently publicly report our quality data. The current process is costly, the data definitions change quarterly, and the validation process is difficult to work with. The current measures that we collect increase every year. Payments are based on the validation of the measures; thus, we must absolutely ensure the CDAC interprets the data as we have.

As you formalize the new proposal regarding the OPPS rule, please consider hospitals are still attempting to master the original inpatient measures; when this task has been mastered would be the most appropriate time to add outpatient quality indicators and the indicators should be added for **all** at the same time; currently Ambulatory Surgical Centers do not have to meet this requirement.

The definition for inpatient measures should be narrowed to a simple approach for interpretation of meaning before adding outpatient quality indicators.

The additional measures for outpatient will heavily burden hospitals requiring additional staff to collect the measures and improve on the data collected with no additional payment incentive.

Finally, the proposal also states, the current indicator for pneumonia and influenza is acceptable for an outpatient. This in incorrect for the vaccination status is assessed in the ED; however, we question the appropriateness to vaccinate a patient with acute pneumonia in the ED. The current quality indicators ask about assessment and vaccination and not just if they were assessed as the proposal reflects.

Thank you for the opportunity to comment on this initiative and we sincerely hope you will take our recommendations into consideration.

Respectively submitted,

Submitter : **Date: 10/10/2006**

Organization :

Category : **Hospital**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

"see attached" letter from the Medical University of South Carolina

CMS-1506-P-450-Attach-1.DOC

#450

MUSC
MEDICAL UNIVERSITY
OF SOUTH CAROLINA

Revenue Systems Department
1005 Harborview Towers
19 Hagood Avenue
Charleston, SC 29425

10th October, 2006

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

We appreciate the opportunity to provide comments on CMS-1506-P. We would like to highlight the severe negative impact these proposed rates will have on breast conservation therapy. We have two major areas of concern in the HOPPS proposed rule: 1) the proposed assignment of 19296 and 19297 to new APCs and 2) the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007.

The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in less than acceptable decreases in 2007 payment. The table below illustrates the proposed reductions, ranging from -22.8% to -37.0%

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	-22.8%
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	-37.0%

Should CMS finalize the proposed APC assignments, we will not be able to offer this breast cancer treatment option to Medicare eligible women. The cost of the device will surpass the proposed payment rate.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned to must cover the cost of the device. Of note, the cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Additionally, our hospital purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is ***extremely important*** that CMS continue with the current "cost to charge ratio payment methodology" in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In closing, The Medical University of South Carolina (MUSC) recommends that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow CMS the opportunity to collect additional claims data. Additionally, MUSC recommends that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Respectfully,

Reece Hamilton

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Ms. Cathleen O'Keefe** **Date: 10/10/2006**

Organization : **Fresenius Medical Care**

Category : **End-Stage Renal Disease Facility**

Issue Areas/Comments

GENERAL

GENERAL

See attachments

CMS-1506-P-451-Attach-1.PDF

#451

Fresenius Medical Care

October 9, 2006

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4125-P, Proposed Rule to the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List; and the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Administrator McClellan:

US Vascular Access Holdings, LLC (USVA), a division of Fresenius Medical Care North America, is pleased to submit these comments to the above referenced Proposed Rule that was published in the *Federal Register* on August 23, 2006. Specifically, USVA urges CMS to include CPT code 35475 (Transluminal Balloon Angioplasty, brachiocephalic trunk or branches, each vessel) in the list of ASC eligible services effective January 1, 2007, and also in the ASC approved list subject to the revised payment system, effective January 1, 2008.

I. Background

In its November 2004 proposed rule, CMS recommended additions and deletions to the list of services appropriate to the Ambulatory Surgical Center (ASC) setting, and added CPT codes 35475 (arterial angioplasty) and 35476 (venous angioplasty) to the list. The Final Rule, published on May 4, 2005, removed both CPT codes 35475 and 35476 from the list stating the Agency had received "a single comment" opposing the additions of CPT codes 35475 and 35476 on the basis of a concern about "major vessel" involvement. CMS determined that "angioplasty codes are more appropriately limited to the hospital outpatient and inpatient settings at this time." In response to the Final Rule, CMS received a number additional comments objecting to the exclusion of 35476 and 35475, emphasizing the importance of these procedures in maintaining vascular access for patients on hemodialysis. Commenters included nephrologists, interventional nephrologists, vascular surgery centers, ASC trade organizations, the Society of Interventional Radiology, the Renal Physicians Association and the National Kidney Foundation.

In its recent 2007 Update to the Ambulatory Surgical Center Covered Procedure List, the Proposed Rule once again includes 35476, but excludes 35475, arterial angioplasty, citing that this procedure "did not meet required clinical criteria." CMS further clarified the exclusion of 35475 by listing this procedure as requiring an overnight stay. For reasons clarified in this correspondence, we urge CMS to reconsider this exclusion of CPT code 35475 from both the 2007 update and the revised ASC payment system, effective January 1, 2008.

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II. Long Definitions of Arterial Angioplasty Procedures

CMS lists thirteen CPT codes for arterial angioplasty procedures, all with a short description of "repair arterial blockage." The CPT long definitions of these procedures and the settings which CMS believes are most appropriate are as follows:

Approved for ASC in 2008

35473 Transluminal balloon angioplasty, percutaneous; iliac
35474 Transluminal balloon angioplasty, percutaneous; femoral-popliteal

Requires an Overnight Stay

35458 Transluminal balloon angioplasty, open; brachiocephalic trunk or branches, each vessel
35470 Transluminal balloon angioplasty, percutaneous; tibioperoneal trunk or branches, each vessel
35471 Transluminal balloon angioplasty, percutaneous; renal or visceral artery
35472 Transluminal balloon angioplasty, percutaneous; aortic
* 35475 Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel (procedure at issue in this comment)

Excluded from ASC because 80% are performed on inpatient basis

35459 Transluminal balloon angioplasty, open; tibioperoneal trunk and branches

Inpatient Only

35450 Transluminal balloon angioplasty, open; renal or other visceral artery
35452 Transluminal balloon angioplasty, open; aortic
35456 Transluminal balloon angioplasty, open; femoral-popliteal
35454 Transluminal balloon angioplasty, open; iliac

III. Current Situation With Regard to Vascular Access in Hemodialysis

The optimal treatment of patients receiving hemodialysis is dependent on access to their bloodstream, which is necessary for the conduct of the dialysis procedure, or on their "vascular access." In the US, hemodialysis vascular access failures, procedures and complications account for greater than 20% of hospitalizations for hemodialysis patients, resulting in over $1 billion per year in government expenditures.[1] The superiority of arteriovenous (AV) fistulas over AV grafts has been shown to significantly improve patency rates, lower complication and infection rates and lower mortality rates.[2] In view of these statistics, the National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF-DOQI) guidelines for vascular access recommend an aggressive approach to the creation of AV fisulas.[3]

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[1] Ilizler T, Himmelfarb J, Trials and trade-offs in hemodialysis vascular access monitoring. *Nephrology Dialysis Transplantation* 2006

[2] Beathard G, Interventionalist's Role in Identifying Candidates for Secondary Fistulas. *Seminars in Dialysis* – Vol 17, No 3 (May – June) 2004 pp.233-236

[3] National Kidney Foundation: NKF-K/DOQI clinical practice guidelines for vascular access guideline

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The guidelines propose that primary AV fistulas should be created in at least 50% of all new patients requiring hemodialysis, with a long-range goal of maintaining fistulas in 40% of eligible patients who remain on dialysis. In support of this goal, CMS is leading a national effort to increase the use of fistulas by creating, funding and overseeing the Fistula First quality initiative bringing together a project team that is working with major stakeholders, including dialysis providers, primary care physicians, nephrologists, vascular access surgeons, interventional radiologists/nephrologists, professional societies and patient advocacy groups.[4]

Because of the significance of vascular access to hemodialysis patients, interventional nephrologists commonly perform a variety of vascular access procedures, including angioplasty for venous stenosis, treatment of thrombsed vascular access (declotting), salvage of undeveloped AV fistulas, management of tunneled dialysis catheters and other related procedures. Transluminal balloon angioplasty of peripheral veins and arteries in the arm (35475, 35476) are common procedures to maintain the patency of AV fistulas for hemodialysis access. "Percutaneous balloon angioplasty has become a standard treatment for the management of arteriovenous dialysis access (graft and fistula) stenosis."[5]

IV. CMS Should Include CPT Code 35475 in the 2007 Update and the Revised ASC Payment System, Effective January 1, 2008

Determination of Procedures Requiring an Overnight Stay

The longstanding criterion for determining which procedures are appropriate for inclusion on the ASC list has been that the procedures do not require an extended recovery time. Under §416.65(b)(ii) CMS has historically considered procedures that require more than four hours of recovery time to be inappropriately performed in the ASC setting. More recently CMS has revised this assessment and has published the following guideline: "We are proposing to exclude from payment of an ASC facility fee any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure."

Patients undergoing a CPT code 35475 procedure do not fall within this category. It seems inconsistent, therefore, for CMS to cover two angioplasty procedures performed on diseased native iliac and femerol-popliteal arteries in the lower extremities in the ASC setting (35473, 35474), but determine that angioplasty of the anastomosis of a healthier but stenotic arterial portion of an AV fistula in an upper extremity would require an overnight stay and therefore be excluded from the list of covered procedures in the ASC setting.

Safety of Angioplasty Procedures

We contend that there are no greater significant safety concerns with CPT code 35475 (arterial angioplasty) procedures than with 35476 (venous angioplasty) procedures. We base this conclusion on the following:

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[4] www.cms.hhs.gov/ESRDQualityImproveInit/04_FistulaFirstBreakthrough.asp#TopOfPage

[5] Asif A, Merrill, D, Briones P, et al Inflow stenosis in arteriovenous fistulas and grafts: A multicenter, prospective study. *Kidney International*, Vol 67 (2005), pp. 1986-1992

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- CPT code 35475 is a procedure involving a peripheral blood vessel, not a "major vessel."
- This procedure is an inherently different procedure when performed on a vascular access of the upper extremity (where most AV fistulas are located) than it is in diseased vessels of the lower extremities.
- In angiography of an AV fistula, the physician accesses the anastamosis of a vein and an artery, and generally does not directly access the native arterial vessel alone, which is typical in angioplasty of vessels in the lower extremities.
- The vessels that are dilated during AV fistula angioplasty are inherently healthy, but have been affected by the anatomic vascular shunt. The lesions in an AV fistula are predominately due to fibrous hyperplasia as opposed to destructive artherosclerotic vessel disease. The risk of complication from a procedure performed on a healthy anastomosis of vein and artery with some degree of fibrous hyperplasia is far less than angioplasty of a native vessel in the lower extremity, which is likely to be diseased and artherosclerotic.
- CPT code 35475 is an approved procedure in the extension of practice and hospital outpatient settings.
- Most patients are discharged to home or to the dialysis clinic for treatment following percutaneous angioplasty of their AV fistula. There is no expectation that this procedure would require extensive post-procedure observation.

In addition, frequently the arterial angioplasty procedure of an AV fistula is performed in concert with venous angioplasty and possibly a thrombectomy. Decisions regarding which procedures are indicated are made by the interventional provider at the time the case is underway, and are not made in advance of fistula studies. Based upon radiological findings, the physician determines whether an arterial lesion at the anastomotic site requires dilatation. A requirement to perform angioplasty of the arterial lesions in AV fistulas in a separate setting from where the venous portion of the AV fistula is corrected will unnecessarily increase the cost of care and will inconvenience dialysis beneficiaries, as it would require them to undergo two separate procedures in perhaps two separate locations to fully resolve their vascular access problem.

Finally, the creation of the AV fistula is a covered procedure in the ASC setting (CPT code 36819), which furthers the goals of CMS's Fistula First quality initiative[6] to promote use of fistulas in larger percentage of dialysis patients. Non-approval of safe procedures to maintain the patency of the fistula in the same setting is inconsistent with these goals.

V. Conclusion

We applaud the Agency's decision to approve CPT code 35476 (venous angioplasty) in its 2007 Update to the Ambulatory Surgical Center Covered Procedure List. This is appropriate and will serve to benefit patients receiving chronic hemodialysis who rely on this procedure to maintain patency of their vascular access, which in turn allows them to maintain life via hemodialysis. However, the decision not to also include 35475 (arterial angioplasty) as a covered procedure in the ASC setting is inconsistent with decisions to approve procedures that, by their nature, carry a higher degree of risk (35473, 35474) and with the goals of a CMS ESRD quality initiative to promote use of AV fistulas in dialysis patients.

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[6] www.cms.hhs.gov/ESRDQualityImproveInit/04_FistulaFirstBreakthrough.asp#TopOfPage

Fresenius Medical Care

We strongly urge CMS to include CPT code 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel) specific to vascular access for hemodialysis as a covered procedure in the ASC setting effective January 1, 2007, and also in the ASC approved list subject to the revised payment system, effective January 1, 2008.

Fresenius Medical Care North America and US Vascular Holdings look forward to working with CMS to ensure that hemodialysis vascular access-related procedures that can safely and effectively be performed in the ASC are incorporated into the proposed reforms. Please do not hesitate to contact Kathleen Smith at 202-296-8632 if you have any comments or questions.

Sincerely,

Cathleen O'Keefe

Cathleen O'Keefe, RN, JD
Vice President - Regulatory and Government Affairs
Products and Hospital Group
Fresenius Medical Care North America

Submitter : Terese Ghio **Date:** 10/10/2006

Organization : Ligand Pharmaceuticals Incorporated

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1506-P-452-Attach-1.PDF

#1452

October 10, 2006 **By Electronic Delivery**

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

Re: CMS-1506-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule)

Dear Administrator McClellan:

Ligand Pharmaceuticals appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2007 payment rates, published in the Federal Register on August 23, 2006 (the "Proposed Rule").

Ligand is a San Diego based emerging specialty pharmaceutical company that discovers, develops and markets innovative small molecule drugs and one biological to address critical, unmet medical needs with four Orphan-designated products for oncology and dermatology: ONTAK (denileukin diftitox), TARGRETIN capsules (bexarotene), TARGRETIN gel and PANRETIN gel (alitretinoin), and AVINZA in the area of chronic pain management (morphine sulfate extended-release capsules).

One of Ligand's products, ONTAK, is a recombinant DNA-derived cytotoxic fusion protein that is covered by Medicare under Part B in both hospital outpatient setting and in the physician office. ONTAK received orphan designation from the FDA and is used to treat the limited population of patients with advanced stages of Cutaneous T-Cell Lymphoma (CTCL). This product and the patient population in services truly meet the intent of the legislature's definition of Orphan Product.

Lack of equitable Medicare reimbursement in the hospital outpatient setting and physician setting has historically had a negative impact on patient access to this product, which is for many patients the only option for this debilitating and sometimes deadly disease. Our research indicates that the historical reimbursement structure unfairly discriminated against many patients, including those patients in rural areas.

The transition over the past few years to equivalent reimbursement rates for both the hospital outpatient and physician office settings has partially solved the historical issue of reimbursement rates inappropriately manipulating the practice of medicine by influencing the site of service for products like Ontak that can be administered in either setting based on the specific medical need of the patient. The CMS proposal to cut reimbursement to ASP+5% in the outpatient setting will return us to inequitable and lopsided reimbursement between these two settings. Therefore, we urge CMS to at a minimum maintain equal payment between settings to minimize the influence that reimbursement has on the site of service.

In last years comments Ligand expressed concerns that reimbursement at ASP+6% may not be adequate to ensure beneficiary access. We continue to be concerned and we believe that reducing the payment further to ASP+5% will place additional burdens on hospitals and continue to impede access. For not only does CMS propose to reduce reimbursement for drugs and biologicals, but it also asserts that the proposed rates are sufficient to cover hospitals' pharmacy handling costs. We strongly disagree with this assertion. Pharmacy services can be complex and are labor and resource intensive, especially when working to safely and accurately deliver a complex biological product.

For example, Ontak is a very special product requiring very special handling at both the wholesaler and the hospital pharmacy or physician's office. ONTAK has some very unique requirements including:

a. Its treatment regimen: 3-5 vials/day for 5 days on a 21 day cycle. Therefore patients must usually begin treatment on a Monday. This requires very coordinated planning with the patient and the wholesaler to order the product for drop shipment on a Friday.
b. ONTAK is stored at our distributor at -80 degrees C and must remain frozen and shipped in special packaging to the site of administration who in turn must keep it frozen at -10 degrees C until just before use.
c. ONTAK has specific requirements in its label for solution preparation.
d. Patients typically require pre-medication with steroids (oral or IV) and extra intravenous hydration prior to treatment with ONTAK.
e. In addition, label warnings which require additional monitoring include Acute Hypersensitivity-type reaction (69% patients) and Vascular Leak Syndrome (27% patients). The latter of which can be delayed (usually in first two weeks) and require follow-up phone calls by staff to monitor.

In addition to the fact that the ASP+5% methodology is woefully inadequate for products like ONTAK, CMS should clearly respond to industry's repeated requests for clarifications to the procedures for calculation of ASP. This response should be in the form of a separate proposed rulemaking once CMS receives responses to its broad request for information in the physician fee rule proposal. Only then will industry be able to submit what they feel is accurate and consistent ASP data.

We urge CMS to monitor patient access and increase rates as necessary to ensure that Medicare beneficiaries retain access to critical therapies. This is especially important for

orphan products and for patients with rare disorders and special attention should be paid to the monitoring of access for these entities.

Ligand supports in full the comments submitted by the Biotechnology Industry Organization (BIO). We sincerely appreciate the opportunity to comment on these rules and the open and interactive approach CMS has taken with stakeholders across the medical and health care communities. Please contact me with any questions or to request additional information related to our products or ideas and positions on Medicare policy at 858-550-7569 or tghio@ligand.com.

Respectfully Submitted,

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