AMERICAN SOCIETY
OF ANESTHESIOLOGISTS

Office of Governmental Affairs
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November 7, 2006

Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-FC
Mail Stop C5-11-24
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: **CMS-1321-FC and CMS-1317F – Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Values, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B.**

Dear Ms Norwalk:

It has come to the American Society of Anesthesiologists' attention that the Centers for Medicare and Medicaid Services (CMS) used budget neutralized work relative value units (RVUs) in its calculation of practice expense relative value units published in CMS-1321-FC. This is contrary to the Agency's published intention to use the unadjusted work units (see page 87 of CMS-1321-FC as posted on the CMS website on November 1, 2006) and results in practice expense relative values that are lower than they should be. While anesthesia codes do not have procedure-specific work and practice expense RVUs, the error impacts anesthesiology because CMS calculated the practice expense share of the anesthesia conversion factor using work RVU proxies that had been subject to the budget neutrality adjustor.

We understand that AMA/Specialty Society RVS Update Committee (RUC) staff has alerted you to this error. It is essential that CMS not only publish the corrected practice expense values for codes subject to the RBRVS payment methodology, but also recalculate the anesthesia conversion factor using the correct values.

We appreciate your prompt attention to this matter.

Sincerely,

Mark J Lema

Mark J. Lema, MD, PhD
President

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LNRO
LAKE NORMAN RADIATION ONCOLOGY CENTER

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November 16, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
P.O. Box 8014
Baltimore, MD 21244-8014

Attention: Physician Fee Schedule Rule# CMS-1321-FC

Dear Administrator:

Thank you for allowing me to provide comments about the Centers for Medicare and Medicaid Services' final rule #CMS-1321-FC. I am troubled with the interim rates of reimbursement proposed for CPT 77372, SRS, linear based (intracranial, single fraction), 77373, SBRT delivery (body, 1-5 fractions), and CPT 77435, SBRT Management.

As you know, the cost of the equipment and related capital expenditures necessary to provide the stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) technologies referenced by these CPT codes is in excess of $4,000,000 per machine, and thus the proposed payments do not cover the cost of such services. The same equipment is applied in both the hospital outpatient and freestanding clinic settings, and thus the payments should be the same under both OPPS and Part B. The payment which CMS is proposing for CPT codes 77372 and 77373 will have a detrimental impact on the ability of Medicare patients to receive SRS and SBRT treatment options.

Similarly, the payment for SBRT management under CPT 77435 understates the significant amount of physician work applied in providing this technology, and thus the associated payment rate should also be revised, in order not to limit the application of this technology to Medicare patients.

Access to SRS and SBRT are critical, since they spare patients from invasive, more costly, and more dangerous surgical interventions. Since this technology is offered primarily on an outpatient basis, it more effectively applies limited CMS financial resources. The reimbursement rates proposed by CMS for this technology will not adequately cover the time and technical skill required to prepare and treat such patients, and thus CMS will be limiting access to this technology.

Accordingly, I urge CMS to increase the relevant Practice Expense and Physician Work RVUs proposed for SRS and SBRT, in order to preserve the opportunity to provide this cutting edge technology to Medicare patients.

Sincerely,

Arthur W. Chaney, III, M.D.
Medical Director

cc: Senators Dole and Burr, Congressman McHenry

3.

JAN -2 2007

HEALTH INDUSTRY GROUP PURCHASING ASSOCIATION

January 2, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Room 314-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; File Code CMS-1321-FC

I write on behalf of the Health Industry Group Purchasing Association ("HIGPA") to comment on the Centers for Medicare & Medicaid Services' ("CMS") final rule ("Final Rule") relating to the calculation of average sales price ("ASP") for Medicare Part B drugs and biologicals under §414.804(a)(2), in general, and the treatment of administrative fees ("GPO Fees") paid by manufacturers to group purchasing organizations ("GPOs"), in particular.

HIGPA is a broad-based trade association that represents GPOs. HIGPA's GPO members include for-profit and not-for-profit corporations, subchapter T cooperatives, purchasing groups, associations, multi-hospital systems and health care provider alliances.

Our comments are set forth in two parts. First, we explain why GPO Fees do not constitute "price concessions" and, as such, should not be included in the calculation of ASP, regardless of whether such Fees satisfy the safe harbor for "bona fide services fees" or "BFSF". Second, we respectfully request certain clarifications with respect to several of the requirements of the BFSF safe harbor.

I. GPO Fees Are Not Price Concessions

As a threshold matter, GPO Fees simply are not "price concessions" extended by a manufacturer to a purchaser. Rather, they are payments made to legally independent organizations in order to ensure purchasing efficiencies in the supply chain. Those efficiencies benefit both the manufacturer (in creating a vehicle for joint contracting rather than negotiating hundreds or thousands of separate purchase agreements) and the purchaser (in realizing the purchasing power of larger organizations and limiting expenditures relating to the purchaser's supply chain infrastructure).

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GPO Fees are paid to bona fide, third parties — the GPOs — that, by definition, are separate from, and independent of, the purchasing parties. See 42 C.F.R. §1001.952(j)(2) (defining "group purchasing organization"). These Fees have long been recognized by Congress and the U.S. Department of Health and Human Services ("HHS") as an integral (and non-abusive) part of the hospital supply chain and, as such, have been afforded both statutory and regulatory protection from the prohibitions of the federal health care program anti-kickback law ("Anti-Kickback Law"), provided certain conditions are met.

Importantly, protection for GPO Fees has not been through the "discount" exception and safe harbor to the Anti-Kickback Law, 42 U.S.C. §1320a-7b(b)(3)(A) and 42 C.F.R. §1001.952(h), but under a separate, GPO-specific exception and safe harbor, 42 U.S.C. §1320a-7b(b)(3)(C) and 42 C.F.R. §1001.952(j). Indeed, it is precisely because GPO Fees cannot be protected by the discount exception or safe harbor — because such Fees are not price concessions from a "seller" to a "buyer" — that the GPO exception and safe harbor are necessary.

The fact that some GPOs — pursuant to their by-laws or member agreements — distribute a portion of their own revenues to their hospital members does not mean that any portion of the GPO Fees paid by manufacturers to the GPOs should be treated as price concessions from the manufacturer to the purchaser. Simply stated, if a GPO decides to make a distribution to its members of its own volition — and not pursuant to any agreement or other legal arrangement between the GPO and the manufacturer — this distribution cannot possibly be deemed a "price concession" by the manufacturer, or otherwise attributed to the manufacturer, for ASP purposes. Put differently, it cannot be that pursuant to their own, independent business decisions, GPOs can unilaterally inflate or deflate drug manufacturers' prices and ASPs. Only the manufacturer of a drug can be allowed to control the price that is attributable to the manufacturer for ASP purposes. (It follows, of course, that if a drug manufacturer enters into an agreement with a GPO pursuant to which the GPO will pay its members 50 percent of the Fees paid by the manufacturer to the GPO, then the 50 percent should be considered a price concession from the manufacturer to the purchaser and, as such, should be included in the calculation of the manufacturer's ASP.)

For these reasons, we would respectfully request that CMS amend the ASP regulations by adding the following "safe harbor" as (new) §414.804(a)(2)(iii):

> *For purposes of paragraph (a)(2)(i), fees paid by a manufacturer to a bona fide group purchasing organization, as defined at 42 C.F.R. §1001.952(j)(2), will not constitute a price concession by the manufacturer unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization.*

II. Clarification to BFSF Safe Harbor

While many GPO Fees may well satisfy the BFSF safe harbor requirements, given the unique nature of GPO Fees, we would respectfully request that CMS clarify some of these requirements as they apply to GPO Fees:

- **Bona Fide, Itemized, Actually Performed on Behalf of the Manufacturer and "Otherwise Performed"**

In the preamble to the Final Rule, CMS states that it will "interpret these elements of the definition to encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the distribution of drugs." There can be no dispute that GPO fees satisfy this standard. However, in practice, contracting between manufacturers and GPOs will become bogged down in questions of whether the GPO's services have been adequately "itemized," performed "on behalf of" the manufacturer, and the like. The fact is that GPO services are well-recognized, increase the efficiency of the supply chain, and add value for the manufacturer. A deeming provision that protects GPO Fees paid at arms length to a bona fide GPO, as defined at 42 C.F.R. §1001.952(j)(2), will avoid needless disputes without eliminating any of the protections afforded by these elements of the BFSF safe harbor.

- **Fair Market Value**

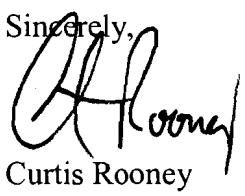
The preamble to the Final Rule confirms that percentage of goods purchased is an appropriate methodology for the calculation of fees. GPO Fees are, in our view, necessarily consistent with fair market value: they are negotiated (at times vociferously) at arm's-length between highly sophisticated parties. While the preamble to the Final Rule indicates that "manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value," requiring GPO Fees to meet a fair market value standard may, in practice, require one or more of the parties to hire valuation experts to provide regulatory comfort, thereby needlessly adding costs to the system. Both Congress and HHS-OIG wisely imposed no separate "fair market value" requirement for GPO Fees in the statutory exception and regulatory safe harbor to the Anti-Kickback Law. CMS should do the same, and provide that a GPO Fee that is paid pursuant to bona fide arms length negotiations to a bona fide GPO, as defined at 42 C.F.R. §1001.952(j)(2), will be deemed to be consistent with fair market value.

- **Not Passed On**

As set forth above, GPO Fees are paid to bona fide, independent entities. For the reasons set forth in Part I above, such Fees should be deemed not to be "passed on" for purposes of the BFSF safe harbor unless the GPO's distribution or payment to its members or customers is made pursuant to an agreement between the manufacturer and the GPO.

Thank you for your consideration. If I can be of assistance to you in the future, please contact me at (202)367-1215.

Sincerely,



Curtis Rooney
President, HIGPA

ASDS
American Society for
Dermatologic Surgery

December 21, 2006

Leslie V. Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Room 314 G
200 Independence Avenue, Southwest
Washington, DC 20201

Re: Changes in Mohs Micrographic Surgery Exemption from the Multiple Surgery Reduction Rule, in CMS 1321 FC - Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

Dear Administrator Norwalk:

As President of the American Society for Dermatologic Surgery, the largest medical specialty organization in the United States dedicated to dermatologic surgery, I represent over 4700 dermatologic surgeons, including the great majority of those performing Mohs micrographic surgery. I am writing regarding an apparent change that would have a significant impact on our membership.

It has come to our attention that the 2007 American Medical Association Current Procedural Terminology (CPT) manual has been changed such that the new Mohs micrographic surgery codes (17311-17315), unlike their predecessor codes, are no longer listed in Appendix E -Summary of CPT Codes Exempt From Modifier -51. This suggests that these codes will no longer be exempt from the Multiple Surgery Reduction Rule, which is a departure from a longstanding exemption agreed to by CMS since 1992. We are concerned that this CPT change may reflect a change in reimbursement policy by the Centers for Medicare and Medicaid Services regarding Mohs micrographic surgery without allowing adequate notice or opportunity for public comment.

Mohs micrographic surgery is a specialized technique for the removal of certain complex or ill-defined skin cancers. The new Mohs codes 17311-17315 still include excision of a cancer, tissue mapping, and the precise pathologic examination of tissue margins by the operating surgeon. Following determination of clear margins, reconstructive procedures are then undertaken, if necessary. However, Mohs surgery excisions are performed independently, at separate operative sessions from reconstructive procedures. In its review of the Mohs codes in 1992, CMS agreed that Mohs excisions are "separate staged procedures; they will be paid separately with no multiple surgery reductions." This exemption has been maintained by CMS since 1992 and was not even questioned during the CMS mandated five-year review of the Mohs codes undertaken this year and presented to the AMA Relative Value Update Committee (RUC) in October 2006. No notice had been given by CMS regarding any contemplated change in this exemption.

ASDS
American Society for
Dermatologic Surgery

We also want to stress that a significant portion of the physician work for Mohs surgery is the pathology component, and that pathology services have also historically not been subject to multiple procedure reduction.

Elimination of the exemption from the Multiple Surgery Reduction Rule would represent a change in payment policy by CMS. The Administrative Procedures Act requires that such changes be subject to standard rule making requirements including the public notice and comment process. In the Medicare Physician Fee Schedule (MPFS) proposed rule for calendar year 2007, CMS did not propose to eliminate the modifier -51 exemption nor suggest that it was considering such a change. As such, the ASDS, our members, and other interested parties have been deprived of our statutory right to comment. Since this proposed change will have a significant impact on our members and our patients, we respectfully request that the longstanding exemption of the Mohs micrographic surgery codes (17311-17315) from the Multiple Surgery Reduction Rule be maintained in 2007 until such time as a formal notice and comment process has been undertaken.

To avoid confusion for our members, we also request an urgent response on or before January 2, 2007, when the proposed change would otherwise take effect. Should you require additional information, please do not hesitate to contact Katherine J. Svedman, Executive Director of the ASDS, at ksvedman@asds.net or (847) 956-9125. I appreciate your attention to this important matter.

Sincerely,

Alastair Carruthers, FRCPC
President

Cc: Herb Kuhn, Deputy Administrator, CMS
Liz Richter, Director, Hospital Ambulatory Policy Group, CMS
Terrence Kay, Deputy Director, Hospital and Ambulatory Policy Group, CMS
Amy Bassano, Director, Ambulatory Services Division, HAPG, CMS
Katherine Svedman, Executive Director, ASDS
Ted Thurn, Advocacy and Socioeconomics Manager, ASDS
Steve Stone, M.D., FAAD, President, AAD
Ronald A. Henrichs, CAE, Executive Director and CEO, AAD
Norma Border, Senior Manager, Coding and Reimbursement, AAD
Brett Coldiron, M.D., FAAD, Chair, Health Care Finance Committee, AAD
Daniel Siegel, M.D., FAAD, AADA RUC Representative
David Brodland, M.D., FAAD, President, ACMMSCO
Georganne Dixon, Executive Director, ACMMSCO
John Zitelli, M.D., FAAD, Chair, ACMMSCO CPT Coding Task Force

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PPTA
Plasma Protein Therapeutics Association

January 2, 2007
Reference No.: FASC0701

JAN -2 2007

Leslie V. Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Administrator Norwalk:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the final rule with comment period regarding revisions to payment policies under the Medicare physician fee schedule, published in the *Federal Register* on December 1, 2006 (the "Final Rule").[1] As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

PPTA is the association that represents the commercial producers of plasma protein therapies. These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80 percent of the plasma protein therapies for the United States market and more than 60 percent worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins ("IVIG") used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors ("A1PI") used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

PPTA is very concerned that the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing IVIG therapies is jeopardizing

[1] 71 Fed. Reg. 69624.

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PPTA Offices in Washington · Annapolis · Brussels · Tokyo

patient access to IVIG. Because access to these life-saving therapies is essential for all patients, including more than 10,000 Medicare beneficiaries who rely upon them, PPTA urges the Centers for Medicare and Medicaid Services ("CMS") to take a number of steps to improve reimbursement so that it does not continue to impede access to IVIG. We appreciate the decision to continue the payment for preadministration-related services for IVIG and believe that it is imperative that this payment be maintained throughout 2007. In order to ensure access, additional steps, however, must be taken, including the implementation of a payment adjustment for IVIG and recognition that the administration of IVIG should be billed under the same codes as other biological response modifiers.

CONTINUING THE PAYMENT FOR IVIG PREADMINISTRATION-RELATED SERVICES

IVIG is the only effective treatment for primary immunodeficiency disease and has also been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States-licensed IVIG therapies are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals afflicted with diseases or conditions treated with IVIG must depend on this life-saving therapy for the duration of their lives. Each individual patient requires maximum access to the specific formulation that not only best meets their unique needs, but also significantly limits the risk of exposure to serious and potentially life threatening complications.

After first proposing to discontinue the payment for the preadministration-related services for IVIG for 2007, 71 Fed. Reg. 49506, 49604 (Aug. 23, 2006), in the Final Rule, the agency said that it will continue this payment in 2007. In doing so, CMS noted that it "will continue to review IVIG access during CY 2007 as additional information becomes available, and [it] will discontinue this temporary preadministration-related service payment during CY 2007 through rulemaking if [it] determine[s] it is no longer warranted." 71 Fed. Reg. at 69679. While PPTA appreciates the continuation of the payment and the recognition that the payment cannot be discontinued without rulemaking, we believe it would be inappropriate for CMS to discontinue this payment during 2007. This payment ensures that physicians are adequately reimbursed for providing IVIG to their patients and access throughout 2007 must be maintained. Further, any change to payments related to IVIG should not be done in isolation, which would be the case if the preadministration-related services were to be eliminated during 2007. Ensuring beneficiary access to IVIG requires an examination of the total payments for IVIG, including the payment for administration services, the preadministration-related services payment, and the payment for the product. Altering one component without considering the other components could further jeopardize patient access and, thus, would be inappropriate.

PAYMENT ADJUSTMENT FOR IVIG

As CMS acknowledged in the Final Rule, there are continuing concerns about access to IVIG. 71 Fed. Reg. at 69678-79. While that is cited as the basis for continuing the payment for preadministration-related services, the net result is that payments to physicians and suppliers will not be materially different in 2007 than they have been in 2006. As such, the Final Rule does not provide any mechanism to enhance access to IVIG, as CMS has been told is needed.

PPTA believes a payment adjustment to the average sales price ("ASP") payment rates for IVIG is required to remove the reimbursement disincentives that physicians and suppliers currently encounter in the provision of IVIG. This payment adjustment needs to be reflective of the true costs to physicians and suppliers of making IVIG available to their patients. We recognize that CMS is awaiting data from the two current IVIG access studies being conducted by the Department of Health and Human Services – one by the Office of Inspector General and one by Assistant Secretary of Planning and Evaluation. Beneficiaries who rely upon IVIG, however, do not have the luxury of waiting for the completion of these studies, much less the agency's subsequent policy decisions based on these studies. A payment adjustment is needed at the beginning of 2007 to ensure beneficiary access to IVIG. The agency's assertion that it does not have the authority to make a payment adjustment, 71 Fed. Reg. at 69679, lacks merit in light of the legal opinion that PPTA has provided to CMS on this very point. CMS has failed to rebut this opinion.

Furthermore, the agency and its contractors have experience with the type of payment adjustment PPTA is seeking such that it should not be administratively burdensome for the Medicare program. Specifically, as directed by statute,[2] CMS provides an add-on payment to the ASP rate for the furnishing of blood clotting factors. This payment adjustment has been in place since CY 2005, and has been adjusted for inflation to $0.152 for CY 2007. As commenters have told CMS, the payment rates for IVIG are not sufficient to ensure access for Medicare beneficiaries such that a payment adjustment is also needed for IVIG. Given the success of the blood clotting factor payment adjustment in maintaining beneficiary access to these therapies and the ease of the implementation of such payment adjustment, PPTA urges CMS to implement a similar payment adjustment for IVIG as soon as practicable.

[2] 42 U.S.C. § 1395u(o)(5) (2006).

IVIG SHOULD BE TREATED AS A BIOLOGICAL RESPONSE MODIFIER FOR PURPOSES OF PAYMENT FOR THE ADMINISTRATION OF IVIG

Beginning in 2006, physicians have billed for drug administration services using a number of Current Procedural Terminology ("CPT") codes that were first effective in 2006. Under these new codes, chemotherapy administration codes apply to parenteral administration of biological response modifiers, according to the language contained in the CPT book. As a result, any product that is a "biological response modifier" should be billed under such codes. IVIG is such a therapy and PPTA asks CMS to explicitly clarify that the service of administering IVIG should be billed as such.

According to the U.S National Library of Medicine, biological response modifier therapy is defined by reference to "immunotherapy," which is defined as "treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases."[3] IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki's disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Thus, IVIG qualifies as a biological response modifier.

In the Final Rule, CMS notes that the term "biological response modifier" appears in the text preceding certain CPT codes and thus it is for the American Medical Association ("AMA") to address whether IVIG should be treated as a biological response modifier. 71 Fed. Reg. at 69679. CMS' position that this is for the AMA to decide is contradicted by the actions of its own contractors. Contractors such as Empire Medicare Services recognize that the AMA has not specified what products are "biological response modifiers" and it has moved to fill this gap by establishing a listing of biological response modifiers.[4] Since a Medicare contractor can identify which products are biological response modifiers, CMS' deferral of the identification of IVIG as a biological response modifier is not appropriate. Accordingly, PPTA urges CMS to identify IVIG as a biological response modifier so that physicians administering the product are paid appropriately for such service.

SEPARATE HCPCS CODES FOR IVIG THERAPIES

As you know, PPTA has advocated for the establishment of separate HCPCS codes for plasma protein therapies because of the significant clinical differences among the brand name IVIG products. We believe that setting payment rates for each IVIG product based on its own ASP information could help to alleviate the reimbursement hurdles that physicians and suppliers encounter in furnishing IVIG to their patients. We are aware that CMS recently considered a similar issue related to sodium hyaluronate

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[3] See http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy.
[4] See http://www.empiremedicare.com/news/nynews05/030405charts.pdf (chart 4).

products in conjunction with the ASP statutory structure. Because of our belief that unique products should be paid based on ASP information specific to them, we continue to pursue this objective and would like to work with the agency to that end as we learn more about the ramifications of the decision on the sodium hyaluronate products.

CONCLUSION

PPTA appreciates the opportunity to comment on the Final Rule. While we appreciate the agency's reversal of its proposed elimination of the preadministration-related services payment for IVIG, unfortunately, that merely preserves the status quo for IVIG. In light of the concerns that PPTA and others have identified to CMS during this rulemaking, the status quo in not good enough. We urge CMS to utilize the mechanisms discussed above to improve payments for IVIG. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer
Executive Director
PPTA North America

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JAN -2 2007

KIDNEY CARE
PARTNERS

January 2, 2007

Leslie Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-FC and CMS-1317-F
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Part B (CMS-1321-FC and CMS-1317-F) Final Rule

Dear Ms. Norwalk:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology Final Rule (Final Rule).[1] KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2]

KCP would like to express its support for the recommendations offered by the Renal Physicians Association regarding revisions to the RVUs associated with evaluation and management (E&M) service codes, as well as our previous recommendation for the

[1] 71 *Fed. Reg.* 69623 (Dec. 1, 2006).

[2] A list of Kidney Care Partners coalition members is included in Attachment A.

potential use of these revised values to determine RVU levels for nephrologist services provided to dialysis patients.

As noted in our comments on the proposed rule on the Five-Year Review and the Revised Practice Expense Methodology, KCP supports the RPA recommendation that outpatient and inpatient dialysis services that use E&M codes as "building blocks", or components of their valuation, should have the full increases for the E&M codes incorporated into their values as well. We noted that the monthly dialysis codes should be revised to correspond to the sum of their E&M building blocks based on the mid-level adult G-code (G-0318) and extrapolated proportionately to other codes in the family, and that the inpatient dialysis code should be revised upward to reflect the increases of their E&M elements. These services are surrogates for the E&M care that would be provided to dialysis patients in the absence of these services. These changes are necessary because they are consistent with the intent and spirit of the RUC recommendations and the CMS notice to apply the E&M code increases to both the outpatient and inpatient dialysis codes.

As a result, we share RPA's concern that the Agency's response in the Final Rule did not address these issues. It is highly inequitable that the E&M increases would apply to all of the bundled code families except for the dialysis families of codes. Further, the changes will have a profound impact on the relativity of the dialysis code families to both E&M codes and other codes in the fee schedule. However, CMS's discussion in the Final Rule only notes that because the descriptors are markedly different than the previously valued codes, CMS is unable to make the recommended changes. The final rule does not provide a rationale for making these decisions. In light of these significant changes and their likely negatively impact, KCP urges CMS to revise the 2007 work RVUs for the dialysis families of codes so that they reflect the increases provided to their E&M coding elements.

KCP members appreciate your review of our concerns and look forward to working with the Agency on issues affecting the care provided to the nation's kidney patient population. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you have questions regarding these comments.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

Attachment A

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

7.

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ATTORNEYS AT LAW

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202-457-6000

Facsimile 202-457-6315
www.pattonboggs.com

January 2, 2007

The Honorable Leslie Norwalk
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1321-FC:** Revisions to Payment Policies, Five Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule and Other Changes to Payment Under Part B for CY 2007

Dear Ms. Norwalk:

I am writing on behalf of BioSphere Medical, Inc., to provide you with comments about the new CPT code and reimbursement rates for Uterine Fibroid Embolization (UFE), which appear in the Revisions to Payment Policies, Five Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule and Other Changes to Payment Under Part B for CY 2007 (Final Rule).[1] Specifically, I am concerned that CMS has adopted the value recommended by the RVS Update Committee (RUC) of the American Medical Association (AMA), which is based upon a zero global days. Even though it may be possible in the future to routinely perform UFE without a required overnight hospital stay, current clinical practice indicates that an overnight stay for observation and pain management is customary. Thus, we urge CMS to revisit its decision and adopt a ten-day global with the appropriate and corresponding RVUs. As an alternative, we suggest phasing-in the change over a four-year period to avoid the nearly 60 percent cut in reimbursement from hitting physicians in a single year.

BioSphere specializes in the development of embolotherapy technology, including the use of microsphere embolization for the treatment of benign uterine fibroid tumors. We work

[1] 71 *Fed. Reg.* 69623 (Dec. 1, 2006).

with physicians, patients, and patient advocates to raise awareness about UFE as a safe and effective alternative to surgical options, such as myomectomy and hysterectomy.

I. CMS Policies Should Encourage, Not Threaten, Access to UFE.

UFE provides women with a uterine-sparing, non-surgical option for the treatment of benign uterine fibroid tumors, one of the most prevalent women's health problems in the United States today. Uterine fibroids grow on the muscle tissue of the uterus. These tumors cause pelvic pressure, abdominal bloating, heavy menstrual bleeding, anemia, urinary pressure or incontinence, and possible infertility. Twenty to forty percent of women of childbearing age experience fibroids; more than five million women are symptomatic. African-American women are three times as likely to be affected by the condition.

Traditionally, women suffering from fibroids have had to have a hysterectomy (removal of the entire uterus) or a myomectomy (removal of the affected portion of the uterus). Researchers estimate that more than one-third of the 600,000 hysterectomies performed in the United States each year is undertaken to treat uterine fibroids. Both of these surgical procedures are invasive, painful, and require a lengthy recovery period. In addition, they can result in complete infertility and health complications during and after surgery.

UFE is a newly developed procedure that provides women with an FDA market-cleared, non-surgical alternative treatment for uterine fibroid tumors. Controlled clinical studies demonstrate that UFE is minimally invasive, clinically effective, and cost-efficient. In addition, it allows women to retain their uterus and fertility. UFE is performed by inserting two small catheters to inject tiny particles into the uterine blood stream that block the blood supply to the tumor. Clinical data demonstrate that one year after UFE 90 percent of women are symptom free; five years after the procedure 73 percent of patients remain symptom free.[2] The cost associated with UFE is generally lower than surgical treatment. A recent study found that 96 percent of women who undergo UFE are satisfied with the treatment 12 months following the procedure. All of these evidence-based attributes are remarkable for a procedure that has emerged in such a short time period.

Many women prefer UFE. First, it shortens the hospitalization period. The procedure generally includes an overnight hospital stay, rather than the two-to-four day hospitalization associated with surgical treatments. Second, it provides for a quicker recovery. Patients can

[2] James B. Spies, *et al*, "Uterine Artery Embolization for Leiomyomata," *Obstetrics & Gynecology* (March 2001), 98, 29-34; James B. Spies, *et al*, .Long-Term Outcome of Uterine Artery Embolization of Leiomyomata," *Obstetrics & Gynecology* (November 2005), 106, 933-939.

usually return to their activities of daily living and work in 7-10 days, as opposed to the several weeks of recovery following surgical treatment. Third, it preserves fertility. Because the uterus is not removed, a high percentage of patients may still have children, if desired.

In addition to its clinical benefits and patient-friendly attributes, UFE has also been shown to be more cost-effective than traditional surgical treatments for fibroid tumors. The procedure generally allows a patient to go home the next morning rather than staying in the hospital for three-to-four days, as would be the case with a hysterectomy. This difference alone significantly reduces the costs of treating fibroid tumors. Furthermore, because a patient is typically able to return to work and normal activity within 10-11 days instead of waiting the four-to-six weeks required for recovery after a hysterectomy, there is also less expense associated with recovery costs of the procedure. Given the significant population of women who experience fibroid tumors and the number of procedures undertaken each year to treat this condition, the development of UFE as a clinically effective and cost efficient treatment method holds tremendous promise for patient benefit and savings.

II. The Final Rule Threatens Access to UFE for Women Because It Assigns Zero Global Days, which Does Not Accurately Reflect Clinical Practice

The Final Rule's assignment of zero global days threatens the ability of women to have access to UFE. This decision does not reflect the current clinical standard of care and, therefore, establishes an inappropriate reimbursement rate. Although the RUC establishes the RVUs, CMS must assign the correct global day period. Therefore, we strongly urge CMS to establish a ten-day global period for the new UFE code and to adjust the RVUs accordingly. If not done, the reimbursement rates for UFE will be cut approximately 60 percent. Such a dramatic cut may make it impossible for physicians to continuing to offer the procedure to their patients. Given that UFE is more efficient and cost-effective overall than surgical options, CMS should encourage its use through appropriate reimbursement policy. Furthermore, because UFE is a relatively new treatment option that is still gaining support among patients and clinicians, a flawed reimbursement policy is even more likely to have a negative impact on the availability of this procedure, thus stifling the growth of an important treatment alternative for women.

BioSphere Medical appreciates the importance of establishing codes that properly capture the cost of providing medical services and CMS's role as a responsible fiduciary for the federal government. As part of this responsibility, it is especially important that CMS exercise its resources to ensure that the value inputs assigned to individual service codes reflect the true costs of furnishing the service. We also understand the difficulty in assigning a global day period that is different than the period assumed by the RUC in developing its value recommendations.

However, the critically important task of determining an appropriate value and reimbursement level that will not impede patient access to a procedure warrants the extra time and consideration necessary to assess the proper global day period and associated value for the UFE code.

Currently, interventional radiologists bill for the service using a combination of existing office visit, radiology, and transcatheter placement CPT codes to capture all of the components of the UFE procedure. Given the difficulties multiple codes create in the billing and auditing process, we appreciate the need to establish a single code. Nonetheless, it is important that this single code incorporate all of the physician time that is associated with the procedure.

First and foremost, we are concerned that the physician survey data used by the RUC in its development of a recommended code value for UFE contained a critical error in the number of global days that it assumed CMS should assign to the procedure. As Dr. James Spies (Professor of Radiology, Chairman and Chief of Service, Department of Radiology at Georgetown University Hospital) discussed at our August meeting with CMS staff, the clinical literature on UFE focuses on only a small time segment of the actual UFE procedure. These studies describe the process from the time the catheter is inserted in the patient to the time it is removed. As an author of many of these studies, Dr. Spies stresses that they do not account for the preparation time or the follow-up care. Clinicians who actually perform these services (and many of whom were not surveyed during the SIR process) suggest that while the procedure is performed on an outpatient basis, most UFE patients spend the night following the procedure at an inpatient facility for pain management and observation purposes. In fact, in one of the leading peer-reviewed clinical studies on the UFE procedure involving more than 3000 patients. Ninety-four percent of the patients were kept in the hospital overnight and discharged the next day.[3] They also typically receive several follow-up calls with their physician during the week following the procedure and a follow-up office visit. Thus, while some patients may go home the day of the procedure, the vast majority of patients have one night of inpatient care as standard practice. When these factors are taken into account, the ten-day global is most appropriate for the new code.

We appreciate that it may be difficult for CMS to assign a ten-day global period when the RUC value fails to incorporate the additional period of care in its recommended value. However, CMS has the authority to adopt the global day period and the RVUs for new CPT codes. When additional consideration is needed to reconcile differences between the global period assumed by the RUC and the global period most appropriate based upon the clinical

3 Robert Worthington Kirsch, et al., "The Fibroid Registry for Outcomes Data for Uterine Embolization," 106 Obstetrics & Gynecology (July 2005).

requirements of a procedure, CMS should exercise its authority to undertake this extra effort to ensure proper reimbursement for the service at issue.

III. To Ensure Access to UFE for All Women, CMS Should Delay Adoption of the UFE CPT Code.

To ensure that all women have access to UFE, any new code must appropriately account for the time, skill, and intensity it takes to provide UFE. The proposed code likely to be adopted is based upon an incorrect number of global days and, thus, will undervalue the work involved. Therefore, we urge CMS to refrain from adopting a new CPT code for UFE until appropriate data that is based on an accurate understanding of the procedure can be gathered. Until that time, CMS should allow physicians to use the set of codes that are currently used to process claims.

CMS has the authority not to adopt all of the CPT codes proposed by the AMA. We understand that the code will remain in the AMA CPT code book even if CMS does not immediately adopt the new code. However, under the HIPAA transactions and code set regulations, all health insurers must use codes that have been adopted by the agency for electronic claims transactions.[4] If CMS does not adopt this particular code, it will not become part of the HIPAA code set and, therefore, cannot be used to process claims transactions. We understand that applying the HIPAA rule in this manner should be a rare occurrence. However, given the potential harm that the new CPT code and its possibly inappropriate global period could create, we believe this measure should be exercised in order to provide additional time to gather and assess accurate data on the UFE procedure.

If CMS does not adopt the code, the specialists who perform this procedure will have the additional time they need to resolve the outstanding questions and concerns. Although Medicare beneficiaries do not frequently suffer from fibroid tumors, it is nonetheless important that the procedure is properly valued given the impact of Medicare values on reimbursement in other sectors, including Medicaid and the private insurance market. To assist with the appropriate valuation of the codes, we encourage CMS to acknowledge that it agrees that a ten-day global period would be appropriate to assign to the code. In addition, CMS should encourage the interested parties to resolve the issue in a transparent, thoughtful, and deliberative manner that demonstrates a comprehensive understanding of the procedure and the needs of patients.

IV. As an Alternative, CMS Should Phase-In the Implementation of the New Code and Value.

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[4] 45 C.F.R. 162.925.

Alternatively, if CMS chooses to move forward with the code values as proposed, it should be willing to address the drastic nature of this payment cut by providing a phase-in period for the new code values. As noted earlier, the adoption of the new code and value for UFE will ultimately result in an estimated payment cut of nearly 60 percent for physicians performing this procedure. A payment reduction that is so significant could certainly have a chilling effect on the uptake of this new technology in the marketplace, ultimately limiting patient access to an extremely promising treatment option for uterine fibroids.

Historically, CMS has phased-in the reimbursement changes to allow physicians to adjust to the payment changes and avoid an interruption or reduction in availability of services. For example, in its recent implementation of reimbursement changes related to the geographic wage index, CMS recognized the potential impact on Medicare providers that would experience significant payment reductions under the new policy and provided for a phase-in period of four years in order to allow those physicians to prepare for the new reimbursement rates. A phase-in period is especially critical for new technologies and services, such as UFE, that are still developing a patient and physician following in the market and thus are more likely to be directly impacted by shifts in reimbursement.

V. Conclusion

BioSphere Medical appreciates the opportunity to comment on this important issue for women. It is imperative that CMS ensure that its coding decisions do not threaten access to UFE and thwart the desire of many Members of Congress who are working to educate more women, especially those in the African-American community, about this important and effective new alternative to surgery. We also understand the role of the RUC in assisting CMS with the valuation of codes; however, there are times when it is appropriate for the Agency to address issues that may have been overlooked in the RUC process, such as the appropriate assignment of global days. Thus, to remain consistent with Agency's overall objective to assign appropriate values to codes and to ensure patient access to promising, new technologies, CMS should not adopt the UFE CPT code in the Final Rule or, at the very least, provide a phase-in period for the new code to allow physicians to adjust to the drastic reduction in reimbursement.

We would welcome the opportunity work with CMS to ensure the code is appropriately values and available for adoption next year. Please do not hesitate to contact me at 202-457-6562.

Sincerely,

Kathleen J. Lester
Partner

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December 22, 2006

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

Re: Final Rule: Medicare Program; Revisions to Payment Policies, Five Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Final Rule (CMS-1321-FC)

Dear Ms. Norwalk:

The American College of Radiation Oncology ("ACRO") is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Final Rule: Medicare Program; Revisions to Payment Policies Five Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Proposed Rule (CMS-1321-FC).[1] With a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology.

Physician Payment Update

ACRO would like to extend its appreciation for the opportunity to comment on the final regulations and other recent developments concerning physician reimbursement. In particular, we support the recent legislation eliminating the 5.1% proposed cut in Medicare physician payment.[2] While this is welcome to relief to an onerous cut, yet again, it is a temporary one-time fix to a larger problem. The sustainable growth calculation methodology is a flawed system for compensating physicians. In order to preserve beneficiary access to care, physicians must receive annual updates that reflect the increase in our practice expenses. Physicians must pay more every year for office space rent, professional liability insurance, and staff salaries. A payment methodology that does not keep pace with the most basic indicators of medical inflation is untenable. ACRO continues to support alternative solutions to the budget neutrality provisions.

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[1] Final Rule: Medicare Program; Revisions to Payment Policies, Five Year Review of Work Relative Value Unites, Changes to the Practice Expense Methodology Under the Physician Fee Schedule and Other Changes to Payment Under Part B; Final Rule (CMS-1321-FC). *Federal Register*, Volume 71, No. 231, December 1, 2006, p. 69623.

[2] House of Representatives Bill H.R. 6111 and Senate Amendment to same.

Medicare must develop a system that fairly compensates physicians and accounts for the actual cost of caring for our patients.

Practice Expense Revisions

ACRO also appreciates the re-valuation of the PE/HR for radiation oncologists that CMS undertook in 2006. The updated data more accurately reflect the work involved in providing radiation oncology services. ACRO was pleased to join a coalition of radiation oncology professional associations in support of the Association of Freestanding Radiation Oncology Centers (AFROC) study. ACRO believes it is essential for CMS to use current wage rates for medical physicists and dosimetrists, the most highly compensated allied healthcare professionals in radiation oncology.

We remain concerned, however, about the CMS interpretation of which services are subject to the cuts in Medicare imaging reimbursement under Section 5102 of the Deficit Reduction Act (DRA),[3] and the impact of such interpretation upon the care that Medicare beneficiaries receive. Specifically, ACRO feels that all radiation oncology services should be outside of the DRA provisions. These therapeutic services are not part of the changes intended for diagnostic radiology. They are specific for the safe and effective treatment delivery of radiation therapy for cancer care. Specifically, the following codes should be exempted from the provisions of the DRA:

76950 – Echo guidance for radiotherapy
76965 - Ultrasonic guidance for interstitial radioelement application
77014 – CT guidance for placement of radiation therapy field (previously 76370)
77417 - Port films
77421 - Stereoscopic x-ray guidance

ACRO believes that radiation therapy or brachytherapy cannot be delivered without the services described in these codes. They are clearly not diagnostic imaging services, but components of care integral to the ongoing treatment of cancer patients, and as such should not be included in the DRA changes.

Physician Self-Referral Issues

We remain concerned about the growing trend of non-radiation oncology specialists purchasing or leasing building space for radiation oncology equipment that they also purchase or lease. Previously, these specialists would refer their patients to an independent radiation oncologist for a consultation including exploration of the full range of treatment options appropriate for the patient. However, under the recent, growing trend, these non-radiation oncology specialists employ a radiation oncologist and bill globally for radiation oncology services under the centralized building component of the in-office ancillary exception to the Stark Law. As CMS well understands, Section 1877 of the Social Security Act (the so-called Stark Law) generally prohibits financial arrangements between physicians and entities providing designated health services (DHS), except under certain exceptions. These provisions were enacted after a number of studies showed a consistent correlation between such arrangements and over utilization of health care services.

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[3] Section 5102 of Deficit Reduction Act of 2005 (Pub. L. 109-171).

While Congress created the in-office ancillary exception to protect services that are truly ancillary to the referring physician's practice from being prohibited under the Stark Law, ACRO believes Congress also meant to balance such exceptions against the critical need to protect against program or patient abuse. Indeed, in its Phase I Final Rule on Physician Self-Referrals to Health Care Entities With Which They Have Financial Relationships, published on January 4th, 2001, CMS (then the "Health Care Financing Administration") stated:

> *"We share this commenter's concerns about inappropriate financial incentives driving the provision of DHS. We are concerned that heightened downward pressure on physician incomes will generate increased upward pressure to expand in-office ancillary services as a means of offsetting income losses."*

ACRO believes "integration" of radiation therapy services into specialty practices is a direct result of such financial incentives. While we have no objection to the multi-specialty concept, we believe that CMS and legislators do not condone the use of upstream patient contact as a proper mechanism to drive patterns of care or to allow self-referral for financial gain. In addition, we think this trend restricts treatment options and limits choice in radiation therapy (for the obvious result that physicians who own such centers will only refer patients for treatment through their centers as opposed to offering other treatment options). In addition, it is probable that prostate cancer survivors will be referred to a urology-owned radiation center for a second (non-urologic) cancer regardless of the radiation expertise at the center.

CMS notes that Section 1877(b)(2) of the Social Security Act "authorizes the Secretary to determine additional terms and conditions relating to the supervision and location requirements of the in-office ancillary services exception as may be necessary to prevent a risk of program or patient abuse." ACRO urges CMS to use its authority under Section 1877(b)(2) to impose regulations "as needed to protect against program or patient abuse" to curb the increasing practice of the purchase or creation of radiation oncology centers by non-radiation oncology specialists.

Our continued goal is to promote quality radiation therapy and to see that patients have unbiased access to a diversity of radiation services. Service continuity is one aspect of quality, and development of a full range of advanced technology is another. We believe that such goals can only be achieved through a specialty dedicated to radiation oncology. ACRO would be interested in discussing these concerns directly with CMS as it deliberates on how to proceed.

Sincerely,

D. Jeffrey Demanes, M.D.
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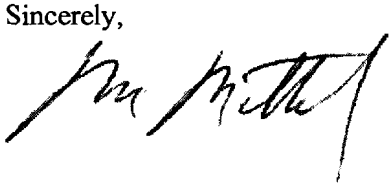
Sincerely,



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cc: Terrence Kay, Centers for Medicare and Medicaid Services
Herb B. Kuhn, Centers for Medicare and Medicaid Services

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January 2, 2007

BY HAND DELIVERY

The Honorable Leslie V. Norwalk, Esq.,
Acting Administrator
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Washington, DC 20201

Re: CMS–1321–FC: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007

Dear Acting Administrator Norwalk:

On December 1, 2006, the referenced Centers for Medicare & Medicaid Services' ("CMS") final rule with comment period ("Final Rule") was published in the Federal Register, 71 Fed. Reg. 69624. Among other things, the Final Rule addresses the calculation of "average sales price" ("ASP") for Medicare Part B drugs and makes certain corresponding amendments to CMS' ASP regulations, 42 C.F.R. § 414.800 et seq.[1] On behalf of Novation, LLC ("Novation"), University HealthSystem Consortium ("UHC"), and VHA, Inc. ("VHA"), we respectfully submit comments to these amendments.

UHC is a legal cooperative that is owned, governed and controlled by state-owned and private, non-profit academic medical centers and teaching hospitals. VHA is a legal cooperative that is owned, governed and controlled by non-profit, tax-exempt,

[1] All citations are to Title 42 of the Code of Federal Regulations, unless otherwise indicated.

community based hospitals. Both UHC and VHA are idea-generating and information-disseminating enterprises that help their members pool resources, create economies of scale and improve clinical care and operating efficiency. Consistent with their missions, UHC and VHA offer their members (among other things) group purchasing programs. For purposes of these programs, UHC and VHA act both directly and through their jointly-owned agent, Novation.

I Final Rule

The Final Rule provides that subject to certain exclusions and exceptions, the ASP of a particular drug is equal to (1) the total dollar value of all units of the drug sold by its manufacturer to all "purchasers" during the quarter at issue, divided by (2) the total number of units covered by these sales.[2] The Final Rule further provides that, in calculating a drug's sales price, the manufacturer must deduct "price concessions" and, more specifically, "volume discounts," "prompt pay discounts," "cash discounts," "free goods that are contingent on any purchase requirement," and "chargebacks and rebates (other than rebates under the Medicaid program)."[3]

Over time, questions have arisen as to whether certain "fees" paid by manufacturers to purchasers or others constitute "price concessions" for purposes of calculating ASP.[4] The Final Rule addresses these questions (at least in part), providing that "bona fide services fees" are not "price concessions" for purposes of calculating ASP.[5] The Final Rule defines "bona fide services fees" as:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.[6]

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[2] 42 C.F.R. § 414.804(a)(1).

[3] 42 C.F.R. § 414.804(a)(2)(i).

[4] 71 Fed. Reg. 48982, 49001 (Aug. 22, 2006).

[5] 42 C.F.R. § 414.804(a)(2)(ii).

[6] 42 C.F.R. § 414.802.

II Comments

A. CMS Should Clarify That Payments Not Meeting the Definition of "Bona Fide Services Fees" are Not Necessarily Price Concessions

The Final Rule provides that if a drug manufacturer pays a "bona fide services fee," that payment does not constitute a "price concession" for ASP purposes. Given the importance of this issue, and in light of certain potentially ambiguous statements in the Preamble,[7] we would urge CMS to clarify that the converse is not true. That is, just because a drug manufacturer's payment does not meet the definition of a "bona fide services fee" does not mean that the payment is, necessarily, a "price concession."

This clarification would be consistent both with (1) the structure and plain terms of the Final Rule and (2) common sense. As to the former, the Final Rule identifies, in § 414.804(a)(2)(i), the categories of "price concessions" (including certain "discounts" and "rebates") to be included in the calculation of ASP; it then provides, in § 414.804(a)(2)(ii), that "bona fide services fees" are not "price concessions." The regulations, however, do not provide that if a payment does not meet the definition of a "bona fide services fee" then the payment, necessarily, constitutes a "price concession."

Indeed, were this CMS' intention, it could simply have amended existing § 414.804(a)(2) to provide that "[i]n calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items": (1) "volume discounts," (2) "prompt pay discounts," (3) "cash discounts," (4) "free goods that are contingent on any purchase requirement," (5) "chargebacks and rebates (other than rebates under the Medicaid drug rebate program)," and (6) *"fees paid by the manufacturer to an entity that are not 'bona fide services fees' under 42 C.F.R. § 414.802."*

This is not how CMS amended the ASP regulations, however. Presumably, CMS did not take this approach because, if it did, any payment made by a drug manufacturer to any "entity" could be deemed a "price concession," even if the payment plainly does not fall into that category. For example, drug manufacturers use electricity and, as such, make payments to utility companies (i.e., "entities"). Such payments may not qualify as a "bona fide services fee" (for example, the amount paid by the manufacturer to the utility might be more or less than fair market value). Plainly, however, the fact

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[7] See, e.g., 71 Fed. Reg. at 69668 ("In codifying the definition of bona fide service fees, we seek to clarify a framework for differentiating between those price concessions that must be included in the calculation of ASP and bona fide service fees, which are not included in the calculation of ASP.")

that the manufacturer's payment to the utility does not qualify as a "bona fide service fee" does not mean that the payment constitutes a "price concession" for ASP purposes.

In order to avoid any confusion or misinterpretation of the Final Rule, we believe that it is important for CMS to clarify that while payments that qualify as "bona fide services fees" are "safe harbored" — that is, such payments do not, as a matter of law, constitute "price concessions" for ASP purposes — payments that do not qualify as "bona fide services fees" may or may not constitute "price concessions" for ASP purposes.

B. CMS Should Clarify That Pending the Issuance of Further Guidance, Fees Paid to GPOs and PBMs Do Not Have To Be Included In the Calculation of ASP

In the Preamble to the Final Rule, after discussing the new "bona fide services fee" provision, CMS notes "many commenters asserted that all fees and other payments" to group purchasing organizations ("GPOs") and pharmacy benefit managers ("PBMs") "should be excluded from ASP."[8] In response, CMS states that it is "continuing to develop [its] understanding of the variety of agreements made with entities such as PBMs and GPOs and the possible effects of these arrangements on the calculation of ASP and provider acquisition costs."[9]

> For this reason, at this time we believe it is premature for us to provide specific guidance with respect to treatment of fees paid by manufacturers to PBMs and GPOs in the ASP calculation . . . Instead, we will continue to consider the comments received and to study the matter further . . . In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices. These assumptions should be submitted along with the ASP data.[10]

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[8] 71 Fed. Reg. at 69669.

[9] 71 Fed. Reg. at 69669.

[10] 71 Fed. Reg. at 69669.

We believe that the most reasonable interpretation of this statement is that until CMS provides specific guidance with respect to the treatment of GPO and PBM fees, if a manufacturer's customary business practice is (for example) to exclude such fees from the calculation of ASP — on the assumption that fees paid to a third party do not constitute "price concessions" offered to a "purchaser" — the manufacturer may continue this practice.

Although we believe that this is the most reasonable interpretation of CMS' statements in the Preamble relating to GPO and PBM fees, in order to avoid uncertainty and confusion among manufacturers, PBMs, GPOs and other third parties, and in an effort to ensure uniformity in ASP reporting to the greatest extent possible, we would urge CMS to make the aforementioned clarification.

C. CMS Should Create a Separate Safe Harbor for Payments Made by a Third Party to a Purchaser That Are Not Controlled by the Manufacturer; Alternatively, CMS Should Amend the "Bona Fide Services Fee" Definition to Achieve the Same Result

Under the current ASP regulations, any "fee" that is paid by a manufacturer to any "entity" will not qualify as a "bona fide services fee" — and, therefore, could potentially constitute a "price concession" for ASP purposes — if the fee is "passed on" by the "entity" to one if its "clients" or "customers". For the reasons set forth below, we believe that there are certain payments that plainly are not "price concessions" but — depending on the meaning of "passed on" — could potentially fall into the non-"bona fide services fee" category. A hypothetical helps demonstrate the point. Assume the following:

- On January 1, 2007, Manufacturer enters into a personal services agreement with Entity. Pursuant to this agreement, Entity furnishes services to Manufacturer on January 1, and Manufacturer pays Entity a $1,000 fee for these services on January 15.

- On February 1, Entity enters into a personal services agreement with Provider (one of Entity's customers). Pursuant to this agreement, Provider furnishes services to Entity on February 1, and Entity makes a $1,000 payment to Provider on February 15.

- Manufacturer was not involved in the negotiation of, and is not a party to, the Entity-Provider agreement.

- On March 1, in discussions with Entity, Manufacturer learns of Entity's agreement with (and $1,000 payment to) Provider.

- During the first quarter of 2007, Manufacturer sells 20 units of Drug A for $100 per unit. 10 of these units are sold by Manufacturer to Provider.

Under these circumstances, it might be contended that the $1,000 fee paid by Manufacturer to Entity (on January 15) does not qualify as a "bona fide services fee" on the ground that it was "passed on" by Entity to Provider (on February 15). (Although we do not believe that this would be a fair or reasonable interpretation of "passed on," the term is not defined in the Final Rule, and this issue is not discussed in the Preamble.) Even were CMS to concur with this interpretation, however — and, as such, conclude that the fee does not qualify as a "bona fide service fee" — CMS presumably would not take the position that the $1,000 fee constitutes a "price concession" by Manufacturer to Provider for ASP purposes.

It is true that the funds for the payment from Entity to Provider came from Manufacturer — at least in the macro sense that $1,000 flowed from Manufacturer to Entity on January 15, $1,000 flowed from Entity to Provider on February 15, and money is fungible. It also is true that Manufacturer had knowledge of this payment. These two facts, however, are not sufficient to establish that Manufacturer made a $1,000 "price concession" to Provider.

The reason for this is straightforward: although (1) the funds originated (again, in a macro sense) with Manufacturer, and (2) Manufacturer had knowledge of the payment by Entity to Provider, Manufacturer did not control this payment. That is, the payment by Entity to Provider was not made pursuant to a contractual (or other legal) obligation that Entity owed to Manufacturer. Rather it was made pursuant to a separate, independent agreement between Entity and Provider, an agreement that Manufacturer did not negotiate and was not a party to. Under these circumstances, we do not believe that it can be said that the $1,000 payment by Entity to Provider is a "price concession" by Manufacturer to Provider.

Indeed, were the case otherwise, third parties would be permitted effectively — and unilaterally — to deflate or inflate a manufacturer's ASP. In the above hypothetical, for example, if Manufacturer is not required to take the $1,000 payment by Entity to Provider into account, then the ASP of Drug A would be $100.[11] If Manufacturer is required to take the $1,000 payment into account — notwithstanding the fact that

[11] That is, $2,000 (the total amount received by Manufacturer from purchasers), divided by 20 units (the total number of units sold to purchasers).

Manufacturer had no control over the payment, which was not made pursuant to any obligation that Entity owed to Manufacturer — then the ASP of Drug A would be reduced by 50 percent, to $50.[12]

In order to ensure that manufacturers (and others) can be confident that payments under circumstances such as these will not be deemed "price concessions" for ASP purposes, we urge CMS to consider amending the ASP regulations by adding the following "safe harbor" as (new) § 414.804(a)(2)(iii):

> *For the purposes of paragraph (a)(2)(i), where an entity (other than the manufacturer) makes a payment to one of its clients or customers, this payment will not constitute a price concession by the manufacturer if the payment was not made pursuant to a contractual or other legal obligation owed by the entity to the manufacturer.*

It should be emphasized that this safe harbor would not protect payments that are, in effect, rebates or other price concessions offered by a manufacturer, but that simply flow through a third party. For example, assume the following:

- Effective January 1, 2007, Manufacturer and Entity enter into an agreement, pursuant to which (1) Manufacturer agrees to sell Drug A to Provider for $100 per unit, (2) Manufacturer agrees to pay Entity a fee equal to two percent of Provider's purchases of Drug A, and (3) Entity agrees that for each $2 in fees that it receives from Manufacturer, it will pass $1 of this $2 back to Provider.

- On January 1, Provider purchases one unit of Drug A from Manufacturer for $100. Pursuant to the Entity-Manufacturer agreement, Manufacturer pays Entity $2 on January 15, and Entity passes $1 of this $2 back to Provider on February 1.

Under these circumstances, the $1 payment by Entity to Provider could — quite reasonably — be considered a "price concession" by Manufacturer to Provider (and would not be protected by the safe harbor proposed above). Although the payment at issue was made by Entity to Provider, it was made pursuant to a preexisting contractual obligation owed by Entity to Manufacturer. Indeed, as a practical matter, the Manufacturer-Entity agreement effectively provided (1) for Manufacturer to pay a one

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[12] That is, $1,000 (or the total amount received by Manufacturer from purchasers, $2,000, minus the $1,000 payment by Manufacturer to Entity), divided by 20 units (the total number of units sold to purchasers).

percent fee to Entity and (2) for Manufacturer to pay a one percent rebate to Provider, which rebate simply was administered by Entity.

* * *

As an alternative to developing a new safe harbor, CMS could amend the "bona fide services fee" definition. As revised, the definition of this term would be:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. *For purposes of this definition, a payment by an entity to one of its clients or customers will not be considered "passed on" if the payment is not made pursuant to a contractual or other legal obligation owed by the entity to the manufacturer.*

D. CMS Should Create a Safe Harbor for Payments That are Made by a Manufacturer to an Entity Other Than a Purchaser and Not Passed on to a Purchaser; Alternatively, CMS Should Amend the "Bona Fide Services Fee" Definition to Achieve the Same Result

Under the current ASP regulations, any "fee" that is paid by a manufacturer to any "entity" will not qualify as a "bona fide services fee" — and, therefore, could potentially constitute a "price concession" for ASP purposes — if the fee does not represent "fair market value," even if the fee is not "passed on," in whole or in part, to a purchaser. For the reasons set forth below, we believe that there are certain payments that could potentially fall into this (non-"bona fide services fee") category but plainly should not be considered "price concessions" offered by a manufacturer to a purchaser. Again, a hypothetical helps demonstrate the point. Assume the following:

- Manufacturer has a personal services agreement with Entity. Pursuant to this agreement, Entity furnishes services to Manufacturer on January 1, 2007, and Manufacturer pays Entity a $2,000 fee for these services on January 15.

- The "fair market value" of the services furnished by Entity to Manufacturer is $1,800.

- During the first quarter of 2007, Manufacturer sells 20 units of Drug A for $100 per unit.

- Entity does not make any payments to any of the purchasers of Drug A.

Under these circumstances, the $2,000 payment from Manufacturer to Entity would not qualify as a "bona fide services fee" because it is greater than "fair market value." By the same token, we assume that CMS would not deem the payment a "price concession" by Manufacturer to a purchaser because no portion of the $2,000 paid by Manufacturer to Entity was ever paid, passed on or otherwise transferred to any purchaser.

In order to ensure that manufacturers (and others) can be confident that payments under circumstances such as these will not be deemed "price concessions," we urge CMS to consider amending the ASP regulations to add the following "safe harbor" as (new) § 414.804(a)(2)(iv):

> *For the purposes of paragraph (a)(2)(i), where a manufacturer makes a payment to an entity other than a purchaser, and this payment is not passed on in whole or in part by the entity to a purchaser, this payment will not constitute a price concession by the manufacturer.*

Once again, as an alternative to developing a new safe harbor, CMS could simply amend the "bona fide services fee" definition as follows:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. *Where a manufacturer makes a payment to an entity other than a purchaser, and this payment is not passed on in whole or in part by the entity to a purchaser, this payment need not represent fair market value in order to qualify as a bona fide services fee.*

E. CMS Should Create a "Fair Market Value" Deeming Provision for Fees That Result From Arm's Length, Bona Fide Bargaining Between a Manufacturer and a GPO

As noted above, one of the elements of the "bona fide services fees" definition is that the fee represent "fair market value." CMS correctly notes in the Preamble that the "appropriate method or methods for determining whether a fee represents fair market value may depend upon the specifics of the contracting terms," and that "manufacturers are well-equipped to determine the most appropriate, industry-accepted method" for determining fair market value.[13] "Therefore," CMS concludes, "we are not mandating the specific method manufacturers must use to determine whether a fee represents fair market value for purposes of excluding bona fide service fees from the calculation of ASP."[14]

While we wholeheartedly agree that CMS should not mandate the specific method manufacturers must use to determine whether a fee represents fair market value, we would urge CMS to consider developing one or more "deeming" provisions that would enable manufacturers to rely upon the protections of the "bona fide service fee" safe harbor (or any other safe harbors that include a "fair market value" element) without having to engage in potentially costly and time consuming valuations.

Toward that end, we respectfully submit that it would be appropriate to develop and implement such a deeming provision with respect to fees (1) paid by manufacturers to a "group purchasing organization," as that term is defined at 42 C.F.R. § 1001.952(j)(2), (2) pursuant to arm's length, bona fide negotiations between the manufacturer and the GPO. Such fees have long been recognized by Congress and the U.S. Department of Health & Human Services as an integral part of the hospital supply chain and, indeed, have been afforded statutory and regulatory exemption from the prohibitions of the federal health care program anti-kickback law.

Accordingly, we urge CMS to consider amending the ASP regulations to further clarify — by adding a new definition to the ASP regulations, amending the definition of "bona fide services fee," or otherwise — that a fee paid by a manufacturer to a group purchasing organization, as that term is defined in 42 C.F.R. § 1001.952(j), represents "fair market value" if the fee results from arm's length, bona fide bargaining between the manufacturer and the GPO.

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[13] 71 Fed. Reg. at 69669.

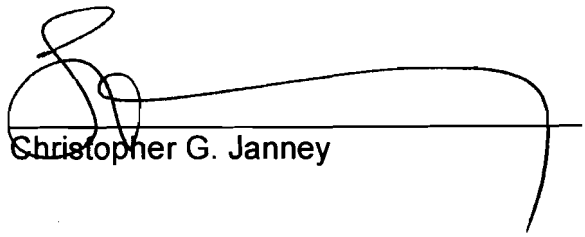
[14] 71 Fed. Reg. at 69669.

* * *

In closing, we would like to thank CMS for providing us with this opportunity to comment on, and make recommendations concerning, the Final Rule. Please do not hesitate to contact us if you have any questions concerning these comments or require further information.

Respectfully,

SONNENSCHEIN NATH & ROSENTHAL LLP

By: 
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American Society of Pediatric Nephrology

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January 2, 2007

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

RE: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Part B (CMS-1321-FC and CMS-1317-F) Final Rule

Dear Ms. Norwalk:

The American Society of Pediatric Nephrology (ASPN) is a professional society composed of pediatric kidney specialists whose goal is to promote optimal care for children with renal disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. The ASPN currently has over 600 members, making it the primary representative of the pediatric nephrology community in North America. Approximately one-percent of the end-stage renal disease (ESRD) population is comprised of children, and ensuring that they receive adequate care is one of our primary concerns.

We are writing to express our serious objection to the Agency's decision in the final rule not to apply the 'building block' increases in the evaluation and management codes (E&M) to the current series of monthly dialysis codes (temporary G-codes). We are concerned that the care of children with ESRD will be adversely impacted by this decision due to decreasing reimbursement for physician services.

CMS has indicated in the final rule that it did not increase the values for dialysis services because the descriptors for these codes are markedly different from what had been previously approved for use for these services. However, the reason the dialysis code descriptors are markedly different is because CMS itself changed the methodology for reimbursing for these services, despite stated objections by the majority of the renal community, including the ASPN.

It is known that the previous monthly dialysis service codes (CPT codes developed through standardized, broad-based review) were based on an E&M building block methodology, approved and implemented by the then Health Care Financing Administration. Therefore, the Agency's response in the final rule raises serious concerns that CMS did not follow its own methodology for re-valuing bundled health service categories that are derived from E&M code elements. **For these reasons, the ASPN requests the Agency revisit its decision, and instead provide an interim revision of the work RVUs for inpatient and outpatient dialysis codes.**

Thank you for your prompt consideration of our comments. We stand ready to work with CMS in its efforts to improve the quality of care provided to the nation's pediatric ESRD patients. Please contact Jennifer Shevchek at 202-546-4732, or by email, jshevchek@dc-crd.com, if you should need additional information or clarification regarding ASPN's comments.

Sincerely,

Sharon P. Andreoli, M.D.
President

CC: Dr. Barry Straube
Brady Augustine

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December 29, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Service
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

Dear Ms. Norwalk:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007" Final Rule published in the Federal Register on December 1, 2006. In our comments, the ACR will focus on the following issues in the final rule:

- Budget neutrality adjustment to the physician work values
- Delay in implementation of proposals on the reassignment rule
- Practice expense
- Imaging procedures affected by the Deficit Reduction Act (DRA)
- Geographic practice cost indices

Budget Neutrality

The ACR is very disappointed and remains concerned that the Centers for Medicare and Medicaid Services (CMS) decided to apply the budget neutrality adjustment required for the Five Year Review to the physician work, as this is a dramatic departure from previous Five Year Review budget neutrality adjustments. The CMS decision is contrary to the views of the medical community that were expressed in numerous comments, including those from the ACR, the American Medical Association (AMA) and the AMA/Specialty Society Relative Value Scale Update Committee (RUC). The vast majority of professional societies whose members treat Medicare beneficiaries recommended that the budget neutrality adjustment be made to the conversion factor and not to the physician work values. Budget neutrality adjustments required by changes in work RVUs have

been applied to the conversion factor since 1999, consistent with the agency's commitment and the long-standing recommendations of the RUC.

The ACR believes that being consistent with previous adjustments to the conversion factor is a more fair and equitable application of budget neutrality adjustments. The ACR is opposed to the CMS decision because it places a disproportionate burden on hospital-based physicians whose compensation for medical services is derived only from the professional component (PC) and is thus heavily dependent on the work RVU.

In addition, CMS should be cognizant that maintaining the stability of the work RVUs is essential since Medicare's RVUs are used by many other payers. They are often the basis of physician compensation and productivity analyses. Merely publishing unadjusted work values in Addendum B does not change the fact that CMS is proposing to scale the work values as a result of the Five Year Review. While we understand it is not the intention of the Agency, by scaling the RVUs it makes it seem to outside observers that the physician work of the services unaffected by the Five Year Review has decreased as a result of the Five Year Review.

The ACR strongly recommends that CMS reconsider applying the budget neutrality adjustment to the conversion factor and not to the physician work RVU.

Reassignment Rule and Physician Self-Referral

In its comments on the Proposed Rule, the ACR offered strong support for the proposed amendments to the reassignment provisions at §424.80, as well as for the adoption of further amendments to §424.80(d) that CMS is considering. The ACR again strongly recommends that diagnostic tests in the Designated Health Services (DHS) category of radiology and certain other imaging procedures should not be excepted from those amendments. The ACR again recommends that an anti-markup provision should also apply to the reassignment of the professional component (PC) of diagnostic tests performed under a contractual arrangement and again suggests that CMS consider a larger and more appropriate minimal square footage in the Stark II regulatory definition of "centralized building" for radiology and certain other imaging procedures.

The ACR is disappointed that CMS has decided to "study the issue further and issue final regulations in the near future." The ACR is particularly concerned that CMS indicated it delayed issuing final regulations because implementing these proposals might limit the ability of some group practice arrangements to "enable Medicare beneficiaries to have the convenience of receiving medical services at one location."

The ACR believes that group practice arrangements that advocate and perpetuate self-referral improperly use the rationale of "patient convenience" to justify the need for self-referral. If, at the time of an office visit, the patient needs a urinalysis, blood count, or EKG, these tests can be done immediately and greatly enhance patient convenience. However, if the patient needs a CT, MRI, or PET scan, there are several factors that make it improbable, if not impossible, for the test to be done at the same visit, thus negating any "convenience of receiving medical services at one location." From a clinical perspective, CT, MRI, and PET all require some degree of patient preparation, including

bowel opacification and fasting prior to contrast injection. Many times, the imaging equipment owned by the self-referring practice is at an entirely different location from the physician's office. Additionally, scheduling conflicts in a busy self-referring practice may make it difficult for patients to receive these examinations on the same day as their office visit. Therefore, for the vast majority of patient office visits, any necessary CT, MRI, or PET scans are scheduled at a different time. In fact, the patient's convenience could actually be enhanced if the hospital's or radiologist's imaging facility were nearer their home than the office of the self-referring group practice arrangement.

The ACR strongly urges CMS to adopt its proposed changes to the reassignment rules through final regulations in the near future. The ACR is willing to work closely with CMS to further define how changes to the reassignment rules can further reduce inappropriate imaging referral practices and also provide better care for patients.

Practice Expense

The ACR appreciates CMS accepting its comments to run the practice expense methodology independently from the Five Year Review budget neutrality step.

The ACR continues to be concerned with the practice expense rate per physician hour for radiology and how that rate was calculated by the Lewin Group. In addition to the additional part-time hours that were added to the formula, the ACR is concerned that there are calculation errors similar to those that took place in the calculations of the radiation oncology PE/hr rate.

The ACR would like to work with CMS in the coming year to address this issue and explore its further resolution to achieve a more accurate PE/hr for radiology.

Deficit Reduction Act: Reduction in TC for Imaging Services Under the PFS to OPD Payment Amount and Payment for Multiple Imaging Procedures for 2007

The ACR appreciates CMS applying the multiple procedural reduction prior to the DRA cap for the 2007 Medicare Physician Fee Schedule (MPFS) payments. Applying this step prior to the DRA comparison mitigates the "double hit" that was of concern to ACR. We very much appreciate your consideration of the data and arguments ACR presented within the past year. The ACR also appreciates CMS' careful consideration of ACR's data and the decision not to raise the reduction to 50 percent for 2007. However, since the Ambulatory Payment Classification (APC) payment inherently accounts for the cost savings of contiguous imaging procedures, the ACR remains concerned that the 25 percent reduction for many contiguous imaging procedures, even if applied before the DRA comparison, will reduce payment below the APC level and thus result in an inappropriate level of reduced payment.

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Exclusion of Carrier Priced Services

The ACR strongly disagrees with CMS' interpretation that the Deficit Reduction Act legislation applies to carrier priced services. Section 5102 of the DRA requires a comparison of the APC payment to the technical component (TC) payment established under the MPFS. However, since CMS has elected not to establish a technical component (TC) payment for PET and PET/CT under the MPFS, there is no comparison to be made. In addition, the statute requires the Secretary initially to determine whether the PFS amount for the imaging service exceeds the OPPS amount without regard to geographic adjustment. If it does, then the payment (based on the APC amount) is adjusted by the geographic adjustment factor. Since geographical adjustments are applied to services with established RVUs and not to carrier-priced services, we continue to believe that the DRA does not apply to carrier-priced services. With regard to Category III codes, there is an imbalance between the hospital outpatient prospective payment system (HOPPS) and the MPFS with respect to how these codes are handled. Category III codes are meant to be carrier priced while data on costs and indications are collected. The MPFS allows for this carrier independent data to be collected. However, Medicare chooses to place Category III codes in APCs under HOPPS. Setting a preliminary lower price on these procedures in hospital outpatient and thus the office setting establishes a troubling precedent on how their corresponding Category I codes might be valued in the future. This pricing effect on new technologies is inaccurate and inappropriate.

The ACR urges CMS to reconsider its apparent broadening of the intent of the DRA legislation and the negative effect that broadening will have on the well-established process of accumulating data to accurately value new technology.

Global Period for Remote Afterloading High Intensity Brachytherapy Global Procedures

The ACR appreciates CMS' decision to finalize its proposal to change the global period for codes 77781, 77782, 77783 and 77784 from a 90 day to XXX global period.

Geographic Practice Cost Indices (GPCI)

Although the current floor of 1.00 for the work GPCI will be extended one more year (under a provision of the Tax Relief and Health Care Act of 2006), the ACR remains concerned with the practice expense and malpractice GPCIs for Puerto Rico (and the work GPCI that would otherwise have applied absent the recent Congressional intervention), since low GPCI values make it difficult for physician practices in Puerto Rico to retain professional and technical staff, who are being recruited away by physician offices from locales with much higher GPCIs. The ACR understands that Medicare will be looking into the GPCI issues further this year and ***encourages CMS to consider alternative data sources or ways to configure payment localities that would address the problem with the GPCI for Puerto Rico.***

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Conclusion

Thank you for the opportunity to comment on this final rule. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues with respect to radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

cc: Herb Kuhn, CMS
Ken Simon, MD, CMS
Carolyn Mullen, CMS
Pamela West, CMS
Rick Ensor, CMS
Ken Marsalek, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
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December 28, 2006

Ms. Amy Bassanno
Director of Practitioner Services
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
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7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Bassanno:

RE: Comments on Interim Relative Value Units (RVUs) for Selected Procedure Code CPT 22857

DePuy Spine, Inc. is an operating company of DePuy, Inc. one of the world's leading designers, manufacturers and suppliers of orthopedic devices and supplies. We are known throughout the medical world for the development of innovative solutions for a wide range of spinal pathologies.

The purpose of this letter is to seek clarification regarding the recent adoption of RVUs specific to code 22857. It is submitted as a formal comment in accordance with the instructions for submitting comments on the Final Rule With Comment Period published in the December 1, 2006 Federal Register (71 FR 69624). It appears that the assigned values for this code were significantly underestimated to the point where it may limit patient access.

CPT	Description	Work RVU	Facility PE RVU	Malp RVU	Total RVU
22857	Total disc arthroplasty (artificial disc), anterior approach, including diskectomy to prepare interspace (other than for decompression), lumbar, single interspace	26.93	8.80	3.56	39.29

In the IDE study, the CHARITÉ Artificial Disc was compared to an anterior interbody fusion (ALIF) with BAK and an autograft. The amount of mean operative time (minutes) to perform the surgical procedures was 111 minutes for CHARITÉ Artificial Disc and 114 minutes for the ALIF. There are three codes that describe the ALIF procedure:

CPT	Description	Work RVU	Facility PE RVU	Malp RVU	Total RVU
22558	Arthrodesis, anterior interbody technique, including minimal disckectomy to prepare interspace (other than for decompression), lumbar	23.33	12.86	3.16	39.35
22851	Application of intervertebral biomechanical device(s)	6.70	3.18	1.49	11.37
20937	Autograft (including harvesting); local, obtained from same incision	2.79	1.37	.54	4.70
	Total	32.82	17.41	5.19	55.42

There are additional components to the CHARITÉ Artificial Disc procedure that should also be taken into account:

- A greater degree of clinical decision-making to determine appropriate patients. The physician must make a differential diagnosis from the subset of fusion patients and determine who is clinically appropriate and would best benefit from this therapy, as well as direct a separate treatment plan for the patient.
- The CHARITÉ Artificial Disc surgical procedure requires higher-level technical skills.
- The surgeon must thoroughly prepare the intervertebral disc space for placement of the CHARITÉ Artificial Disc by completely removing all natural disc material in order to ensure proper placement. Additionally, the posterior longitudinal ligament must be exposed, and the vertebral body itself must be specifically prepared to accept the endplate for the CHARITÉ Artificial Disc.
- There is an increase in the surgeon's practice overhead expense from the increased staff time spent on securing prior authorization for appropriate patients.

For these reasons cited above, the final RVUs for lumbar total disc arthroplasty were expected to be higher than the total RVUs assigned to the comparator (55.42 RVUs). Instead, the final 2007 total RVUs for the lumbar total disc arthroplasty (39.29 RVUs) was **29% LESS** than the comparator.

Upon further research, the Work RVU for lumbar arthroplasty (22857) recognized a 15.4% increase over the RVU for an arthrodesis, anterior interbody technique (22558). However, the application of an intervertebral biomechanical device (22851) was excluded in the RVU calculation for 22857. This omission represents **11.37 Total RVUs missing from 22857**. In addition, the Total RVUs associated with the autograft (20937) was also excluded. **This omission represents another 4.70 Total RVUs missing from 22857**. The comparative value should be aligned with the existing coding scenario for an ALIF.

There is a 32% (4.06 RVUs) difference between the Facility Practice Expense for 22857 (8.80 RVUs) compared to 22558 (12.86 RVUs). CMS offers no explanation for this disparity in the practice expense RVUs for these two similar codes. In fact, as just noted, one would expect code 22857 to have higher practice expense RVUs after also accounting for the practice expenses associated with code 22857.

DePuy Spine analyzed the specialty mix data from the top 57 surgeons in 2006. This data represents 40% of total CHARITÉ Disc procedures. Based on this information, the specialty mix is 83% orthopaedic surgeons and 17% neurosurgeons. The practice expense per hour for orthopaedic and neurosurgery is $138 and $105, respectively. We request that CMS adjust the Facility Practice Expense calculation to properly reflect the appropriate utilization mix.

Recommendations

We recommend that CMS appropriately value the RVUs for Total disc arthroplasty (artificial disc), anterior approach, including diskectomy to prepare interspace (other than for decompression), single interspace, lumbar (22857) to account for an additional 11.27 RVUs for the application of an intervertebral biomechanical device (22851) plus 4.70 RVUs for the work associated with the autograft procedure, and 4.06 RVUs in the Facility Practice Expense. The result would be that the total RVUs for 22857 become 59.42 = 39.29 + 11.37 +4.70+ 4.06. Lastly, we remain open to extending the dialog during the review period with a follow up meeting, to better understand how CMS derived at the published values

Thank you for the opportunity to provide commentary on the interim relative value units for lumbar total disc arthroplasty.

Sincerely,

Richard M. Toselli, MD, MBA
Worldwide Vice President, Clinical Evidence and External Relations
DePuy Spine, Inc.

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ACP

AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

December 21, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore MD 21244-1850

RE: CMS-1321-FC

Dear Ms. Norwalk:

The American College of Physicians (ACP) is pleased to have the opportunity to comment on the final rule on revisions of payment policies for physicians in the Medicare program (CMS-1321-FC).

Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
ACP agrees with the Centers for Medicare and Medicaid Services (CMS) decision to implement its proposal to calculate indirect practice expense using a bottom-up approach. This new approach should help to improve the transparency of the inputs into physician payments. ACP also agrees with the decision to implement the proposal to phase-in the practice expense calculation changes over a four-year period. ACP believes this phased approach will allow physicians to adjust to any drastic changes in payment that result from the new methodology.

ACP understands the CMS decision to accept the supplementary practice expense surveys submitted by specialties. These specialties met the requirements set out by CMS. However, it is important to note the disparity in indirect practice expense that can be seen between those specialties that completed supplemental surveys and those that did not. This large disparity once again highlights the importance of the upcoming multi-specialty practice expense survey coordinated by the American Medical Association (AMA). ACP was pleased to see CMS continuing to support this effort through comments in the final rule.

ACP has made a financial commitment to this multispecialty practice expense survey in order to ensure that all specialties receive fair treatment when determining indirect practice expense. This is of utmost importance in maintaining an appropriate relative value system that is fair to all specialties. ACP looks forward to reviewing the results of the pilot test of this survey at upcoming meetings and the eventual inclusion of this data in the practice expense calculation.

ACP disagrees with the CMS decision to use adjusted work RVUs in calculating indirect practice expense. This decision further devalues physician work that is already devalued by the decision to adjust the work for budget neutrality in the first place. This issue was made particularly complex by what was termed an error in the preamble of the rule which stated that CMS decided to use unadjusted RVUs. CMS made the decision to publish unadjusted RVUs with the understanding that these are the true relative values of these codes. Given the mistake in printing and the recognition of the unadjusted values as the true relative values, ACP urges CMS to reverse its published correction and use unadjusted work values in calculating indirect practice expense.

ACP, in its comments on the June 29, 2006 proposed rule (CMS-1512-PN) recommended that CMS implement two proposals regarding practice expense on which it had requested guidance in the past. ACP recommended that CMS reduce the 11% interest assumption used in pricing equipment to more closely reflect market conditions. ACP also recommended that CMS change the utilization rate assumption of 50% to reflect the much-higher utilization of very expensive equipment. CMS, in its final rule, notes that the Medicare Payment Advisory Commission (MedPAC) has also made such a recommendation. ACP believes that this issue is still very important.

ACP is pleased that CMS has committed to examine the issue of this element of the methodology in its comments attached to the final rule. ACP urges CMS to implement these changes as it continues to refine the practice expense methodology. The interest rate assumption should be greatly reduced to reflect market rates for the costs of capital rather than the 11% assumption that is currently used. The utilization assumption for most high-cost equipment should be increased based on a review of the actual utilization of this equipment which is likely much higher. These changes will allow physicians to receive a more accurate payment for services and reduce incentives for physicians to invest in high-expense equipment beyond its clinical utility.

Deficit Reduction Act (DRA)

ACP requests that CMS continue to closely examine the issue of imaging payments and the reductions in payments for contiguous body parts. ACP notes that MedPAC requested more information about the analysis presented to CMS which triggered the decision to continue with a 25% reduction in payment instead of a 50% reduction, but further information was not provided in the final rule. ACP finds it unfortunate that savings achieved through these reductions will not be returned to physicians in the form of a budget neutrality adjustment but continues to believe that all services should be reimbursed fairly.

ACP supports the CMS decision to implement the ultrasound abdominal aortic aneurysm (AAA) benefit as proposed. This newly reimbursed service should be of great use to those who are eligible for it. However, ACP repeats its concerns that fewer beneficiaries will receive this benefit than appropriate because it is tied to the Initial Preventive Physical Examination (IPPE).

As has been stated in the past, this code is undervalued and confusing to physicians and for those reasons it is rarely used. If CMS increases the value of the IPPE to fully recognize the work and other inputs, it will increase beneficiary access to this important service and any services that are tied to it.

ACP also supports the required elimination of the deductible for colorectal screening, but once again notes that counseling provided to patients prior to covered screenings is not a covered service. ACP is encouraged by the recent announcements by CMS highlighting interest in prevention, but requests that all services related to preventive services be properly paid. By recognizing the important work of primary care physicians in contributing to the overall care of Medicare beneficiaries, the program can see improved health in those patients and potential cost savings as more preventive benefits are used.

Health Care Information Transparency Initiative

ACP supports the initiative to increase the transparency of health care costs to patients. Patients should always have the opportunity to understand the costs of the services that will be provided to them in a healthcare setting. However, after reviewing the material that is intended to serve as information for patients on the CMS website released after the close of the comment period, ACP is concerned that this information does not meet the CMS stated requirement of being "useful". ACP understands that this is merely a first step in this initiative, but the information presented as an example of prices for physician services would be unintelligible to all but the savviest Medicare beneficiary. In order for this effort to be successful, the information presented must be understandable to the ordinary beneficiary that is faced with making health care choices.

Even if CMS can improve pricing information to the point that the average beneficiary can understand it, there is still much progress to be made. Understanding the cost of a single service will not necessarily lead a beneficiary to make health choices that are most beneficial to the goals of the individual. In order for patients to make the best decisions, there must be an understanding of the total cost of care, a far more complex number than the payment assigned to a single CPT code. Obtaining this information will take time and ACP encourages CMS to be diligent in pursuing the goal of making accurate and useful information available to beneficiaries.

Five-Year Review of Work Relative Value Units

Evaluation and Management Services

ACP commends CMS for its decision to implement its changes to the values of evaluation and management services as proposed. As CMS noted, there was strong support from many commenters in support of this change, including both the RUC and MedPAC. ACP also commends CMS for being careful to reject criticism from other parties and their flawed analysis that was not appropriate for cognitive services. The recognition that cognitive services must be

valued in a way that is appropriate for the patients of today was a very important one. ACP was pleased to see that CMS recognized the increasing disease burden of the Medicare patients.

ACP agrees with the CMS decision to not accept a recommendation to transition the E/M changes over time. As discussed in the final rule, work changes have never been transitioned in the past and there is no compelling argument to start doing so now.

ACP urges CMS to adjust the values assigned for End Stage Renal Disease (ESRD) services to reflect the updated values in E/M services used as building blocks for the values of these codes as was suggested in ACP's comments on the proposed rules. The devaluation of these codes is not appropriate and they should be increased to match those codes on which they were based.

ACP supports the CMS decision to include nursing facility codes, home visit codes, and domiciliary codes in the 5 year review based on data that will be presented in 2007. ACP looks forward to reviewing this data during the RUC process.

Cardiothoracic Surgery
ACP disagrees with the CMS decision to not finalize its proposal on the work values of cardiothoracic surgery codes. As CMS notes in both the proposed and the final rule, the work values for these codes were not established using the standard survey process. They were instead established using data from the Society of Thoracic Surgery (STS) database. ACP acknowledges the value of the STS database for patient quality purposes and as a supplement to RUC work surveys. However, in a relative value system, it is of utmost importance to maintain the same tool in determining the work values for codes. Based on the comments in the proposed and final rule, CMS seems to agree that the methodology used for these codes is flawed, but then makes the decision to accept higher work values. ACP urges CMS to maintain the standard of a single process that will maintain the appropriate relativity of the system.

Other Issues under the Five Year Review
ACP appreciates the interest of CMS in further examining the issue of the appropriateness of paying for services under 10 or 90 day global periods. Physicians should be appropriately reimbursed for the work that they perform. ACP again urges CMS to perform a study to determine if the visits contained in the surgical packages are consistent with the number of visits performed on a typical patient. The study should also determine the cost of additional administrative work for CMS and any unintended consequences of any potential changes to the global periods.

Budget Neutrality
ACP strongly disagrees with the CMS method of achieving budget neutrality necessitated by the increases in values that were part of the five year review. Nearly all of the physician organizations disagreed with the CMS proposal to adjust work downward in order to achieve

budget neutrality. An adjustment to the conversion factor would be preferable because it recognizes that budget neutrality is a fiscal issue and not an issue of relativity. ACP notes that one of the stated reasons that CMS choose to implement this proposal was because of the anticipated negative update to the conversion factor. With the passage of the Tax Relief and Health Care Act of 2006 after the release of the final rule, there will not be a negative update on the conversion factor. ACP urges CMS to recognize this change and make the budget neutrality adjustment to the conversion factor instead of to work.

ACP does appreciate the CMS commitment to publish the unadjusted RVUs, but is concerned that private payers will follow the lead of CMS and use adjusted RVUs to calculate payment. ACP strongly encourages CMS to reexamine this issue and make budget neutrality adjustments through the use of the conversion factor.

Review Process
ACP agrees with the comment of MedPAC stating that there are not appropriate mechanisms within the current system to identify overvalued codes. While the 5 year review process is very good at identifying undervalued codes, there is no incentive to identify misvalued codes. ACP supports the RUC efforts to examine this issue further and asks CMS continue to pay attention to this very serious issue.

In addition to the RUC review of this issue, ACP reiterates its recommendation for an outside panel to be responsible for investigating the issue of overvalued codes. This independent expert panel could best be charged with examining these issues.

Interim Relative Value Units

Work Relative Value Unit Refinement of Interim Relative Value Units
ACP commends CMS for publishing the RVUs for all services, including those that are not covered by Medicare. Most private insurers in the country use some form of RBRVS to establish payments and publishing all of the available data will make the payments for all services consistent with the values determined by the RUC. ACP asks that CMS continue to publish the values for all services on an annual basis.

Establishment of Interim Work Relative Value Units for New and Revised Physician's Current Procedural Terminology Codes
ACP strongly disagrees with the CMS decision to consider anticoagulation management codes (99363 and 99364) to be bundled into the work of evaluation and management codes. The initial impetus for the creation of this code was the statement by CMS that these services were not managed as well as they should be and that the existing coding structure failed to provide incentives to optimize care. In reaction to this, ACP created a code that would recognize the very important work that a physician does in managing this very serious medication regimen.

The complete range of this work is not reimbursed under the current system. During the creation of the code, the CPT editorial panel and the RUC were very careful to create protections in the code that would prevent work from anticoagulation management being included in selecting the level of evaluation and management codes. CMS did not offer any explanation for its decision to bundle these codes into E/M services. The new CPT codes are recognition of the important work of managing serious disease and the CMS decision to not pay for this service could have a devastating impact. ACP reviewed a proposed Correct Coding Initiative (CCI) edit to be used to prevent the billing of a 99211 on the same day of these codes. ACP opposed this edit based on the possibility that such an event could take place on the rare occasion, but will support the edit if it will prevent any potential fraud that CMS envisions. ACP strongly encourages CMS to reverse its decision and pay for these services in the future.

ACP appreciates the opportunity to comment on this final rule. If you have any questions, please contact Brian Whitman, Senior Analyst for Regulatory and Insurer Affairs at (202) 261-4544 or bwhitman@acponline.org. Thank you.

Sincerely,

Joseph Stubbs, MD
Chairman, Medical Service Committee

AMA
AMERICAN
MEDICAL
ASSOCIATION

December 21, 2006

Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B.

Dear Ms. Norwalk:

The RUC Health Care Professionals Advisory Committee (HCPAC) Review Board appreciates the opportunity to provide comments on the notice of Final Rule for the 2007 Medicare Physician Payment Schedule, published in the December 1, 2006 *Federal Register.*

First, the HCPAC sincerely appreciates that the Centers for Medicare and Medicaid Services (CMS) has accepted the HCPAC recommended work relative value units (RVUs) for the medical nutrition therapy codes.

Five-Year Review Refinement of Work Relative Value Units (p. 69719)
Second, the HCPAC Review Board disagrees with CMS' decision to reject the HCPAC recommended work values for five CPT codes predominantly reported by podiatry: 10060, 11040, 11041, 11042 and 29580. These codes underwent additional review as part of the CMS refinement panel process, and while the HCPAC appreciates that slight modifications were made to the work RVUs for codes 10060 and 11040, the HCPAC would like to reiterate that we continue believe that the original HCPAC recommendations were appropriate and should have been adopted.

The HCPAC believes that the American Podiatric Medical Association (APMA) presented valid surveys which were discussed in detail. Although the survey data indicated decreases in the times associated with these services, the intensity measures must also be considered in determining RVUs. The HCPAC agreed that the valuation of these services were incorrect due to a flawed methodology used in the previous Harvard valuation for all six codes. The HCPAC urges CMS to not rely solely on a comparison between the existing Harvard-based times and the RUC surveyed times, but the recent survey data since it accurately reflects the current practice of these services. The HCPAC requests that the values recommended for all six codes reviewed by the HCPAC should be accepted and urge CMS to reconsider its decision on these five codes predominantly reported by podiatry. *Attached is a detailed comment letter from APMA.*

The following table summarizes the outcome of the third Five-Year Review process for the six codes presented by APMA:

Code	2005 Work RVU	HCPAC Recommended Work RVU	CMS Proposed Work RVU	CMS Final Work RVU
10060	1.17	1.50	1.17	1.19
11040	0.50	0.55	0.48	0.50
11041	0.82	0.82	0.60	0.60
11042	1.12	1.12	0.80	0.80
11730	1.13	1.10	1.10	1.10
29580	0.57	0.60	0.55	0.55

The RUC HCPAC appreciates your consideration of these comments. We look forward to work with CMS to further improve the RBRVS. If you have any specific questions regarding our recommendations, please contact Susan Clark at the AMA at (312) 464-4308 or via e-mail at Susan.Clark@ama-assn.org.

Sincerely,

Arthur Traugott, MD

Mary Foto, OTR

cc: HCPAC Participants
Edith Hambrick, MD
Ken Simon, MD
Carolyn Mullen

December 14, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1321-FC
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS-1321-FC
Comments on Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; Final Rule (71 Fed. Reg. 69624, December 1, 2006)

Dear Ms. Norwalk:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's foot and ankle surgeons, is pleased to submit comments on the final rule with comment period that includes discussion of the five-year review of work relative value units.

Five-Year Refinement of Relative Value Units (p. 69719)
The APMA is disappointed that the Centers for Medicare & Medicaid Services (CMS) did not adopt the original Health Care Professionals Advisory Committee (HCPAC) work relative value unit (RVW) recommendations for codes 10060, 11040, 11041, 11042 and 29580. These codes underwent additional review as part of the CMS refinement panel process, and while APMA appreciates that slight modifications were made to the RVWs for codes 10060 and 11040, we continue to believe that the original HCPAC recommendations were appropriate and should have been adopted. The following table summarizes the outcome of the 5-year review process for the 6 codes presented by APMA that went through the five-year review at CMS's request:

Code	2006 RVW	HCPAC RVW	CMS Proposed RVW	CMS Final RVW
10060	1.17	1.50	1.17	1.19
11040	0.50	0.55	0.48	0.50
11041	0.82	0.82	0.60	0.60
11042	1.12	1.12	0.80	0.80
11730	1.13	1.10	1.10	1.10
29580	0.57	0.60	0.55	0.55

In describing the refinement process, CMS states:

> "We convened a multi-specialty panel of physicians to assist us in the review of comments. We submitted 30 codes for evaluation by the panel. The panel discussed the work involved in each procedure under review in comparison to the work associated with other services on the fee schedule. We assembled a set of reference services and asked the panel members to compare the clinical aspects of the work for services they believed were incorrectly valued to one or more of the reference services. In compiling the reference set, we attempted to include: (1) Services that are commonly furnished for which work RVUs are not controversial; (2) services that span the entire spectrum of work intensity from the easiest to the most difficult; and (3) at least three services performed by each of the major specialties so that each specialty would be represented. Group members were encouraged to make comparisons to these reference services. The intent of the panel process was to capture each participant's independent judgment based on the discussion and his or her clinical experience. Following the discussion for each service, each participant rated the work for that procedure. Ratings were individual and confidential; there was no attempt to achieve consensus among the panel members.
>
> "We then analyzed the ratings based on a presumption that the RVUs published in the proposed notice were correct. To overcome that presumption, the inaccuracy of the proposed RVUs had to be apparent to the broad range of physicians participating in the panel. Ratings of work were analyzed for consistency among the groups represented on the panel. In general terms, we used statistical tests to determine whether there was enough agreement among the groups on the panel, and if so, whether the agreed-upon RVUs were significantly different from the proposed RVUs that appeared in the June 29, 2006 proposed notice to demonstrate that the proposed RVUs should be modified. We did not modify the RVUs unless there was a clear indication for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group, and looked for agreement among the remaining groups as to the basis for new RVUs. We used the same methodology in analyzing the ratings that we first used in the refinement process for the CY 1993 physician fee schedule final rule published in the November 25, 1992 Federal Register which described the statistical tests in detail (57 FR 55938).
>
> "Our decision to convene a multi-specialty panel of physicians and to apply the statistical tests described above in this section was based on our need to balance the interests of those who commented on the work RVUs against the

> redistributive effects that would occur in other specialties. Of the 30 codes reviewed by the multi-specialty panel, all were the subject of requests for increased values. Of the proposed codes that were reviewed, 11 increased, and 19 were not changed."

The APMA was under the impression that CMS would discuss the results of the refinement panel in greater detail in the final rule and would provide the specifics of each code reviewed, including the recommendations submitted by the panel members. We are interested in analyzing those results as they pertain to each of our codes subjected to refinement and request that CMS provide us with the detailed information we are seeking.

Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

David M. Schofield, DPM
President

AMA
AMERICAN
MEDICAL
ASSOCIATION

December 21, 2006

Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B.

Dear Ms. Norwalk,

The American Medical Association/Specialty Society RVS Update Committee (RUC) appreciates the opportunity to provide comments on the Final Rule for the 2007 Medicare Physician Payment Schedule, published in the December 1, 2006 *Federal Register*. On November 3, 2006, the RUC submitted its initial comments on this Rule. We continue to support these comments and have attached them to this letter for your review. At this time, we would like to provide additional comments regarding this Rule.

Five Year Review - 2005

The Centers for Medicare and Medicaid Services (CMS) announced that the agency had reviewed all of the RUC's recommendations and accepted 95 percent of the RUC recommended values. We are particularly pleased that CMS has accepted the RUC's recommendations for the Evaluation and Management procedures. Furthermore, the RUC recommended and CMS accepted that the full increase of the E/M be incorporated into the surgical global periods for each CPT code with a global of 010 and 090. As you are aware, the RUC and its participants put a great deal of time and effort into developing recommendations that were equitable across all specialties. This arduous task could not have been accomplished without great support of the RUC members, specialty society staff and the input from CMS representatives. We appreciate CMS' validation of these efforts.

Unfortunately, there were several codes which the RUC recommendations were not accepted by CMS. These codes include the following:

22612 *Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)* - CMS proposes 21.79 work RVUs for this code, rather than accept the RUC recommendation of 22.00 work RVUs.

31360 *Laryngectomy; total, without radical neck dissection* – CMS proposes 26.22 work RVUs for this code, rather than accept the RUC recommendation of 28.00 work RVUs

31365 *Laryngectomy; total, with radical neck dissection* - CMS proposes 35.00 work RVUs for this code, rather than accept the RUC recommendation of 37.00 work RVUs

31367 *Laryngectomy; subtotal supraglottic, without radical neck dissection* - CMS proposes 27.00 work RVUs for this code, rather than accept the RUC recommendation of 27.36 work RVUs

31368 *Laryngectomy; subtotal supraglottic, with radical neck dissection* - CMS proposes 30.50 work RVUs for this code, rather than accept the RUC recommendation of 36.00 work RVUs

31390 *Pharyngolaryngectomy, with radical neck dissection; without reconstruction* - CMS proposes 38.33 work RVUs for this code, rather than accept the RUC recommendation of 40.00 work RVUs

31395 *Pharyngolaryngectomy, with radical neck dissection; with reconstruction* - CMS proposes 39.50 work RVUs for this code, rather than accept the RUC recommendation of 44.00 work RVUs

34201 *Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision* - CMS proposes 17.94 work RVUs for this code, rather than accept the RUC recommendation of 18.31 work RVUs

35102 *Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, abdominal aorta involving iliac vessels (common, hypogastric, external)* - CMS proposes 34.00 work RVUs for this code, rather than accept the RUC recommendation of 36.28 work RVUs

35556 *Bypass graft, with vein; femoral-popliteal* - CMS proposes 25.00 work RVUs for this code, rather than accept the RUC recommendation of 27.25 work RVUs

35566 *Bypass graft, with vein; femoral-anterior tibial, posterior tibial, peroneal artery or other distal vessels* - CMS proposes 30.00 work RVUs for this code, rather than accept the RUC recommendation of 32.00 work RVUs

35585 *In-situ vein bypass; femoral-anterior tibial, posterior tibial, or peroneal artery* - CMS proposes 30.00 work RVUs for this code, rather than accept the RUC recommendation of 32.00 work RVUs

42845 *Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with other flap* - CMS proposes 29.00 work RVUs for this code, rather than accept the RUC recommendation of 32.00 work RVUs

44120 *Enterectomy, resection of small intestine; single resection and anastomosis* - CMS proposes 18.00 work RVUs for this code, rather than accept the RUC recommendation of 20.11 work RVUs

44130 *Enteroenterostomy, anastomosis of intestine, with or without cutaneous enterostomy (separate procedure)* – CMS proposes 20.00 RVUs for this code, rather than accpet the RUC recommendation of 20.87 work RVUs

47600 *Cholecystectomy*; - CMS proposes 15.85 work RVUs for this code, rather than accept the RUC recommendation of 15.88 work RVUs

63048 *Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis)), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)* - CMS proposes 3.47 work RVUs for this code, rather than accept the RUC recommendation of 3.55 work RVUs

95872 *Needle electromyography using single fiber electrode, with quantitative measurement of jitter, blocking and/or fiber density, any/all sites of each muscle studied* - CMS proposes 2.88 work RVUs for this code, rather than accept the RUC recommendation of 3.00 work RVUs

The RUC supports its recommendations for these procedures and requests that CMS further reconsider these issues. We urge you to accept all RUC recommendations.

In preparation for the fourth Five Year Review, which CMS will call for comments November 1, 2009, the RUC formed the *Five-Year Review Identification Workgroup* to identify potentially misvalued services using objective mechanisms for reevaluation during the upcoming Five-Year Review. The need for objective review of potential misvaluation has been a priority of the RUC, CMS and MedPAC in recent years.

The RUC will rely on the recommendations of this Workgroup, based on established objective criteria, to identify codes that will be considered for reevaluation in the upcoming Five-Year Review. The Five-Year Review Identification Workgroup develops and maintains processes associated with the identification of services that meet various objective and data-derived criteria that may indicate potential misvaluation. These criteria include, but are not limited to services that have evolved in primary site of service since their inception and original valuation, services that may or may not be appropriately bundled, and services utilizing "new technology." Already, CMS has provided very valuable data that the Workgroup will rely on for portions of its review. We appreciate the cooperation of CMS and hope to continue to work collaboratively with the Agency to ensure the efficacy of the Five Year Review Process as well as the integrity and relativity of the entire RBRVS.

New and Revised Process: CPT 2007

The Centers for Medicare and Medicaid Services (CMS) announced that the agency had reviewed all of the RUC recommendations and accepted 98 percent of the RUC recommended values. The RUC sincerely appreciates the confidence that CMS has displayed in our process. We also acknowledge the valuable contribution of your staff in attending and observing our meetings.

However, there are four codes which the RUC recommendations were not accepted by CMS. These codes include:

94005 *Home ventilator management care plan oversight of a patient (patient not present) in home, domiciliary or rest home (eg, assisted living) requiring review of status, review of laboratories and other studies and revision of orders and respiratory care plan (as appropriate), within a calendar month, 30 minutes or more* – The RUC recommended value is 1.50 RVUs

96040 *Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family* – The RUC recommended only practice expense inputs for this procedure

99363 *Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements* - The RUC recommended value is 1.65 RVUs

99364 *Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; each subsequent 90 days of therapy (must include a minimum of three INR measurements)* - The RUC recommended value is 0.63 RVUs

CMS determined that these four codes should be bundled into the evaluation and management services and offered no rationale for this decision. The RUC respectfully disagrees with this determination and strongly believes that each of these procedures is a separate and distinct service not adequately described in the evaluation and management services.

Specifically, the anti-coagulant management codes were created to address a concern from 2001 when the Centers for Medicare and Medicaid Services (CMS) stated that the standard of care for anticoagulant services was suboptimal and the current payment policy requires the physician to have the beneficiary make an office visit to discuss prothrombin time tests results and necessary adjustments to receive separate payment. Although it is clinically optimal for a physician to discuss results with a patient and make an adjustment during a face-to-face encounter under some circumstances, physicians often engage in these activities outside of a face-to-face encounter with the patient. The CPT Editorial Panel agreed with the specialty that bundling this post service time into the payment for the visit is unfair when physicians are managing patients on long-term anticoagulants. In addition, the Panel believed that CMS policy provides inadequate avenues for physicians to be paid for managing patients on long term anticoagulant may contribute to the problem of underutilization of anticoagulant drugs that has adverse effects on the health of patients. Failure to receive anticoagulant drugs when indicated can increase patient risk of thrombosis and embolism, and under- or over-anticoagulation can increase patient risk of bleeding. The CPT Editorial Panel discussed the issue at its February 2006 meeting and created two new codes to allow the reporting of anticoagulant management services. To ensure appropriate utilization of these codes, the Panel added minimum International Normalized Ratio (INR) measurements, eight for the initial anticoagulant management and three for subsequent therapy, and stated that this service cannot also be reported with another Evaluation and Management (E/M) code. The RUC strongly urges CMS to changes the status indicator for all of the aforementioned codes to "active" and accept the associated RUC recommendations.

Moderate Sedation (99143-99150)

In the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) comment letter regarding the NPRM from August 22, 2006, we urged CMS publish RVU recommendations for all services whether or not they are covered. The RUC identified 31 services that have been reviewed by the RUC, yet were not included in the Medicare Physician Payment Schedule. In the Final Rule, CMS indicated that it had accepted the RUC's recommendation to publish the RVUs for these services regardless of coverage determination. Thank you for accommodating our request.

The moderate sedation codes continue to be included on the fee schedule as Status Indicator "C" (Carrier Priced), with no published RVUs. Given CMS' direct involvement in the development of these codes, it disappoints us that the Status Indicator for the codes is "C." We urge you to accept the April 2005 RUC recommendations for these services. If CMS, would like further RUC review of this issue, the RUC would be able to accommodate such request at its April 2007 RUC Meeting.

In its November 21, 2005 *Federal Register* 2006 Medicare Physician Fee Schedule comments, CMS stated that it was "uncertain whether the RUC assigned values are appropriate and has carrier priced these codes in order to gather information for utilization and proper pricing." While we appreciate CMS' reconsideration of paying for sedation services not previously covered and understand this is an interim position, we request that CMS consider the following arguments in revising its position.

These CPT codes (99143-99150) were surveyed by several specialty societies in order to provide the RUC with data necessary to appropriately value the service. Codes were developed to simplify reporting these services into age-specific categories. The RUC-recommended values for these six codes were based on valid surveys and carefully vetted through the RUC process. We are confident in the accuracy of the values assigned. While CMS has assigned these codes to Status Indicator "C," the RUC believes that they should be listed with Status Indicator "A" (Active) and their RUC-recommended RVUs published.

Providing moderate sedation to patients undergoing certain outpatient procedures requires an enhanced level of provider skill and training and incurs additional medical-legal liability. Compared to patients not receiving sedation care, it is also associated with greater patient satisfaction and possibly improved outcomes. Additionally, moderate sedation often produces cost savings over similar procedures provided with anesthesia care in an operating room. Furthermore, the far-reaching shortage of pediatric anesthesiologists at children's hospitals has created the need for moderate sedation services provided by other hospital-based physicians. In most metropolitan areas of the United States, these children's hospitals form the safety net for subspecialty care provided to children in the Medicaid program. This critical service is directly supported by the publication of relative values of these codes.

Appendix G ("Summary of CPT Codes That Include Moderate Sedation") in the CPT manual was developed to identify services where sedation is an inherent part of the procedure. We firmly believe that any service performed that is *not* listed in Appendix G should be appropriately paid

when reported with a moderate sedation code. There is significant additional cognitive skill required and this is reflected in JCAHO mandates addressing specific credentialing criteria for individuals providing moderate sedation. The work involved in providing sedation is *not* included in the RVUs for any procedure not included in Appendix G and the RUC believes that physicians should be adequately compensated for providing such services.

For these reasons, the RUC respectfully requests that CMS reconsider its decision to list the moderate sedation codes as carrier-priced. We urge CMS to publish the RUC-approved RVUs and assign these codes as Status Indicator "A" (Active) codes.

CMS Requests

CMS has made requests in its *Proposed Rules* published on June 29 and August 22, 2006 and its *Final Rule* published November 1, 2006 to have several procedures reviewed for various reasons. The RUC upon receiving these requests initiated a level of interest process to determine which specialty societies had an interest in developing recommendations for these procedures. These procedures are to be presented at either the February or April 2007 RUC Meetings. These requests, CPT code numbers, rationale for request and status of presentation have been summarized in the attached table.

Carrier Priced Codes - Table 17

In the *Final Rule*, CMS states, "We are carrier-pricing the global and TC for the codes listed in Table 17. The TC is not paid in the facility setting under the PFS and the RUC did not forward recommendations in the non-facility setting because these services are performed infrequently, if at all in the non-facility setting. Work RVUs will continue to be used to establish payment for the PC." To clarify the RUC has reviewed each of these codes in this table. For the vast majority of these services, the RUC recommended that the relative values of these codes should be NA in the non-facility setting. However, we understand that the American College of Cardiology has responded to your request to review practice expense inputs for the cardiac catheterization codes and will present their recommendations at the February 2007 RUC Meeting. The RUC would also note that there are codes included in Table 17 that appear to be listed in this table in error, for example, 93503 *Insertion and placement of flow directed catheter (eg, Swan-Ganz) for monitoring purposes.* We urge CMS to issue a technical correction notice addressing this issue.

The RUC appreciates the opportunity to offer these comments to CMS. We look forward to our continued relationship to further improve the RBRVS.

Sincerely,

William L. Rich, III, MD, FACS

cc: RUC Participants

CMS Requests Status Report

Request for Review	CPT Codes	Rationale for Review	Status of Presentation
Partial Mastectomy	19301	CMS request review as part of the Five Year Review Process	To be presented at the February 2007 RUC Meeting
Proctosigmoidoscopy	45300, 45303, 45305, 45307, 45308, 45309, 45315, 45317, 45321, 45327	CMS request as part of the Five Year Review Process	To be presented at the February 2007 RUC Meeting
Anoscopy	46600, 46604, 46606, 46608, 46610, 46611, 46612, 46614, 46615	CMS request as part of the Five Year Review Process	To be presented at the February 2007 RUC Meeting
Computer-Aided Detection (CAD)	77051, 77052	CMS request to review direct PE inputs	To be presented at the February 2007 RUC Meeting
Dual-Energy X-Ray Absorptiometry	77080, 77081, 77082	CMS request to review direct PE inputs	To be presented at the February 2007 RUC Meeting
Proton Beam Treatment Delivery	77520, 77522, 77523, 77525	CMS request to review four codes to assign practice expense inputs for the non-facility setting	To be Presented at the April 2007 RUC Meeting
Remote Afterloading High Intensity Brachytherapy	77781, 77782, 77783, 77784	CMS request to review four codes due to a change in global period from 90 day to XXX, which will permit separate payment each time services are provided	Referred to CPT for Review
Eye Exams	92002-92014	CMS request as part of the Five Year Review Process	To be presented at the February 2007 RUC Meeting
Cardiac Catheterization	93501-93572	CMS request to develop direct cost inputs for these services	To be presented at the February 2007 RUC Meeting
Nursing Facility Care	99304-99318	CMS request review as part of the Five Year Review Process	To be presented at the February 2007 RUC Meeting
Domiciliary Care	99326-99337	CMS request review as part of the Five Year Review Process	To be presented at the February 2007 RUC Meeting
Home Care	99343-99350	CMS request review as part of the Five Year Review Process	To be presented at the February 2007 RUC Meeting

Gynecologic Oncology		CMS request to review supplies that should be included in the standard global package, if the specialty believes inputs are currently missing	To be presented at the February 2007 RUC Meeting

November 3, 2006

Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C5-11-24
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B.

Dear Ms. Norwalk

Thank you for the opportunity to provide initial comments regarding the November 1, 2006 Final Rule on the Medicare Physician Payment Schedule. We have identified a number of issues that we hope to see addressed in a technical correction of the final rule. These issues include corrections to the revised practice expense (PE) methodology, publication of non-covered services, and acceptance of one previous work RVU recommendation.

Revised Practice Expense Methodology

CMS has announced a new practice expense methodology, which is in summary, a blend between a "bottom up" approach and a "top down" approach. CMS will calculate direct practice expense RVUs using data refined by the RUC and its Practice Expense Review Committee. The indirect practice expenses, making up 60-70% of total payment depending upon specialty, is still based on a "top down" approach, allocating specialty level data from surveys to individual services using work RVUs and direct expenses. In the June 29, 2006 Proposed Rule's description of the methodology for calculating indirect cost PE RVUs, CMS indicates in Step 8 that the work RVU used in the allocation of indirect expenses included the separate work budget neutrality adjustment from the Five-Year Review of the work RVUs. The RUC and many other commenters objected to using budget-neutralized work relative values in the computation of practice expenses. In the Final Rule, CMS acknowledged these comments and changed the methodology, as follows:

> *Comment: Many commenters recommended that we not use the budget-neutralized work RVUs in the indirect PE allocation, but rather use the unadjusted work RVUs.*
>
> *Response: As discussed in section III.D.3. of this final rule with comment period, the BN adjustment necessitated by the 5-Year Review of work RVUs will be accomplished through the use of a separate, BN adjustor applied to the work RVUs. However, as recommended by the commenters, we will not use the budget-neutralized work RVUs to calculate indirect PE.*

However, Addendum B In this final rule reflects practice expense relative values that were computed using adjusted work RVUs. The application of budget neutrality to the work relative values has been applied and utilized in the indirect practice expense allocation, despite CMS clear written statement that this would not occur **We urge CMS to immediately correct this error and use the unadjusted work RVUS as the appropriate allocator in the methodology. We anticipate that a technical correction would be published with a revised Addendum B.**

Publishing Relative Value Units (RVUs) for Non-covered Services

In the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) comment letter regarding the NPRM from August 22, 2006, we urged CMS publish RVU recommendations for all services whether or not they are covered. The RUC identified 31 services that have been reviewed by the RUC, yet were not included in the Medicare Physician Payment Schedule. In the Final Rule, CMS indicated that it had accepted the RUC's recommendation to publish the RVUs for these services regardless of coverage determination. Thank you for accommodating our request.

However, for nine services, 38207-38215 Bone Marrow and Stem Cell Harvesting, RUC staff forwarded the incorrect RVU recommendations rather than the more recent RUC recommendation. We apologize for this error. Shortly after the submission of our comments, we located this error and made efforts to provide the correct recommendations to CMS staff on October 19, 2006. CMS staff indicated that the Final Rule was in production and the original submission of the incorrect recommendations would appear in the Rule. We understand this constraint. At this time, we ask that you publish the appropriate RUC recommended RVUs for these nine services. The RUC recommendations are attached to this comment letter.

Ventricular Restoration

In the November 1, 2006 Final Rule, CMS published the interim RVU rather than the final RUC recommended RVU for CPT code 33548, *Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedure)*. This interim recommendation was forwarded to CMS in April 2005 and the

final recommendation was forwarded in September 2005. The RUC has periodically followed an interim recommendation with a final recommendation following our September meetings. This is the case with this single code. We ask that CMS replace the interim RVU with the final RUC reviewed RVU for this service. The RUC recommendation is attached.

Other Issues

In addition to these comments, we are disappointed by the Agency's decision to apply a separate budget neutrality factor to all work RVUs rather than to the conversion factor. The RUC reaffirms its position that applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward and strongly urges CMS to instead apply any necessary adjustments to the conversion factor.

The RUC strongly objects to using work relative values as a mechanism to preserve budget neutrality. These adjustments to the work relative values cause confusion among the many non-Medicare payers, as well as physician practices, that adopt the RBRVS payment system. According to a recent survey conducted by the AMA, 77% of all public and private insurance payers rely on the RBRVS. We believe that this adjustment should have been transparent and continue to advocate that any budget neutrality adjustments be made to the conversion factor, rather than the work relative values.

Thank you for the opportunity to provide these early comments regarding the Final Rule. We appreciate your attention to these errors and look forward to the technical correction.

Sincerely,

William L. Rich, III, MD

cc: RUC Participants

attachments

AMA/Specialty Society RVS Update Committee
Summary of Recommendations

April and September 2002

Bone Marrow Procedures

Thirteen new CPT codes were added and two were deleted to provide greater granularity to accurately code the specific procedures performed for each patient receiving bone marrow or stem cell transplantation. The newer techniques used in a transplant laboratory under physician supervision are now captured in these new CPT codes. CPT codes 38205-38215 replace codes 38231 *Blood-derived peripheral stem cell harvesting for transplantation, per collection* (Work RVU = 1.50) and 86915 *Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (e.g., T-cells, metastatic carcinoma)* to allow for different types, work, and techniques now used for different types of cell harvesting and also transplant preparation as well as the critical work and techniques involved in stem cell processing prior to a Bone Marrow Transplant. Present codes 38231 and 86915 were not designed for modern procedures in bone marrow transplant and have virtually no relevance to the present stem cell harvesting and processing work and procedures. The RUC understands that these services are not commonly performed on the Medicare population and very few centers perform these services (50 centers), therefore, the smaller number of survey respondents (21) was expected.

38204 ***Management of recipient hematopoietic progenitor cell donor search and cell acquisition***
The RUC reviewed the survey results and the similarities in physician work of the reference code, 80502 *Clinical pathology consultation; comprehensive, for complex diagnostic problem, with review of patient's history and medical records* (Work RVU=1.33). The RUC believed that this service was more intense than 80502 as there was zero tolerance for error. The RUC understands that this newly reported service would be billed one time per recipient. The RUC also compared this service to CPT code 99204 *Office or other outpatient visit for the evaluation and management of a new patient* ... a level 4 new patient office visit representing 45 minutes of physician time (work RVU = 2.00). The RUC agreed that the time spent on this type of per patient management reflected the specialty's recommended 25th percentile surveyed intra-service time. The RUC agreed that there is no pre- and post-service time. **The RUC recommends a relative work value of 2.00 for CPT code 38204.**

38205 ***Blood derived hematopoietic progenitor cell harvest for future transplantation per collection; allogeneic***
38206 ***Blood derived hematopoietic progenitor cell harvest for future transplantation per collection; autologous***
These two codes were previously billed as code 38231 *Blood derived peripheral stem cell harvesting for transplantation, per collection* (Work RVU = 1.50). The specialty society recommended a value of 2.0 stating code 38231 had been undervalued. The

RUC however found no compelling evidence to increase the value, and believed it had been appropriately valued by the RUC when reviewed in 1995. **The RUC recommends a relative work value of 1.50 for CPT codes 38205 and 38206.**

38210 & 38207 – 38215

In April 2002, the RUC reviewed CPT code 38210 *Transplantation preparation of hematopoietic progenitor cells; cryopreservation and storage; specific cell depletion within harvest, T-cell depletion* as an anchor code for family 38205 through 38215. The RUC first recognized that the vignette did not reflect an accurate description of the service of 38210, however the RUC did believe that the work involved in code 86077 *Blood bank physician services; difficult cross match and/or evaluation of irregular antibody(s), interpretation and written report* (Work RVU = 0.94) was similar. The RUC also reviewed the codes in comparison to the work of evaluation and management services. The RUC was concerned regarding the accuracy of the survey data for these services. However, the RUC agreed that a repeated survey would not be appropriate as it would have to be circulated to the same physicians/centers. The RUC recommends that a consensus panel of physicians, with the participation of one or more RUC members, review these codes again for the September 2002 RUC meeting. The RUC however, felt strongly, that these services require physician work and recommends interim work values to be assigned for 38207-38215. The RUC emphasized that these interim values should not be viewed as a "ceiling" for the future review, but serve as the best alternative until future review is completed. Considering the similarities in work of code 86077 and 38210, the RUC had recommended an interim value of 0.94 for code 38210.

The RUC compared similarities in work and intensity of codes 86077 and 38210, and then agreed with the rank order established by the specialty society for the family of codes 38207 through 38215. The RUC agreed with the specialty society's recommended rank order for the family, but also understood that the values being established were interim pending future RUC review and consideration at the September 2002 meeting. The RUC had recommended the following interim work relative values for CPT codes 38207-38215:

CPT Code	April 2002 Interim RUC Recommendation
38207	0.47
38208	0.56
38209	0.24
38210	0.94
38211	0.71
38212	0.47
38213	0.24
38214	0.24
38215	0.55

In September 2002, the RUC formed a facilitation committee to extensively discuss each of the services described in new CPT codes 38207 – 38215 and establish work relative value recommendations. The committee affirmed the decision made in April 2002 that these services do require direct physician involvement on a per patient level and should have assigned physician work. The RUC, however, remains concerned that the survey instrument and the corresponding summary of recommendation forms were not properly constructed. In addition, the RUC was concerned that further clarification is necessary in the CPT nomenclature for a few of these codes. Therefore, the RUC recommends that after further CPT revision, the specialty society conduct a re-survey of these services. The RUC proceeded to develop revised relative value recommendations, but will consider these relative values interim until the specialty society has the opportunity to re-survey.

In April, as an attempt to assign interim values, the RUC cross-walked the work relative value for 86077 *Blood bank physician services; difficult cross match and/or evaluation of irregular antibody(s), interpretation and written report* (Work RVU = 0.94) to new CPT code 38210 S*pecific cell depletion within harvest, T-cell depletion.* Work relative values were then extrapolated to the remaining codes in this family, utilizing the relativity established by the specialty society recommendations. In September, the specialty suggested, and the RUC agreed, that the 86077 should have been cross-walked to 38212 *Red blood cell removal*, rather than 38210. The RUC intra-service time for 86077 is 40 minutes, which is closer to the survey intra-time of 38212 (30 minutes) than is the survey intra-time of 38210 (60 minutes).

The RUC reviewed, in detail, the physician involvement and work in the service described in CPT code 38212. The physician work is as follows:

Pre-work: Reviewing data available prior to the time cells arrive in lab. This includes the phenotyping on donor and recipient; antibody information; and donor and recipient body weight. The committee agreed that the survey pre-time of 5 minutes seemed reasonable.

Intra-work: The intra-work begins when the cells arrive in the lab. The tech would get the Hct. The physician would then look at CD 34 (flow cytometry) on monitor. Based on the cell counts and Ab counts, the physician would decide which technique to use to deplete the red blood cells. The tech then does the process. After the bleed off of red blood cells, the physician judges where to divide the sample. A Hct and CD34 are repeated. The physician looks at the results and decides whether to recombine components and repeat the separation. The typical patient has this process one time through (without the recombining), about one-third require re-separation. The RUC agreed that 30 minutes of physician intra-service work was reasonable. This includes multiple flow cytometry readings, decision-making, and other interactions with the technician.

Post-work: Report and documentation. The RUC agreed that the specialties indication that this takes the form of a handwritten note is reasonable, given the detailed, sensitive information. The survey post-time of 15 minutes may be slightly over-stated. The RUC agreed that 10 minutes of post-service time was reasonable for the written report.

The RUC noted several additional factors in walking through the physician involvement and work in providing this service:

- The procedure requires intermittent physician time, sometimes over several hours. During that time, the physician is interacting with the technicians intermittently to determine how best to process cells.
- The procedure does not involve face-to-face patient contact. It occurs in an isolated laboratory.
- Physician work related to this procedure includes quality assurance work to support quality assurance for the lab. Physicians have not historically been separately compensated for quality assurance in the lab. Therefore, it is legitimate to consider this work as part of the work of the procedure.
- The risks to the patient are real. Mistakes can cause patient death. This adds to the stress of the procedure and decision-making.

Doctor Paul Rudolf, from the Centers for Medicare and Medicaid Services, informed the committee that deleted CPT code 86915 *Bone marrow or peripheral stem cell harvest modification or treatment to eliminate cell type(s) (e.g., T cells, metastatic carcinoma),* where the services described in 38210-38213 were previously reported is paid on the clinical lab fee schedule. He noted that currently the payment for 86915 is based on reasonable cost. The specialty and RUC agreed that CMS would need to make a technical correction to the cost reporting instructions to eliminate the physician compensation from these specific labs if compensation for the physician's professional service is included on the cost report. *Staff Note: Subsequent to the RUC meeting, the specialty determined that current program instructions provide for Code 86915 to be reimbursed on a reasonable charge basis when performed by independent laboratories and through the hospital outpatient prospective payment system when performed in outpatient departments. This information was shared with CMS.*

The RUC reviewed the proposed crosswalk of code 86077 *Blood bank physician services*, which has 40 minutes of intra-time and a work relative value of 0.94, to CPT code 38212. The RUC noted that since documentation is also required for 86077, the 40 minutes of intra-time may include some actual post-work. The RUC also agreed that the intensity of 38212 would be greater than 86077. After reviewing 38212 in detail, the RUC agreed that a comparison and cross-walk between 86077 and 38212 was reasonable.

The RUC also reviewed the appropriate work relative value for 38212 by using a building block method. CPT code 38212 includes two flow cytometry procedures. 88180 *Flow cytometry; each cell surface, cytoplasmic or nuclear marker* (work rvu = 0.36), includes a pre-time of 5 minutes, intra-time of 10 minutes, and post-time of 10 minutes. The RUC agreed that a multiple of two 88180, with additional work for the interaction with the technician and the medical decision-making offered another validation of a work relative

value of 0.94 for 38212. The RUC also recommends that a note be added to CPT to indicate that 88180 should not be reported in addition to this series of codes, as they include the work of flow cytometry.

The RUC recommends a work relative value of 0.94 for CPT code 38212. The RUC recommends physician time of 5 minutes pre-time, 30 minutes intra-time, and 10 minutes post-time.

The RUC then discussed the best way to extrapolate the appropriate value of 0.94 for 38212 to the rest of the family of codes. The RUC no longer agreed that the specialty society's recommended values were in the appropriate relativity, as these were derived from a very small consensus panel (two or three physicians). The survey medians appeared to correspond with the intra-service time for most services, so the committee agreed to use the survey medians for relativity. The RUC agreed that the intra-service survey time should be used, but felt that a standardized pre-time of 5 minutes, and standardized post-time of 10 minutes should be applied to all of the codes in this family. The RUC had significant concern, however, regarding the survey medians for three codes, 38208, 38209, and 38213. CPT code 38213 P*latelet depletion* was grossly overvalued by the survey respondents. CPT codes 38208 *thawing of previously frozen harvest* and 38209 *washing of harvest* should be referred back to CPT to create codes that describe thawing without washing and thawing with washing. The specialty had indicated a specimen must always be thawed before washing, so the current coding structure is not appropriate.

The RUC, therefore, recommends the following for this family of services:

- **CPT should add a note to this family of services to specify that CPT code 88180 *Flow cytometry* should not be reported in addition to these services as it is included in the valuation of these codes.**
- **CPT should review the coding language for codes 38208 and 38209, as thawing of the harvest must always occur prior to washing of the harvest. The codes should be formatted as thawing without washing and thawing with washing.**
- **After these changes have been made by the CPT Editorial Panel, the specialty should re-survey the entire family of services with the following improvements to the survey instrument:**
  - **a better reference service list, with other similar services included**
  - **better education of survey respondents regarding the survey process**
  - **better descriptions of the physician work involved**
  - **assistance from the RUC facilitation committee prior to dissemination of the survey instrument**
- **The work relative values developed at the September RUC meeting are more valid than the values developed in April, however, the values for CPT codes 38207 – 38215 should remain interim until after these codes have been re-surveyed and re-presented to the RUC.**

- **A standardized pre-time of 5 minutes and post-time of 10 minutes should apply to each code. The survey median intra-service time should be recorded into the RUC database for all of the services.**

- **The work relative value for CPT code 38212 should be cross-walked from CPT code 86077 and the survey median relativity should be used to extrapolate work relative values to the rest of the services in the family, as follows:**

CPT Code	September 2002 Interim RUC Recommendation
38207	0.89
38208	0.56
38209	0.24
38210	1.57
38211	1.42
38212	0.94
38213	0.24
38214	0.81
38215	0.94

38242 ***Bone marrow or blood-derived peripheral stem cell transplantation; allogenic donor lymphocyte infusions***
The specialty presented a typical patient that is severely ill and in great risk. Approximately 25% of these procedures are complicated by life threatening reactions to the infusion. The RUC agreed with the specialties description of the intensity of intra-service work and 25th percentile time of 30 minutes.

The RUC also understood that this service could be compared to several other intense procedures including critical care code 99292 *Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)* (work RVU = 2.0), however, the work for this code was not quite as intense, and could be more appropriately aligned with code 99357 *Prolonged physician service in the inpatient setting, requiring direct (face-to-face) patient contact beyond the usual service (eg, maternal fetal monitoring for high risk delivery or other physiological monitoring, prolonged care of an acutely ill inpatient); each additional 30 minutes (List separately in addition to code for prolonged physician service* (work RVU= 1.71) for its time and intensity. The RUC in addition, believed code 38242 was less intense than the reference code 38240 *Bone marrow or blood-derived peripheral stem cell transplantation; allogenic* (work RVU = 2.24, Harvard total time 53). **The RUC recommends a relative work value of 1.71 for code 38242,** which has the approval of the specialty society.

Practice Expense: The RUC and the specialty society agreed that these procedures do not have any practice expense inputs and are performed exclusively in the facility setting.

CPT Code (•New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
●38204	AV1	Management of recipient hematopoietic progenitor cell donor search and cell acquisition	XXX	2.00 (May 2002 RUC Recommendation)
●38205	X1	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic	000	1.50 (May 2002 RUC Recommendation)
●38206	X2	autologous	000	1.50 (May 2002 RUC Recommendation)
●38207	X3	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage (For diagnostic cryopreservation and storage, see 88240)	XXX	0.89 (Interim)
●38208	X4	thawing of previously frozen harvest (For diagnostic thawing and expansion of frozen cells, see 88241)	XXX	0.56 (Interim)
●38209	X5	washing of harvest	XXX	0.24 (Interim)
●38210	X6	specific cell depletion within harvest, T-cell depletion	XXX	1.57

CPT Code (•New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
				(Interim)
●38211	X7	tumor cell depletion	XXX	1.42 (Interim)
●38212	X8	red blood cell removal	XXX	0.94 (Interim)
●38213	X9	platelet depletion	XXX	0.24 (Interim)
●38214	X10	plasma (volume) depletion	XXX	0.81 (Interim)
●38215	X11	cell concentration in plasma, mononuclear, or buffy coat layer	XXX	0.94 (Interim)
~~38231~~		~~Blood-derived peripheral stem cell harvesting for transplantation, per collection~~ (38231 has been deleted. To report, use 38205-38206)	000	N/A
●38242	X12	Bone marrow or blood-derived peripheral stem cell transplantation; allogenic donor lymphocyte infusions	XXX	1.71 (May 2002 RUC Recommendation))
~~86915~~		~~Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (eg, T cells, metastatic carcinoma)~~ (86915 has been deleted. To report, use 38210-38213)	XXX	N/A

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38207 Tracking Number: X3 Global Period: XXX ~~**Recommended RVW: 1.0**~~
RUC Rec. RVW: 0.89

CPT Descriptor: Cryopreservation and storage

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: Peripheral blood stem cells or bone marrow have been collected. These cells are to be cryopreserved for later use as part of an autologous transplant where hematopoietic progenitor cells have to first be cryopreserved for a later autologous hematopoietic progenitor cell transplant. In many cases, the bone marrow or peripheral blood progenitor cells are also cryopreserved for allogeneic transplants. This ensures that the cells are ready and available when the patient needs them. The physcian writes separate prescriptions for cryropreservation and thawing of the product. A physcian supervises both cryropreservation and thawing of the product and in an emergency does these procedure himself/herself as a patient life is in jeopardy.
The cryopreservation process is begun. It is important to make sure the freezing process is performed correctly to ensure that the cells have been frozen in a safe manner to be acceptable for transplantation. This requires following validated standard operating procedures. Cryopreservation data are reviewed and quality assessment of the procedure is performed. Cells are stored at a low temperature under controlled monitored conditions until needed for transplant. The physcian may do this procedure in an emergency. The quality of the cryropreserved transplantation product (bone marrow, blood-derived, or umbilical cord blood-derived hematopoietic progenitor cells, allogeneic t-lymphocytes) must be assessed prior to release of product. Examples of quality assurance are nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells, T-lymphocytes, or tumor cells. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if new product needs to be collected.

Description of Pre-Service Work: Review of donor and patient data.

Description of Intra-Service Work: This is basically supervision of the cryopreservation process, review of the freezer curves to make sure they are adequate, review of the CD34 counts, and review of the viability studies to ensure the product is a viable transplant product. A life depends on this evaluation. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 66% Median RVW: 1.42

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.23 75th Percentile RVW: 1.88 Low: 1.00 High: 8.00

Median Pre-Service Time: ~~2.5~~ **5** Median Intra-Service Time: **30**

25th Percentile Intra-Svc Time: 20 75th Percentile Intra-Svc Time: 56.25 Low: 10 High: 420

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	~~12.5~~ **10**	

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
80502	Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records	XXX	1.33

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
~~Median Pre-Time~~	~~2.5~~ 5	~~No RUC data~~
Median Intra-Time	30	No RUC data
Median Immediate Post-service Time	~~12.5~~ 10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.64	3.85
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.93	3.54
Urgency of medical decision making	4.14	3.92

Technical Skill/Physical Effort (Mean)

Technical skill required	4.29	3.62
Physical effort required	2.43	2.08

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.36	4.00
Outcome depends on the skill and judgement of physician	4.21	4.15
Estimated risk of malpractice suit with poor outcome	4.43	4.38

CPT Code: 38207

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	3.13	2.63
Intra-Service intensity/complexity	3.62	3.08
Post-Service intensity/complexity	3.22	2.63

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data an reached consensus in developing the recommended work values

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FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ ____Commonly ____Sometimes ____Rarely

Specialty_____ ____Commonly ____Sometimes ____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes ____No

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AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38208 Tracking Number: X4 Global Period: XXX ~~**Recommended RVW: 1.2**~~
RUC Rec. RVW: 0.56

CPT Descriptor: Thawing of previously frozen harvest

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: The previously cryopreserved marrow and stem cells are thawed in a heated water bath. A sample is obtained for post-thaw quality assessment such as nucleated cell count and viability. Cells are infused immediately post-thaw. The physician may do this procedure in an emergency. The quality of the thawed transplantation product (bone marrow, blood-derived, or umbilical cord blood-derived hematopoietic progenitor cells, allogeneic t-lymphocytes) must be assessed prior to release of product. Examples of quality assurance are nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells, T-lymphocytes, or tumor cells. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if new product needs to be collected.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work: This is management of a thawing. This usually occurs in front of a physician as the PBSC are put in a water bath and immediately thawed. The process can have failure since the bags break frequently or if the thawing process has failure, there is no graft. The risk to the patient is high because if the thawing process lyses cells, there may be no alternative graft. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report.

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 76% Median RVW: 1.42

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.00 75th Percentile RVW: 2.58 Low: 0.37 High: 5

Median Pre-Service Time: **5** Median Intra-Service Time: **45**

25th Percentile Intra-Svc Time: 24 75th Percentile Intra-Svc Time: 60 Low: 5 High: 150

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	~~5~~ **10**	

CPT Code: 38208

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
80502	Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records	XXX	1.33

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	5	No RUC data
Median Intra-Time	45	No RUC data
Median Immediate Post-service Time	~~5~~–10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.63	3.44
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.31	3.19
Urgency of medical decision making	4.19	3.06

Technical Skill/Physical Effort (Mean)

Technical skill required	3.88	3.19
Physical effort required	2.56	2.25

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.06	3.19
Outcome depends on the skill and judgement of physician	3.75	3.38
Estimated risk of malpractice suit with poor outcome	4.00	3.31

CPT Code: 38208

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	3.10	2.50
Intra-Service intensity/complexity	3.75	3.13
Post-Service intensity/complexity	3.20	2.50

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data and reached sonsensus on the recommended work value

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ _____Commonly _____Sometimes _____Rarely

Specialty_____ _____Commonly _____Sometimes _____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes _____No

CPT Code: 38209

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38209 Tracking Number: X5 Global Period: XXX ~~**Recommended RVW: 0.5**~~
RUC Rec. RVW: 0.24

CPT Descriptor: Washing of harvest

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: Blood derived hematopoietic progenitor cells have been harvested but the patient mobilizes very poorly with few stem cells. Thus, it is necessary to freeze them in multiple aliquots. Such harvest material contains a significant number of neutrophils or mature granulocytes, which are not capable of restoring hematopoiesis. Only the primitive cells are able to do this. DMSO is necessary for the cyropreservation. Because the cells have been frozen in multiple aliquots (multiple bags of these products were frozen over many days and then thawed later), the total content of DMSO is large and the patient gets a large exposure to DMSO. Such large amounts of DMSO in the transplant can potentially cause projectile vomiting and other injury to the patient. Thus it is necessary to wash the harvest cells to minimize the DMSO content] A physcian writes a prescription for this procedure based on the review of the cryropreserved product and whether recipient needs to maximize cell dose or minimize DMSO toxicity. The physcian may do this procedure n an emergency.
The thawed cells are washed using an automated cell washer. During the wash process, cells are concentrated and resuspended in infusible grade solutions such as saline/albumin. The physcian may do this procedure in an emergency. Quality assessment of the washed product is performed. The quality of the thawed transplantation product (bone marrow, blood-derived, or umbilical cord blood-derived hematopoietic progenitor cells) must be assessed prior to release of product. Examples of quality assurance are nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells, T-lymphocytes, or tumor cells. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if new or additional product needs to be collected.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work: . This procedure is used when the cell count of the harvest is high due to excessive granulocyte contamination of the progenitor cell harvest. The cell count governs the amount of DMSO used to cryopreserve the cells. DMSO can cause projectile vomiting. This is a washing of immediately thawed stem cells. The washing has to occur over approximately one hour. Since all of these patients would have the thawing intraservice work, the physician effort is incremental to that for the washing. If the washing has a problem the entire graft could be lost and the patient could die. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 57% Median RVW: 1.25

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 0.99 75th Percentile RVW: 2.20 Low: 0.50 High: 4.00

Median Pre-Service Time: 5 Median Intra-Service Time: 37.5

25th Percentile Intra-Svc Time: 25 75th Percentile Intra-Svc Time: 60 Low: 0 High: 240

CPT Code: 38209

Median Post-Service Time:

	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	10	

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
85097	Bone marrow, smear interpretation	XXX	0.94

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	5	No RUC data
Median Intra-Time	37.5	No RUC data
Median Immediate Post-service Time	10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.50	3.27
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.33	2.82
Urgency of medical decision making	4.00	3.09

Technical Skill/Physical Effort (Mean)

Technical skill required	3.92	3.09
Physical effort required	2.42	2.18

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.08	3.36
Outcome depends on the skill and judgement of physician	3.50	3.18

Estimated risk of malpractice suit with poor outcome	3.83	3.27

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	3.33	3.20
Intra-Service intensity/complexity	3.55	2.90
Post-Service intensity/complexity	3.43	3.17

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data and reached consensus on the reommended work value.

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ ____Commonly ____Sometimes ____Rarely

Specialty_____ ____Commonly ____Sometimes ____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes ____ No

CPT Code: 38210

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38210 Tracking Number: X6 Global Period: XXX ~~**Recommended RVW: 2.0**~~
RUC Rec. RVW: 1.57

CPT Descriptor: Specific cell depletion within harvest; T-cell depletion

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: The typical patient is a 10 year old boy with DiGeorge's Syndrome who needs a bone marrow/peripheral blood progenitor stem cell transplant from his father. The marrow has to be T-cell depleted for this allogeneic graft to reduce the risk of graft versus host disease. The physcian writes a prescription ordering this procedure based on recipient needs and the degree of HLA mismatching with the donor. In an emergency the physcian may do this procedure.

T-cell depletion is performed using various methods such as the Baxter Isolex device. This instrument enriches the stem cells (CD34+) and passively removes unwanted cells such as T-cells. In an emergency the physcian may do this procedure. Quality assessment of the product is performed. . The quality of the T-lymphocyte depleted hematopoietic progenitor cell product (bone marrow or blood-derived) must be assessed prior to release of product. Examples of quality assurance are nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells and T-lymphocytes. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if new product needs to be collected.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work:. Intraservice for this is supervision of the soybean lectin e-rosetting. In allogeneic graft for T-cell depletion this usually occurs in the context of a haploidentical transplant. The work is reviewing the quality control, reviewing the adequacy of the antibodies used, reviewing the adequacy of the soybean lectin. For the use of the isolex or the clinimacs cell selection devices, review of the flow cytometry pre- and post-service. This is probably the most complicated cell processing procedure. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report.

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 71% Median RVW: 2.50

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.50 75th Percentile RVW: 3.25 Low: 1.08 High: 10

Median Pre-Service Time: ~~10~~ **5** Median Intra-Service Time: **60**

25th Percentile Intra-Svc Time: 23 75th Percentile Intra-Svc Time: 210 Low: 0 High: 600

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	~~20~~ **10**	

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
80502	Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records	XXX	1.33

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	~~10~~-5	No RUC data
Median Intra-Time	60	No RUC data
Median Immediate Post-service Time	~~20~~-10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	4.13	3.93
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	4.40	3.47
Urgency of medical decision making	4.40	3.47

Technical Skill/Physical Effort (Mean)

Technical skill required	4.60	4.14
Physical effort required	2.67	2.21

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.73	3.93
Outcome depends on the skill and judgement of physician	4.47	3.79
Estimated risk of malpractice suit with poor outcome	4.27	3.79

CPT Code: 38210

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	3.20	2.89
Intra-Service intensity/complexity	4.21	3.47
Post-Service intensity/complexity	3.70	2.80

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data and reached sonsensus on the recommended work value

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ ____Commonly ____Sometimes ____Rarely

Specialty_____ ____Commonly ____Sometimes ____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes ____No

CPT Code: 38211

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38211 Tracking Number: X7 Global Period: XXX ~~**Recommended RVW: 1.5**~~
RUC Rec. RVW: 1.42

CPT Descriptor: Tumor Cell Depletion

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: The typical patient is a 25 year old male with B-cell lymphoma or breast cancer metastatic to the bone marrow. The patient needs an autologous peripheral blood stem cell harvest with later transplant but there is known tumor contamination in the bone marrow. A physcian writes a prescription for this procedure based on review of the patient's disease and risk of tumor contamination. In an emergency, a physcian may do this procedure.

Tumor cell depletion is performed using various methods such as the Baxter Isolex device, which has been FDA approved for tumor depletion. The instrument enriches for stem cells (CD34+) and passively removes unwanted cells such as tumor cells. Quality assessment of the product is performed. In an emergency a physcian may do this procedure. The quality of the tumor cell depleted hematopoietic progenitor cell product (bone marrow or blood-derived hematopoietic progenitor cells) must be assessed prior to release of product. Examples of quality assurance are nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells and or tumor cells. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if new product needs to be collected.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work: Intraservice is for patients with stem cells or marrow contaminated with tumor cells either B-cell lymphoma or breast cancer. The FDA approved machine is the isolex device. The supervision of a processing plus validation of the quality control and the adequacy of the stem cell product, that there is sufficient product for transplantation. Failure to do this increases the patient's risk of relapse. This procedure is slightly less complicated than the T-cell depletion. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 71% Median RVW: 2.27

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.63 75th Percentile RVW: 2.75 Low: 1.00 High: 6.00

Median Pre-Service Time: **5** Median Intra-Service Time: **60**

25th Percentile Intra-Svc Time: 25 75th Percentile Intra-Svc Time: 105 Low: 0 High: 360

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	**10**	

CPT Code: 38211

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
80502	Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records	XXX	1.33

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	5	No RUC data
Median Intra-Time	60	No RUC data
Median Immediate Post-service Time	10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.80	3.86
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	4.07	3.36
Urgency of medical decision making	4.07	3.21

Technical Skill/Physical Effort (Mean)

Technical skill required	4.57	4.00
Physical effort required	2.57	2.15

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.13	3.86
Outcome depends on the skill and judgement of physician	3.93	3.57
Estimated risk of malpractice suit with poor outcome	3.80	3.79

CPT Code: 38211

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	2.90	2.60
Intra-Service intensity/complexity	4.14	3.47
Post-Service intensity/complexity	3.50	2.80

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed and reached consensus on the recommended work value.

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ ____Commonly ____Sometimes ____Rarely

Specialty_____ ____Commonly ____Sometimes ____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes ____No

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CPT Code: 38212

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38212 Tracking Number: X8 Global Period: XXX ~~**Recommended RVW: 1.0**~~
RUC Rec. RVW: 0.94

CPT Descriptor: Red blood cell removal

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 35 year old female with leukemia is blood type O and requires a peripheral blood stem cell transplant. The donor is blood type A. With such a stem cell harvest, ABO blood group barriers are routinely crossed. If fresh bone marrow containing Type A red blood cells is given to the patient, those type A cells will be immediately hemolyzed. This would cause renal failure and ultimately death to the patient because they could not receive post transplant immunosuppression therapy. Because of the different blood types, red blood cell depletion is required from the harvest. The stem cell harvest is then performed. A physcian writes an order for this procedure and supervises it. In an emergency, a physcian may do this procedure.
The red cell depletion can be done by various methods such as mononuclear cell concentration using an FDA approved apheresis device, mononuclear cell enrichment using density gradient solution, hydroxyethel starch which is FDA approved as an infusible solution. In an emergency a physcian may do this procedure. Quality assessment of the product is performed. The quality of the hematopoietic progenitor cells (bone marrow, blood-derived, or umbilical cord blood-derived hematopoietic progenitor cells) must be assessed prior to release of product. Examples of quality assurance are hematocrit, red cell count, nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if new product needs to be collected.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work: This procedure is done when there is major ABO incompatibility. This is a removal of red cells from the product. This is done by hetastart separation. It takes approximately 50 minutes. The physician would ensure there is an adequate CD34 count post-selection and there is minimal red cell contamination. Failure to properly assess red blood cell removal will cause an acute hemolysis with infusion of the graft. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report.

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 71% Median RVW: 1.50

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.00 75th Percentile RVW: 2.10 Low: 0.50 High: 3.00

Median Pre-Service Time: **5** Median Intra-Service Time: **30**

25th Percentile Intra-Svc Time: 12.5 75th Percentile Intra-Svc Time: 120 Low: 0 High: 150

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	~~15~~ **10**	

CPT Code: 38212

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
90935	Hemodialysis procedure with single physician evaluation	000	1.22

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	5	0
Median Intra-Time	30	21
Median Immediate Post-service Time	~~15~~ 10	0
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.33	3.53
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.20	3.00
Urgency of medical decision making	3.60	3.20

Technical Skill/Physical Effort (Mean)

Technical skill required	3.80	3.53
Physical effort required	2.27	2.40

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.07	4.07
Outcome depends on the skill and judgement of physician	3.80	3.67
Estimated risk of malpractice suit with poor outcome	4.33	3.47

CPT Code: 38212

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	2.70	2.70
Intra-Service intensity/complexity	3.50	3.27
Post-Service intensity/complexity	3.40	2.80

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data and reached consensus on the recommended work value.

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ ____Commonly ____Sometimes ____Rarely

Specialty_____ ____Commonly ____Sometimes ____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes ____No

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CPT Code: 38213

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38213 Tracking Number: X9 Global Period: XXX ~~**Recommended RVW: 0.5**~~
RUC Rec. RVW: 0.24

CPT Descriptor: Platelet depletion

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: The typical patient is a 35 year old female with leukemia who requires an allogeneic peripheral blood stem cell transplant. The donor is much smaller than the intended recipient, thus requiring multiple days of harvesting. Because multiple successive days of stem cell collection causes the donor's platelets to become severely depleted, prior platelet depletion of the donor is required. The physcian assesses both donor needs and recipient needs as this procedure will deplete some of the hematopoietic progenitors collected. A physcian writes a prescription for a platelet addback to be obtained and separated from the blood-derived hematopoietic progenitor cell product. A physcian supervises this procedure. In an emergency a physcian does this procedure.
The collected apheresis product is depleted of platelets using a centrifugation method. The separated platelets are infused back to the donor and the stem cells are used for transplantation for the patient. In an emergency a physcian does this procedure. Quality assessment on both products is performed. It is critical to be sure that the donor is not harmed by an excessively low platelet count as part of the transplant process. The physician has to ascertain whether there is a quality platelet product obtained from the donor with minimal risk to the transplant product. . The quality of the platelets (bone marrow or blood-derived) must be assessed prior to release of product. Examples of quality assurance are platelet count, hematocrit,nucleated cell count, viability, and sterility. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product is suitable for infusion.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work: This is basically done via a cell selector such as the Cobe Spectra for removal of platelets from a stem cell collection. There will be loss of stem cells. The platelets will be infused in recipients. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 52% Median RVW: 1.20

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.00 75th Percentile RVW: 1.75 Low: 0.80 High: 3.50

Median Pre-Service Time: ~~10~~ **5** Median Intra-Service Time: **30**

25th Percentile Intra-Svc Time: 20 75th Percentile Intra-Svc Time: 67.5 Low: 0 High: 180

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	**10**	

CPT Code: 38213

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
80502	Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records	XXX	1.33

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	~~10~~ 5	No RUC data
Median Intra-Time	30	No RUC data
Median Immediate Post-service Time	10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.27	3.55
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.18	3.73
Urgency of medical decision making	3.91	3.73

Technical Skill/Physical Effort (Mean)

Technical skill required	4.00	3.82
Physical effort required	2.55	2.82

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.00	3.82
Outcome depends on the skill and judgement of physician	3.55	3.73
Estimated risk of malpractice suit with poor outcome	4.00	3.45

CPT Code: 38213

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	3.33	3.17
Intra-Service intensity/complexity	3.30	3.45
Post-Service intensity/complexity	3.33	3.00

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data and reached consensus on the recommended work value.

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ ____Commonly ____Sometimes ____Rarely

Specialty_____ ____Commonly ____Sometimes ____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes ____No

CPT Code: 38214

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38214 Tracking Number: X10 Global Period: XXX ~~**Recommended RVW: 0.50**~~
RUC Rec. RVW: 0.81

CPT Descriptor: Plasma (volume) depletion

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: The typical patient is a 35 year old female with leukemia who is type A and requires a bone marrow transplant. The only available donor is type O. The donor's type O plasma has sufficient anti-A that it may cause hemolysis with infusion of the marrow product. The plasma needs to be depleted from this product so that there can be a safe transplant. A physcian writes a prescription for and supervises this procedure. In an emergency a physcian does this procedure.
Plasma/volume depletion can be done by various methods (i.e. centrifugation or nucleated cell concentration using an FDA approved apheresis device. In this process, stem cells are concentrated and plasma/excess volume are removed. In an emergency a physcian does this procedure. Quality assessment of the product is performed. The quality of the plasma depleted hematopoietic progenitor cell transplantation product (bone marrow-derived hematopoietic progenitor cells) must be assessed prior to release of product. Examples of quality assurance are nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells or T-lymphocytes. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if the procedure needs to be repeated.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work: This is when there is minor ABO incompatibility to prevent hemolysis of the recipient's red cells by plasma depletion. This is usually done by density gradient. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report.

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 71% Median RVW: 1.30

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.00 75th Percentile RVW: 1.66 Low: 0.50 High: 2.80

Median Pre-Service Time: 5 Median Intra-Service Time: 30

25th Percentile Intra-Svc Time: 10 75th Percentile Intra-Svc Time: 60 Low: 0 High: 120

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	~~5~~ 10	

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
80502	Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records	XXX	1.33

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	5	No RUC data
Median Intra-Time	30	No RUC data
Median Immediate Post-service Time	~~5~~ 10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.27	3.60
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.47	3.13
Urgency of medical decision making	3.73	3.07

Technical Skill/Physical Effort (Mean)

Technical skill required	3.80	3.67
Physical effort required	2.20	2.27

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.13	3.93
Outcome depends on the skill and judgement of physician	3.67	3.60
Estimated risk of malpractice suit with poor outcome	4.07	3.60

CPT Code: 38214

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	2.70	2.60
Intra-Service intensity/complexity	3.36	3.27
Post-Service intensity/complexity	3.22	2.78

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data and reached consensus on the recoommended work value

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ _____Commonly _____Sometimes _____Rarely

Specialty_____ _____Commonly _____Sometimes _____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes _____No

CPT Code: 38215

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code: 38215 Tracking Number: X11 Global Period: XXX ~~**Recommended RVW: 1.18**~~
RUC Rec. RVW: 0.94

CPT Descriptor: Cell concentration in plasma, mononuclear, or buffy coat layer

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: The typical patient is a 35 year old female with leukemia who is type B and requires a peripheral blood stem cell transplant. The only available donor is type A. Thus, to prevent transplant problems, a purified hematopoietic progenitor cell population (with minimal red cell and plasma contamination) is needed for the graft. A physcian writes an order for this procedure and supervises. In an emergency a physcian may do this procedure.
In this scenario, to avoid hemolytic transfusion reaction, both the RBCs and plasma must be removed. This can be achieved by various methods such as mononuclear cell concentration using an FDA approved apheresis device or density gradients solutions. In this process, stem cells are concentrated and plasma/excess volumes are removed. In an emergency a physcian may do this procedure. Quality assessment of the product is performed. The quality of the mononuclear cell preparation of the hematopoietic progenitor cell transplantation product (bone marrow, blood-derived, or umbilical cord blood-derived hematopoietic progenitor cells) must be assessed prior to release of product. Examples of quality assurance are hematocrit,nucleated cell count, differential, viability, sterility and/or immunophenotyping by flow cytometry for cd34(+) progenitor cells and T-lymphocytes. These parameters are recognized by two accreditation agencies (FAHCT and AABB) as necessary and are included in the regulations recently proposed by the FDA. The physcian then judges if this product remains suitable for transplantation or if the procedure needs to be repeated or if new product needs to be collected.

Description of Pre-Service Work: Review of donor and patient data

Description of Intra-Service Work: This procedure is performed for major/minor ABO incompatibility of the graft or when one standard red cell depletion has not removed all the potential red cells that have caused an acute reaction. This procedure's failure will either cause graft failure or acute hemolysis with graft infusion. Risk to the patient is quite high. Both risk and loss of graft in the allogeneic setting is high because this procedure has a great deal of stem cell loss. The FDA requires physician assessment of this procedure and the product processed.

Description of Post-Service Work: Preparation of report

SURVEY DATA:

Presenter(s) Drs. James Gajewski and Sam Silver

Specialty(s): American Society for Hematology and American Society for Blood and Marrow Transplantation

Sample Size: 21 Response Rate: (%): 71% Median RVW: 1.50

Type of Sample (Circle One): random, panel, convenience. Explanation of sample size:

25th Percentile RVW: 1.18 75th Percentile RVW: 1.99 Low: 0.50 High: 3.60

Median Pre-Service Time: **5** Median Intra-Service Time: **40**

25th Percentile Intra-Svc Time: 25 75th Percentile Intra-Svc Time: 110 Low: 0 High: 150

Median Post-Service Time:	Total Time	Level of Service by CPT Code (List CPT Code & # of Visits)
Immediate Post Service Time:	~~15~~ **10**	

KEY REFERENCE SERVICE:

CPT Code	CPT Descriptor	Global	Work RVU
80502	Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records	XXX	1.33

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

TIME ESTIMATES (Median)	**New/Revis. CPT Code:**	**Key Reference CPT Code:**
Median Pre-Time	5	No RUC data
Median Intra-Time	40	No RUC data
Median Immediate Post-service Time	~~15~~ 10	No RUC data
Median of Aggregate Critical Care Times		
Median of Aggregate Other Hospital Visit Times		
Median Discharge Day Management Time		
Median of Aggregate Office Visit Times		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgement (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	3.47	3.47
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.73	3.27
Urgency of medical decision making	4.00	3.53

Technical Skill/Physical Effort (Mean)

Technical skill required	4.20	3.80
Physical effort required	2.53	2.27

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	4.40	4.33
Outcome depends on the skill and judgement of physician	4.20	3.93
Estimated risk of malpractice suit with poor outcome	4.20	3.93

CPT Code: 38215

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	2.70	2.60
Intra-Service intensity/complexity	3.64	3.20
Post-Service intensity/complexity	3.20	2.60

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation.
A panel of physicians from various related societies reviewed the data and reached consensus on the recommended work value.

FREQUENCY INFORMATION

How was this service previously reported? 86915 (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed)

How often do physicians in your specialty perform this service? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty_____ _____Commonly _____Sometimes _____Rarely

Specialty_____ _____Commonly _____Sometimes _____Rarely

For your specialty, estimate the number of times this service might be provided nationally in a one-year period? If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty _____ Frequency:_____

Specialty _____ Frequency_____

For your specialty, estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? If this is a recommendation from multiple specialties please estimate frequency for each specialty.

Specialty _____ Frequency: No Medicare Data on code

Specialty _____ Frequency_____

Do many physicians perform this service across the United States? X Yes _____No

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

October 11, 2002

American Medical Association
Dept of CPT Editorial Research and Development
515 North State Street
Chicago, IL 60610

Dear Sir/Madam:

As recommended by the AMA RUC at their September 2002 meeting, the American Society of Hematology (ASH) would like to have the phrase "with physician evaluation" added to the definition of CPT 36516 for 2004 (the code is new for 2003). This would change the descriptor to read:

▲36516 ***therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion; with physician evaluation.***

This change is needed to assure that this code is billed only when the physician is present and periodically monitoring the patient during the procedure. The terminology is similar to that already existing for CPT 90935, hemodialysis procedure.

In addition, nine new bone marrow/stem cell processing codes were reviewed by the RUC (CPT codes 38207-38215) and the recommendation made that two of these be revised for 2004 (these are new codes for 2003). Specifically, CPT 38208 and CPT 38209 should change as follows:

▲38208 ***thawing of previously frozen harvest, with washing*** ~~***thawing of previously frozen harvest***~~

▲38209 ***thawing of previously frozen harvest, without washing*** ~~***washing of harvest***~~

The rationale for this revision is that bone marrow/stem cell washing is always done with bone marrow/stem cell thawing. However, all harvests that are thawed are not necessarily washed.

Finally, the AMA RUC recommended we petition CPT to add a note to these nine bone marrow/stem cell processing codes (CPT codes 38207–38215) indicating that physicians may not report flow cytometry (CPT codes 88180, 88182, and 88199) separately.

We understand that we do not need to submit a formal CPT application for these changes. If our understanding is not correct, please advise us as soon as possible.

If you have any questions or need additional information at this time, please feel free to contact Mo Mayrides, ASH Director of Policy and Practice, at (202) 292-6005 or at mmayrides@hematology.org.

Sincerely,

Samuel M. Silver, MD, PhD
Chair, ASH Committee on Practice

AMA
AMERICAN
MEDICAL
ASSOCIATION

October 12, 2005

Stephen M. Phillips
Director, Division of Practitioner Services
Hospital and Ambulatory Policy Group
Center for Medicare Management, C4-03-06
7500 Security Blvd.
Baltimore, MD 21244

Dear Mr. Phillips:

It is with pleasure that I submit to the Centers for Medicare and Medicaid Services (CMS), on behalf of the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC), work relative value and direct practice expense inputs for CPT code 33548 *Surgical ventricular restoration procedure, includes prosthetic patch, when performed (ventricular remodeling, SVR, SAVER, DOR procedures)* which was re-reviewed at the September 2005 RUC meeting. As promised in our May 26, 2005 letter, we are sending the new information related to this service to CMS immediately following our recent meeting.

We appreciate your consideration of the RUC's recommendations. You may contact Sherry Smith with any questions regarding this submission

Sincerely,

William Rich, MD

cc: Ken Simon, MD
Rick Ensor
Edith L Hambrick MD
Carolyn Mullen
Pam West, PT
RUC Participants

AMA/Specialty Society RVS Update Committee
Summary of Recommendations

Ventricular Restoration

September 2005

Due to advancements in technology that has allowed for standardization of the restoration of the ventricle, CPT created a new code to account for this type of procedure that is technically more complicated and involves different work than is described by current codes.

The presenters stated that the existing code 33542 *Myocardial resection (eg, ventricular aneurysmectomy)* (work RVU = 28.21) involves different work and does not accurately describe this procedure. The presenters stated that patients undergoing ventricular restoration are among the sickest patients with advanced heart failure with the average patient staying in the ICU post-operatively 4-5 days. The presenters stated that in about 80 to 90 percent of these patients, bypass surgery is also performed at the same time and it was explained that the recommended value does not include any of the bypass surgery work. However, since the reference code is included in the current five-year review the RUC assigned an interim value so that the code could be evaluated in comparison to a new value approved by the RUC in September, 2005. The current recommendation for code 33548 is based on the RUC approved STS five-year review alternative methodology.

The presenters explained that the interim relative value of 37.97 resulted in an IWPUT of 0.085, which was felt by the society to be too low in comparison to the recently evaluated five-year review codes. The E&M services assigned to the global period were also distorted by derivation from the Harvard assigned visits of the reference code. The reference code 33542 was refined by the RUC and has a RUC recommended value of 44.20 work relative values. Additionally, intra-service time, length of ICU and regular hospital stay, and duration of mechanical ventilation has been acquired for 33548 from the STS database, which recently added this new procedure to its procedure list. 33548 was also surveyed for intensity along with the other adult cardiac codes submitted for refinement. A comparison of the STS data and IWPUT between 33548 and 33542 for the period 2001-2004 is attached. It indicates that 33548 is significantly more intense in intra-service work, more complicated and is associated with significantly more postoperative management physician work (confirming the relationship between the two codes determined by the standard RUC survey) than the reference code.

In recommending a new value for 33548, the specialty considered the following factors:

1. Establishing the new value based on the ratio of refined 33542 and Harvard 33542, adjusting the RUC-approved value of 33548 proportionately. This results in a recommendation of ((44.20/28.21)*36.46) = 57.13
2. Establishing a new value through the utilization of data from the RUC survey performed for the April 2005 RUC meeting, data from the RUC approved reference code value, data from the STS national database, and intensity data from the survey that was used in the 5 year refinement process. This method led to a recommendation of 49.41. The new value includes an additional 99292 visit compared to the workgroup recommendations for the reference code, consistent with the additional ICU stay and ventilator hours for 33548 and consistent with several of our workgroup approved codes with similar ICU stay and ventilator hours. We maintained the RUC approved 99239 discharge for 33548, and this was consistent with other work group recommendations for similar codes. Otherwise, the number and level of the in-hospital visits are the same as for the reference code.

The presenters recommended the lower value, 49.41, for several reasons:

1. The higher value of 57.13 could only be "built" through increasing perioperative time and E&M services to levels above even those recommended by our specialty for similar codes.
2. The higher value would create rank order anomalies with other procedures, should the refinement process interim results be finalized. For example, 33548 would have a higher work value than 33545 *Repair of postinfarction ventricular septal defect, with or without myocardial resection*, RUC recommended RVU = 52.49)
3. The value 49.41 is an appropriate relative value compared to the RUC recommended value for 33542 (44.20), and the relationships of intra-service time, IWPUT, and post-operative E&M services are consistent with STS national database data for both procedures.

The RUC agreed with this analysis and felt that the recommended values placed the code in proper rank order with the recently refined RUC recommended values for the adult cardiac codes values.

The RUC recommends a work RVU of 49.41 for code 33548.

Practice Expense

The RUC recommends the standard inputs for 90 day global procedures performed in the facility setting with the exception of using the RN staff type rather than the standard blend.

CPT Code (•New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
● 33548	E1	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedure) (For Batista procedure or pachopexy, use 33999) (Do not report ● 33548 in conjunction with 32020, 33210, 33211, 33310-33315)	090	49.41

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:33548 Tracking Number: E1 Global Period: 090

Recommended Work Relative Value
Specialty Society RVU: **49.41**
RUC RVU: **49.41**

CPT Descriptor: Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedure)
(For Bastista procedure or pachopexy, use 33999)
(Do not report 33548 in conjunction with 32020, 33211, 33310-33315)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 56 year old man presents with Class IV congestive heart failure symptoms that are refractory to medical management and have required 4 hospitalizations in the past 6 months. He has no angina pectoris, but has a history of multiple myocardial infarctions and several percutaneous revascularizations. Cardiac catheterization reveals a totally occluded proximal LAD and a poor distal LAD supplied by right-to-left collaterals and a diminuitive circulflex coronary system. The right coronary is dominant and without significant in-stent restenosis. Left ventriculography shows anterior and anteroapical akinesis, trace mitral regurgitation, global left ventricular dilatation, and an overall ejection fraction of 15%. Left ventricular regional and global function is carefully assessed through echocardiography and viability studies. He is evaluated for cardiac transplantation, and is found to have prohibitive pre-formed antibodies. He is considered unsuitable for transplantation due to this, his weight of 250 pounds, and an O blood type. A surgical ventricular restoration procedure is recommended and accepted by the patient.

Percentage of Survey Respondents who found Vignette to be Typical: 65%

Is conscious sedation inherent to this procedure? No Percent of survey respondents who stated it is typical? 100%

Is conscious sedation inherent in your reference code? No

Description of Pre-Service Work: - Write pre-operative orders for peri-operative medications
- Review pre-operative work-up
- Review Radiology
- Review Cardiac Catheterization and ECHO Cardiograms
- Review Laboratory findings
- Obtain informed consent
- Review planned incisions and procedure
- Arrange for surgical assistant
- Change into scrub clothes
- Check with lab - check on availability of blood and/or x-ray match
- Review the surgical procedure, post-op recovery in and out of the hospital, and expected outcome(s) with patient and family
- Answer patient and family questions
- Review length and type of anesthesia with anesthesiologist
- Review planned procedure and positioning and draping of patient
- Verify that all necessary surgical instruments, supplies, and devices are available in the operative suite
- Monitor patient positioning and draping, and assist with positioning as needed
- Scrub and gown
- Available in operating room during insertion of monitoring lines and induction of anesthesia

Description of Intra-Service Work: - Skin incision made via standard median sternotomy
- Sternum is divided in the midline
- Cannulation using ascending aorta and two-stage RA venous return
- Cardiopulmonary bypass initiated
- A left ventricular vent is inserted via the Right Superior Pulmonary Vein

- The heart is carefully inspected to assess anteroapical akinetic area for resectability, LAD confirmed to be inoperable and supplied tissue non-viable.
- The ascending aorta is clamped and cardioplegic arrest instituted
- An anterior ventriculotomy is performed to the left of the LAD, and extended to the apex of the heart
- The junction between scarred abnormal myocardium and normal myocardium is determined by visual inspection and palpation.
- An encircling 0-prolene suture is placed at the junction and tied to reduce the orifice and restore the normal elliptical shape of the Left Ventricle (Fontan Stich). Available sizers and intraventricular balloons may be utilized to determine the final corrected LV volume.
- A circular patch of autologous or artificial material is sutured at the level of the Fontan stich to close the defect without reducing ventricular volume further.
- The left ventriculotomy is closed in layers
- The patient is rewarmed and weaned from cardiopulmonary bypass using moderate doses of inotropic agents.
- Hemostasis is obtained, and the surgical wound repaired after placing appropriate drainage tubes.

Description of Post-Service Work: - Apply dressings
- Dictate operative note for patients chart
- Sign OR forms, indicating pre and post-op diagnoses, operation performed
- Write orders for post-op labs, films, medications, diet, and patient activity
- Review intensive care plan and medications with staff
- Discuss procedure outcome with family, patient after emergence from aneshtesia and with referring physician
- Write post-op report
- Coordinate care with other physicians
- Dictate procedure outcome and expected recovery letter for referring physician and/or insurance company
- Remain with patient in ICU 1-3 hours until patient is hemodynamically stable and there is no evidence of postoperative bleeding. Manage inotropic agents and afterload reducing agents to maintain adequate cardiac output and minimize stress on the left ventriculotomy
- Visit ICU 2-3 times (15-20 minutes each) and before leaving hospital at the end of the day.
- Call ICU nurse in the evening to ensure patient progress, modify orders as necessary

On a daily basis as necessary, the postoperative care will include the following:
- Examine and talk with patient, check wounds and patient progress
- Review nursing/other staff patient chart notes
- Answer patient family questions
- Answer nursing/other staff questions, review nursing/other staff patient chart notes
- Write orders for following day's labs, films, medications, diet, and patient activity
- Chart patient progress notes
- Discuss patient progress with referring physician (verbal and written)
- Coordinate care with other physicians
- Review post-discharge wound care and activity limitations with patient
- Review post-discharge labs/films
- Remove sutures/drains
- Dictate patient progress notes for medical chart

SURVEY DATA

RUC Meeting Date (mm/yyyy)	04/2005		
Presenter(s):	John Conte		
Specialty(s):	Society of Thoracic Surgeons/ American Association for Thoracic Surgery		
CPT Code:	33548		
Sample Size:	200	**Resp n:** 20	**Response:** %

CPT Code:3354X

Sample Type: Random						
		Low	25th pctl	Median*	75th pctl	High
Survey RVW:		30.00	3475.00	**37.97**	42.00	49.74
Pre-Service Evaluation Time:				**60.0**		
Pre-Service Positioning Time:				**15.0**		
Pre-Service Scrub, Dress, Wait Time:				**20.0**		
Intra-Service Time:		180.00	207.50	**217.00**	242.50	360.00
Post-Service	**Total Min****	**CPT code / # of visits**				
Immed. Post-time:	**40.00**					
Critical Care time/visit(s):	**158.0**	99291x **2.0** 99292x **1.0**				
Other Hospital time/visit(s):	**202.0**	99231x **1.0** 99232x **2.0** 99233x **3.0**				
Discharge Day Mgmt:	**45.0**	99238x **0.00** 99239x **1.00**				
Office time/visit(s):	**84.0**	99211x **0.0** 12x **0.0** 13x **2.0** 14x **1.0** 15x **0.0**				

**Physician standard total minutes per E/M visit: 99291 (60); 99292 (30); 99233 (41); 99232 (30); 99231 (19); 99238 (36); 99215 (59); 99214 (38); 99213 (23); 99212 (15); 99211 (7).

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU
33542	090	28.21

CPT Descriptor Myocardial resection (eg. ventricular aneurysmetcomy)

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU
35531	090	36.15

CPT Descriptor 1 Bypass graft, with vein; aortoceliac or aortomesenteric

MPC CPT Code 2	Global	Work RVU
61585	090	37.26

CPT Descriptor 2 Orbitocranial approach to anterior cranial fossa, extradural, including supraorbital ridge osteotomy and elevation of frontal and/or temporal lobe(s); with orbital exenteration

Other Reference CPT Code	Global	Work RVU
33860	090	37.94

CPT Descriptor Ascending aorta graft, with cardiopulmonary bypass, with our without valve suspenision;

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 14 **% of respondents:** 70.0 %

TIME ESTIMATES (Median)	**New/Revised CPT Code: 33548**	**Key Reference CPT Code: 33542**
Median Pre-Service Time	95.00	84.00
Median Intra-Service Time	217.00	192.00
Median Immediate Post-service Time	40.00	59.00
Median Critical Care Time	158.0	35.00
Median Other Hospital Visit Time	202.0	69.00
Median Discharge Day Management Time	45.0	0.00
Median Office Visit Time	84.0	24.00
Median Total Time	**841.00**	**463.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)

Mental Effort and Judgment (Mean)

The number of possible diagnosis and/or the number of management options that must be considered	5.00	3.00
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	5.00	4.00
Urgency of medical decision making	3.00	3.00

Technical Skill/Physical Effort (Mean)

Technical skill required	5.00	5.00
Physical effort required	5.00	4.00

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	5.00	5.00
Outcome depends on the skill and judgment of physician	5.00	5.00
Estimated risk of malpractice suit with poor outcome	5.00	4.00

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1

Time Segments (Mean)

Pre-Service intensity/complexity	5.00	5.00
Intra-Service intensity/complexity	5.00	5.00
Post-Service intensity/complexity	5.00	4.00

ADDITIONAL RATIONALE

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

We are recommending 36.47 RVUs, which is the survey median. However, because the key reference service is one of the codes that is being reviewed in the 2005 5-year review process, the STS would like to request that the median value in this survey be considered interim by the RUC for purposes of reporting to CMS for MFS 2006 and that this new code be added to the 5-year review list with the other adult cardiac codes for review during the 5 year review to avoid creating a rank order anomaly within these codes from the outset.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this new/revised code typically reported on the same date with other CPT codes? If yes, please respond to the following questions:

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this new/revised code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 33542-22

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty cardiothoracic surery How often? Rarely

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 1000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period?
If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

CPT Code:3354X

Specialty	Frequency	Percentage	%

Do many physicians perform this service across the United States? No

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Professional Liability Insurance Information (PLI)

Does the reference CPT code selected for physician work serve as a reasonable reference for PLI crosswalk? No

If no, please select another crosswalk and provide a brief rationale. 33860 should be used because it has a work RVU that is more similar.

Indicate what risk factor the new/revised code should be assigned to determine PLI relative value. Surgical

IWPUT ANALYSIS		Reference CPT code: 33542		
Row / Column		D	E	F
				MFS RVW for Ref: 28.21
		Database Data	RUC Standard	RVW
	Pre-service	Time	Intensity	(=time x intensity)
	Pre-service eval & positioning	41	0.0224	0.92
	Pre-service scrub, dress, wait	43	0.0081	0.35
	Pre-service total			1.27
	Post-service	Time	Intensity	(=time x intensity)
	Immediate post	59	0.0224	1.32
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
	ICU 99291	0	4.00	0.00
	ICU 99292	0	2.00	0.00
	NICU 99296	0	16.00	0.00
	NICU 99297	0	8.00	0.00
	99233	0	1.51	0.00
	99232	5	1.06	4.77
	99231	8	0.64	5.12
	Discharge 99238	1	1.28	1.28
	Discharge 99239	0	1.75	0.00
	99215	0	1.73	0.00
	99214	2	1.08	1.62
	99213	0	0.65	0.00
	99212	0	0.43	0.00
	99211	0	0.17	0.00
	Post-service total			14.11
		Time	IWPUT	INTRA-RVW
	Intra-service:	192.00	0.067	12.83

IWPUT ANALYSIS		RUC Five-Year Review Recommendation Reference CPT code: 33542		
Row / Column		D	E	F
			Workgroup 5 RVW	*44.20*
		Database Data	RUC Standard	RVW
	Pre-service	Time	Intensity	(=time x intensity)
	Pre-service eval & positioning	75	0.0224	1.68
	Pre-service scrub, dress, wait	20	0.0081	0.16
	Pre-service total			1.84
	Post-service	Time	Intensity	(=time x intensity)
	Immediate post	40	0.0224	0.90
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
	ICU 99291	2	3.99	7.98
	ICU 99292	0	2.00	0.00
	NICU 99296	0	16.00	0.00
	NICU 99297	0	8.00	0.00
	99233	3	1.51	4.53
	99232	2	1.06	2.12
	99231	1	0.64	0.64
	Discharge 99238	1	1.28	1.28
	Discharge 99239	0	1.75	0.00
	99215	0	1.73	0.00
	99214	1	1.08	1.08
	99213	1	0.65	0.65
	99212	0	0.43	0.00
	99211	0	0.17	0.00
	Post-service total			19.18
		Time	IWPUT	INTRA-RVW
	Intra-service:	207.00	0.112	23.18

IWPUT ANALYSIS		4_2005 RUC Recommendation 3354X		
Row / Column		A	B	C
				MEDIAN Svy RVW: 37.97
		Survey Data	RUC Standard	RVW
	Pre-service	Time	Intensity	(= Time x intensity)
	Pre-service eval & positioning	57	0.0224	1.28
	Pre-service scrub, dress, wait	38	0.0081	0.30
	Pre-service total			1.58
	Post-service	Time	Intensity	(=time x intensity)
	Immediate post	60	0.0224	1.34
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
	ICU 99291	1	4.00	4.00
	ICU 99292	0	2.00	0.00
	NICU 99296	0	16.00	0.00
	NICU 99297	0	8.00	0.00
	99233	1	1.51	1.51
	99232	1	1.06	1.06
	99231	6	0.64	3.84
	Discharge 99238	0	1.28	0.00
	Discharge 99239	1	1.75	1.75
	99215	0	1.73	0.00
	99214	1	1.08	1.08
	99213	2	0.65	1.30
	99212	0	0.43	0.00
	99211	0	0.17	0.00
	Post-service total			15.88
		Time	IWPUT	INTRA-RVW
	Intra-service:	240.00	0.085	20.51

IWPUT ANALYSIS		Revised Recommendation 33548		
Row / Column		A	B	C
				New Rec RVW 49.74
		Survey Data	RUC Standard	RVW
	Pre-service	Time	Intensity	(= Time x intensity)
	Pre-service eval & positioning		0.0224	1.68
	Pre-service scrub, dress, wait		0.0081	0.16
	Pre-service total			1.84
	Post-service	Time	Intensity	(=time x intensity)
	Immediate post		0.0224	0.90
	Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
	ICU 99291		3.99	7.98
	ICU 99292	1	2.00	2.00
	NICU 99296	0	16.00	0.00
	NICU 99297	0	8.00	0.00
	99233		1.51	4.53
	99232		1.06	2.12
	99231		0.64	0.64
	Discharge 99238	0	1.28	0.00
	Discharge 99239		1.75	1.75
	99215	0	1.73	0.00
	99214		1.08	1.08
	99213		0.65	1.30
	99212	0	0.43	0.00
	99211	0	0.17	0.00
	Post-service total			22.30
		Time	IWPUT	INTRA-RVW
	Intra-service:	217.00	0.118	25.61

Svy-T* indicates insert survey time data.
Svy-V* indicates insert survey visit data.
Ref-T* indicates insert reference time data, from RUC database.
Ref-V* indicates insert reference visit data, from RUC database
**Note: Office visit RVW's shown reflect RUC/CMS "discounted" values.

From STS database and Intensity Survey
From 4_2005 RUC Recommendation
From Consensus of Workgroup 5 for 33542

	2001-4	2001-4
CPT Code	33542	3354X
N	277	29
Age	62.6	60.4
% Male Gender	59%	52%
Weight(kg)	81.3	84.2
Diabetes	24%	38%
PVD	13%	12%
CVD	13%	12%
Previous Other Cardiac(PCI)	35%	44%
Congestive Heart Failure	46%	66%
Cardiogenic Shock	10%	14%
Preop IABP	23%	28%
Meds-Antiplatelets	9%	14%
Meds-Inotropic Agents	9%	14%
Meds-ADP Inhibitors	6%	13%
Ejection Fraction	37.0	35.3
Perfusion Time	96	95
Cross Clamp Time	61	64
Skin to Skin Time(min)	207	217
Total Hours Ventilated	32	42
Total ICU Hours	80.8	103.2
Post Operative Length of Stay	8.6	10.2
Readmisson <=30 Days	6%	10%

CPT Code: 33548

AMA/Specialty Society Update Process
PEAC Summary of Recommendation
090 Day Global Period
Facility-ONLY Direct Inputs

CPT	DESCRIPTION	GLOBAL
33548 E1	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedure)	090

CLINICAL STAFF TIME: RN staff type for all activites
Pre-service period clinical staff time: Sixty minutes has been established by a PEAC workgroup as the typical total time it takes on average across all specialties and for all categories of pre-service work to get a patient into a facility for a procedure. This time has been applied.

Service period clinical staff time: The assignment of 15 minutes (as supported by the PEAC) relative to coding of 99239 for discharge management for inpatient services has been applied.

Post-service period clinical staff time: Standard EM postop OFFICE visit times for clinical staff have been applied as appropriate.

SUPPLIES AND EQUIPMENT – POSTOPERATIVE OFFICE VISITS:
Standard PEAC minimum multispecialty office visit supplies and incision care have been applied.

	A	B	C	D	E
1				33548	
2				E1	
3	**Meeting Date: April 2005**	CMS STAFF TYPE, MEDICAL SUPPLY, OR EQUIPMENT CODE		Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedure)	
4				090	
5		**Code**	**StaffType**	**NF**	**FAC**
6	**TOTAL CLINICAL LABOR TIME**	L051A	RN	**N/A**	**200**
7	TOTAL **PRE-SERV** CLINICAL LABOR TIME	L051A	RN		**60**
8	TOTAL **INTRA** CLINICAL LABOR TIME	L051A	RN		**15**
9	TOTAL **POST-SERV** CLINICAL LABOR TIME	L051A	RN		**125**
10	**PRE-SERVICE**				
11	***Start: After visit for procedure/service***				
12	Complete pre-service diagnostic & referral forms	L051A	RN		**5**
13	Coordinate pre-surgery services	L051A	RN		**20**
14	Schedule space and equipment in facility	L051A	RN		**8**
15	Provide pre-service education/obtain consent	L051A	RN		**20**
16	Follow-up phone calls & prescriptions	L051A	RN		**7**
18	***End: Pt. enters site for procedure/service***				
19	**SERVICE PERIOD**				
40	Discharge day management 99239 --15 minutes	L051A	RN		**15**
41	Other Clinical Activity (please specify)				
42	***End: Patient leaves site of procedure/service***				
43	**POST-SERVICE Period**				
44	***End: Patient leaves site of procedure/service***				
45	Conduct phone calls/call in prescriptions				
46	*List Number and Level of Office Visits*				
47	99211 16 minutes	L051A	RN		
48	99212 27 minutes	L051A	RN		
49	99213 36 minutes	L051A	RN		**2**
50	99214 53 minutes	L051A	RN		**1**
51	99215 63 minutes	L051A	RN		
52	***Total Office Visit Time***				**125**
53	Other:				
54	***End: Last office visit in global period***				
55	**MEDICAL SUPPLIES**	**Code**	**Unit**		
56	pack, minimum multi-specialty visit	**SA048**	**pack**		**3**
57	pack, post-op incision care (suture & staple)	**SA053**	**pack**		**1**
58					
59	**Equipment**	**Code**			
60	table, power	**EF031**			**125**
61	light, exam	**EQ168**			**125**