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**GENERAL**

GENERAL

See attachment

CMS-1321-FC-21-Attach-1.DOC

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Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, Attention: CMS–4119–P
P.O. Box 8017
Baltimore, MD 21244–8017

**RE: Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] RIN # 0938–AO58**

Dear Administrator Norwalk:

The American Psychiatric Association (APA), the national medical specialty society representing more than 36,000 psychiatric physicians, appreciates the opportunity to submit these comments in response to the proposed rule by the Centers for Medicare & Medicaid Services (CMS), entitled "Medicare Program; Medicare Part D Data," concerning 42 C.F.R. Part 423 and published in the Federal Register on October 18, 2006.[1]

CMS intends, through this rule, to implement regulations under authority of Section 1860D–12(b)(3)(D) of the Social Security Act (the Act) that essentially broaden access to Part D prescription drug data. CMS proposes to add contract terms with Part D prescription drug plan sponsors (PDPs), under Section 1860D–12(b)(3)(D), "to allow the Secretary to collect the same claims information now collected under the authority of section 1860D–15 of the Act for research, internal analysis, oversight, and public health purposes."[2] CMS later elaborates that it does not actually intend to *collect* this data, rather just to *access* the data already collected under Section 1860D–15.[3] CMS'

[1] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)].

[2] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[3] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447:

reasoning for why the Section 1860D–15 restriction would not apply to the data collected under Section 1860D–15 is that CMS *could have* collected it under Section 1860D–12(b)(3)(D). CMS' stated intent is to allow uses for Part D data that would have been restricted under Section 1860D–15 without those contractual terms.[4]

CMS supports its position for the proposed rule by asserting that Section 1860D–15 data-use restrictions do not apply to Part D data collected in the following situations:

> "Where information is collected under an independent authority (even if the collected information duplicates the data collected under section 1860D–15 of the Act). . .
>
> (I)f the Secretary determines it is necessary and appropriate for him to collect Part D data in order to carry out responsibilities outside section 1860D–15 of the Act, then section 1860D–15 of the Act would not serve as an impediment to such collections." [5]

CMS' rationale, above, seems contrary to its intent not to actually collect the Section 1860D–15 data in any other way. CMS does not explain convincingly how data can be "collected under an independent authority" yet not actually be collected at all, how accessing data is synonymous with collecting it or how data admittedly collected under the authority Section 1860D–15 is not subjected to Section 1860D–15 restrictions just because CMS accesses that data for another purpose.

APA strongly objects to CMS' approach in this proposed rule both on legal and public policy bases. APA does not find a supportable legal basis for CMS to create regulations under the authority of one statutory provision that are designed expressly to circumvent another statutory provision. The goal of the proposed rule is to broadly expand the access and use of Part D prescription data. If implemented, this rule would launch Part D data into spheres that have been intentionally precluded from such access and use through federal statute. This sweeping approach is contrary to sound public policy.

The negative ramifications for doing so include increased risk of patient privacy violations, use of the data to pressure physicians to alter prescribing patterns and to pressure patients to request or accept certain drugs. APA agrees that there may be a degree of public benefit in carefully chosen entities using Part D data for certain, discrete

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"We would be collecting the same claims information collected under section 1860D–15 of the Act. We note that although section 1860D–12(b)(3)(D) of the Act would permit us to independently collect claims data from Part D sponsors, in order to ensure that Part D sponsors would not have to submit the claims information twice, we propose to access the claims data submitted under section 1860D–15 of the Act. This access avoids Part D sponsors engaging in duplicative efforts."

[4] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[5] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

activities. However, we do not agree with CMS' rationale for this proposed rule or that this is the most carefully tailored means by which to attain this goal.

**Part D Program Evaluation**

CMS implies that it needs to proposed rule to evaluate various aspects of the effectiveness and efficiency of Part D program, including matching individual patient-level statistics from Part D with Parts A and B data.[6] However, if CMS wishes to match Part D data with that from Parts A & B, Section 1860D–15(c)(C) already requires CMS to collect such linkable data from PDPs, data which is subject to use restrictions elsewhere in that section:

"(c) ADJUSTMENTS RELATING TO BIDS.—

> (C) DATA COLLECTION.—In order to carry out this paragraph, the Secretary shall require—
> (i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and
> (ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary."

Contrary to CMS' implications in the proposed rule, current laws and regulations do not appear to prevent CMS from using data collected under Section 1860D–15 from evaluating the Part D program. Section 1860D–15 allows the Secretary a wide range of discretion in determining the uses to which it puts the data collected: "for the purposes of, and to the extent necessary in, carrying out this section." If CMS wishes to collect Part D-related data on a PDP's operations, i.e., utilization management,[7] that CMS is not already collecting under Section 1860D–15, CMS can require PDPs to provide the data in future contracts, under Section 1860D-12. CMS would not appear to be precluded from matching separately collected operations data with Part D data collected under Section 1860D–15 for its program evaluation purposes.

**Reporting to Congress and the Public**

APA agrees when CMS states that, "we do not believe that section 1860D–15 of the Act was intended to prohibit the Secretary from reporting to both the public and to the Congress."[8] It is illogical that Section 1860D–15 would mean to preclude CMS from compliance with Section 101(e) of the Medicare Prescription Drug, Improvement, and

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[6] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[7] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61449.

[8] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

Modernization Act of 2003 (MMA) that specifically requires CMS to study the Part D program and report to Congress annually on its operation.[9] Those activities would appear to fall clearly within the Section 1860D–15 test: "for the purposes of, and to the extent necessary in, carrying out this section."

CMS essentially asserts that, if it uses Part D data to report to Congress, or if that data is otherwise not used to "carry out responsibilities outside Section 1860D–15" then Section 1860D–15 restrictions on the use of that data do not apply, even though the data was originally collected under Section 1860D–15.[10] Section 1860D–15 data-use restrictions are effective immediately to any data collected under Section 1860D–15, which specifically limits use of the data "for the purposes of, and to the extent necessary in, carrying out this section." That plainly means that use of that data for purposes outside of carrying out Section 1860D–15 responsibilities is specifically prohibited.

There is nothing in Section 1860D–15 suggesting that HHS is precluded from preparing mandated reports to Congress on Part D data collected under that section, making internal budget neutrality calculations that affect payments, or assessing appropriate use of medications to determine propriety of payments. All of these activities are permissible, as they relate to Part D PDP payments.[11] While reporting to Congress is required of CMS, reporting on Part D data directly to the public is not required; in fact, it is prohibited by Section 1860D–15, unless it is for the strict programmatic purposes of the section.

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[9] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61449, footnote 2:
"2 Section 101(e) of the MMA specifically extended the study authority in section 1875(b) to include the prescription drug program under Title XVIII. Section 1875 now states in pertinent part that the Secretary ''shall make a continuing study of the operation and administration of this title * * * and shall transmit to the Congress annually a report concerning the operation of such programs.'''

[10] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447:
"For example, we are required to report to the Congress regarding whether mandated disease management demonstrations are budget neutral and whether beneficiaries in these demonstrations are on the appropriate medications. Part D claims data are needed for these budget neutrality calculations as well as quality measures assessing appropriate use of medications. We may also need to make reports under the Part D program, for example, the publication of statistics detailing aggregate Medicare and beneficiary spending by class of drug, average number of drugs used by beneficiaries, total Medicare program spending, and other similar statistics. In order to derive such statistics, we would need to collect Part D claims data. These examples demonstrate that in a wide variety of situations it will be ''necessary and appropriate'' for CMS to evaluate the same information collected under section 1860D–15 of the Act, even though such information would not be used to implement section 1860D–15 of the Act. In these situations, we believe the clear language of section 1860D– 12(b)(3)(D) of the Act provides the authority to collect the necessary information, and nothing about such collection will be inconsistent or in conflict with any other part of the statute."

[11] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

However, CMS does not cite to a statutory mandate requiring reporting of Part D data to the public, apart from through its reports to Congress, which may become publicly available records. Contrary to CMS's interpretation that Section 1860D–15 was not intended to prohibit HHS reporting to the public, Section 1860D–15 specifically prohibits such use of the data, unless it complies with this section because it is "for the purposes of, and to the extent necessary in, carrying out this section." Whether or not a given type of public reporting complies with this requirement becomes a question of legal interpretation.

**Sharing Data with External Researchers**

CMS gives examples of ways in which it could share Part D data with external entities, if the proposed rule were implemented. A number of these examples refer to current uses or those that are already enabled by existing laws and regulations. Considerable Medicare data is already accessible to other entities and researchers. CMS currently sponsors two major, publicly available data sets each year on Medicare beneficiaries, "Access to Care" and "Cost and Use," that involve various claims data and can be purchased for only $480 each from the Internet.[12, 13]

CMS states, for example, that this proposed rule would allow CMS to give Part D data to the Food and Drug Administration (FDA) "in order to oversee the safety and effectiveness of prescription drugs and conduct postmarket surveillance . . ."[14] However,

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[12] Medicare Current Beneficiary Survey (MCBS) website: ". . . MCBS, which is sponsored by the **Centers for Medicare & Medicaid Services** (CMS), is the only comprehensive source of information on the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries."
Retrieved December 11, 2006: http://www.cms.hhs.gov/apps/mcbs/default.asp

"The Access to Care PUF contains information on beneficiaries' access to health care, satisfaction with care, and usual source of care. . . To facilitate analysis, the information collected in the survey is augmented with data on the use and program cost of Medicare services from Medicare claims data under fee-for-service. . .

The MCBS cost and use files link Medicare claims to survey-reported events and provides complete expenditure and source of payment data on all health care services, including those not covered by Medicare."
Retrieved December 11, 2006: http://www.cms.hhs.gov/apps/mcbs/DFDesc.asp#ATCfd

[13] **Purchasing Information**
CMS releases MCBS data only under a data use agreement. CMS will release some billing and administrative data with the MCBS survey data, commensurate with demonstrated need. Researchers who have specific needs for more detailed geographic information or for Medicare claims data may request Limited Data Set (LDS) Files from CMS. Requests for these files must include a study protocol with specific justification for the additional data required, along with an Identifiable Data Use Agreement.
Retrieved December 11, 2006: http://www.cms.hhs.gov/apps/mcbs/FileAval.asp

[14] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61448:
"(W)e believe that when information is collected under the auspices of section 1860D–12(b)(3)(D) of the Act, the restrictions of section 1860D–15 of the Act would not apply to such collections. Thus, any information collected for Part D purposes under this proposed rule would no longer be subject to the

FDA already routinely monitors prescription drugs, biologics, and medical devices for drug safety and effectiveness from clinical trials to the post-marketing stage, under its own regulatory authority through its own data collection and usage channels. CMS does not indicate that FDA has sought out Part D claims data from CMS or that it would use it.

The 37 data elements CMS lists on 2006 Part D claims data that are collected under Section 1860D–15 (subject to its use restrictions) do not contain data on patient outcomes, complaints, clinical signs or symptoms, or even the patient's diagnosis for which a drug is prescribed. It is unclear how CMS's sharing of Part D claims data with FDA could be used to accurately monitor "unsafe or suboptimal patterns of use" by drug type, dosage or duration, or identify rare drug complications at the patient or population levels. [15, 16] There would not appear to be claims data to support a causation or correlation between a given prescription and a patient's medical status or outcome at a given point, apart from documenting receipt of a prescription. These listed elements do not show a diagnosis that prompted the prescription or that the patient took the medication even once. All these characteristics of Part D claims data limit their application for certain studies. Also, Medicare beneficiaries constitute only a specific subpopulation of patients, which is a limiting factor in the use of data on them.

It is unclear whether FDA would be willing to use Part D claims data or whether it would improve FDA's work. There are reliability problems inherent with any claims data and issues with meshing Part D data with FDA's own databases. If FDA decided it needed additional data, presumably FDA could collect it without this proposed CMS rule. In certain circumstances, CMS may have the option to collect data separately under Section 1860D–12(b)(3)(D) for FDA or other purposes without of Section 1860D–15 restrictions applying. Those are discussed in more detail, below.

Another reason CMS posits for the proposed rule is its desire to share Part D claims information with external researchers, whose studies include those related to quality and cost of care for Medicare patients. However, CMS notes that Section 723 of the MMA already mandates that HHS develop a plan to improve care quality and reduce cost. For that purpose, Congress specifically provided for Part D data collection under Section 723(b)(3).[17] Therefore, this aspect of data collection and access has already been

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section 1860D–15 of Act limitations and could be shared outside of CMS as appropriate. Thus, for example, to the extent otherwise permitted by law, we would be able to share the data we collect under section 1860D–12(b)(3)(D) of the Act with entities outside of CMS including, for example, the Food and Drug Administration (in order to oversee the safety and effectiveness of prescription drugs and conduct postmarket surveillance) . . ."

[15] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447, where CMS lists the 37 data elements collected in 2006 for PDP payment.

[16] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61452.

[17] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61452.

provided for, obviating any need to alter any existing federal statute or regulations to accomplish this purpose. CMS can share Part D claims data freely with its contractors who are external researchers, since this is a permissible use under Section 1860D–15. As noted previously, CMS also sponsors annual data set releases to the public for research purposes, "Access to Care" and "Cost and Use,"on Medicare beneficiaries that will soon include Part D beneficiary data.

**Section 1860D–15 Restriction on Part D Data Use**

CMS notes in the proposed rule that, "(o)ne of the incorporated provisions at section 1860D–12(b)(3)(D) of the Act is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to its contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary 'with such information * * * as the Secretary may find necessary and appropriate.' We believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes us to collect much of the information CMS is already collecting in order to properly pay sponsors under the statute."[18]

Within the provision entitled, "(d) PAYMENT METHODS," Section 1860D–15(d)(2)(A) of the Act requires, that "a PDP sponsor or MA organization" give HHS "such information as may be required to carry out this section," as a requirement for payment.[19] The immediately following provision, Section 1860D–15(d)(2)(B), refers to the (d)(2)(A) information and imposes a clear restriction on its use:

> (B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of

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[18] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447:
"One of the incorporated provisions at section 1860D–12(b)(3)(D) of the Act is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to its contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary ''with such information * * * as the Secretary may find necessary and appropriate.'' We believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes us to collect much of the information CMS is already collecting in order to properly pay sponsors under the statute."

[19] Social Security Act, "SEC. 1860D-15. *[42 U.S.C. 1395w-115]*"
"(d) PAYMENT METHODS.—
(1) IN GENERAL.—Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.
(2) REQUIREMENT FOR PROVISION OF INFORMATION.—
(A) REQUIREMENT.—Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.
(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section."

Health and Human Services *only for the purposes of, and to the extent necessary in, carrying out this section.* (*Italics* added for emphasis.) [20]

In order to further reinforce this restriction, the drafters put this exact clause into another provision within Section1860D–15(f). Moreover, the statute mandates that this data-use restriction is to be put into each Part D (and Part C) contract:

> "(f) DISCLOSURE OF INFORMATION.— (1) IN GENERAL.—Each contract under this part and under part C shall provide that . . .
>
> (2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section." [21]

CMS' interpretation of this data-use restriction that appears *twice* in Section 1860D–15 is that "section 1860D–15 of the Act contains provisions that *might be viewed* as limiting such collection . . ."[22] *(Italics added for emphasis.)* The statutory drafters intentionally put the restriction into both the payment requirement and disclosure of information provisions. There is nothing equivocal about the choice of the word "only" or the fact that this restriction must be in HHS Part D contracts.

CMS cannot sidestep this clear statutory requirement by using Section 1860D–12(b)(3)(D) as authority to institute contractual terms that contravene or conflict with Section 1860D–15 provisions that govern and restrict the use of Part D data. HHS and its contractors are bound by the Section 1860D–15 data-use restriction, as they are by all applicable federal and state law. A federal agency and its private or public contractors cannot summarily pre-empt or avoid compliance with federal statutory law by contractual agreement.

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[20] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[21] Social Security Act, "SEC. 1860D-15. *[42 U.S.C. 1395w-115]*"
"(f) DISCLOSURE OF INFORMATION.—
(1) IN GENERAL.—Each contract under this part and under part C shall provide that—
(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and
(B) the Secretary shall have the right in accordance with section 1857(d)(2)(B) (as applied under section 1860D-12(b)(3)(C)) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).
(2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section."

[22] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

The lucid, highly restrictive language in Section 1860D–15 makes it is obvious that Congress recognized the need for strict limitations on the ways in which Part D data could be used. This statutory restriction wisely anticipated the potential for broad dissemination and misuse of Part D data. The restrictive provisions properly preclude dissemination of this information beyond the inevitable internal needs of the Part D program. Section 1860D–15 protects against exploitation of Part D data for commercial benefit and from privacy intrusions, both from the patient's and the prescriber's perspectives. This statutory provision was well-conceived and embodies sound public policy considerations that should remain intact.

CMS basically wishes to render inapplicable Section 1860D–15 data-use restrictions by using contractual terms with PDPs, through Section 1860D–12(b)(3)(D)'s authority. This is especially confounding, as it involves use of the same Part D data that CMS acknowledges was collected under Section 1860D–15 and will not be actually collected again, under Section 1860D–12(b)(3)(D). CMS specifically states in the proposed rule that, "(w)e propose to implement section 1860D–12(b)(3)(D) of the Act to allow the Secretary to collect the same claims information now collected under the authority of section 1860D–15 of the Act for research, internal analysis, oversight, and public health purposes."[23] Instead of using an outside legal authority to support this position, CMS quotes itself from the January 28, 2005 Medicare prescription drug benefit final rule:

> [W]e interpret sections 1860D–15(d) and (f) of the Act as limiting the use of information collected under the authority of that section. If information is collected under some other authority, however, we do not believe that section 1860D–15 of the Act would limit its use-because the information would not be collected ''pursuant to the provisions'' of section 1860D–15 of the Act. QIOs have independent authority to collect data, and to fulfill their responsibilities. To the extent QIOs need access to data from the transactions between pharmacies and Part D sponsors, these data could be extracted from the claims data submitted to us.[24]

Section 1860D-15(c)(1)(C) allows HHS to collect Part D drug claims data from PDP sponsors. Any such data is collected "pursuant to the provisions" of 1860D-15 and is subject to Section 1860D-15(d) and (f) use and disclosure restrictions that apply to HHS "officers, employees, and contractors." QIOs and other CMS contractors gain the authority they possess with regard to collecting or using Part D claims data from the authority CMS has under federal statutes. Therefore, both CMS and its contractors must be in compliance with Part D federal statutory restrictions under Section 1860D-15(d).

There are two possible scenarios under Part D data collection may fall outside Section 1860D-15 restrictions. One is where the collected data are different from the data collected under Section 1860D-15. The other is if the data are the same as or

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[23] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[24] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

overlaps Section 1860D-15 data but is actually collected pursuant to legal authority other than Section 1860D-15. It is possible that a court might determine that Section 1860D-15 restrictions would not apply under these situations. However, CMS does not offer legal authority for either of these interpretations. Even if there were extraneous data that could arguably fall outside Section 1860D-15 authority, data collected under Section 1860D-15 cannot avoid the restriction simply because there exists another avenue of collection for the same information.

Section 1860D–15 already allows for Part D data collection and use for HHS/CMS' internal programmatic purposes and even restricts use of it for that purpose. So, the obvious intent of the proposed rule is to expand access to Part D data to those whom the drafters of Section 1860D–15 clearly intended to preclude from having access and use. Despite the clear restriction on use of Part D data under Section 1860D–15, CMS finds ambiguity as to the meaning of the restriction, including as it intersects with 1860D–12(b)(3)(D). CMS explains that, "we are engaging in this rulemaking in order to resolve the statutory ambiguity, as well as to explain how we plan to implement the broad authority of section 1860D–12(b)(3)(D) of the Act."[25]

**Part D Information Collection and Access**

CMS acknowledges that, under Section 1860D–12(b)(3)(D), "(w)e would be collecting the same claims information collected under Section 1860D–15 of the Act."[26, 27] Adopting a parallel or duplicative data collection/use method would seem inconsistent with CMS' stated goal of conserving Medicare program resources for beneficiaries.

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[25] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[26] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61466-7.

SEC. 1860D-12. *[42 U.S.C. 1395w-112]* REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS:

"(b) CONTRACT REQUIREMENTS.—

> . . . (3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):
> . . . (D) Additional contract terms.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA-PD plan shall be treated as expenditures made under part D.

[27] SEC. 1857. *[42 U.S.C. 1395w-27]* CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS
"e) ADDITIONAL CONTRACT TERMS.—

> (1) IN GENERAL.—The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate."

To avoid that issue, CMS proposes to *access* the claims data already submitted under Section 1860D–15 for ostensibly non-Section 1860D–15 purposes, yet concludes that Section 1860D–15 restrictions on using that data would, nonetheless, not apply. Again, no legal authority is cited for CMS' conclusions in that regard. CMS logic is that:

> We would be collecting the same claims information collected under section 1860D–15 of the Act. We note that although section 1860D–12(b)(3)(D) of the Act would permit us to independently collect claims data from Part D sponsors, in order to ensure that Part D sponsors would not have to submit the claims information twice, we propose to access the claims data submitted under section 1860D–15 of the Act.[28]

CMS cannot legally circumvent the clear provisions of a federal statute on the basis of its own unsupported conclusions that the statute does not apply because CMS does not wish for it to apply. Once data are collected under Section 1860D–15 provisions and authority, Section 1860D–15 restrictions on use of the data automatically applies to those data, regardless of whether those data are otherwise accessible or could have been collected by other means. CMS notes that "(t)he claims data for 2006 includes 37 data elements."[29] Among these are highly sensitive information about patients, including their claim number identifying the beneficiary, birth date, gender, prescriber, drug(s) and other prescription information.

**Revised Section 423.505**

APA does not agree with or support any of CMS' proposed regulatory revisions that conflict with, pre-empt or render ineffective any provision of any federal statute. This includes Section 1860D–15 and its prohibitions on impermissible uses of Part D data. In addition, APA urges CMS to redraft this regulation to avoid any implication that it could be construed to circumvent or otherwise negate the effects of Section 1860D–15. CMS should revise the language of Part 423, including § 423.505, to require that application of Part 423 be strictly limited to Part D data CMS collects or accesses that does *not* duplicate, overlap or pre-empt data collected under Section 1860D–15.

CMS proposes to revise regulation § 423.505 "Contract provisions," including adding § 423.505(f)(5), "that would specify that we could use and share the claims information we collect under § 423.505(f) with both outside entities and other government agencies, without regard to any restriction included in § 423.322(b)."[30, 31]

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[28] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[29] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[30] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61451; 61454.

[31] "Sec. 423.322 Requirement for disclosure of information.

The restriction of § 423.322(b) mirrors the language of the Section 1860D–15 data-use restriction, stating that "(o)fficers, employees and contractors of" HHS "may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities." CMS' proposed rule not only specifically intends to circumvent Section 1860D–15 data-use restriction; it also intends to render its prior regulation embodying that concept completely ineffectual.

**Lack of Restrictions in the Proposed Rule**

The proposed rule does not provide the restrictions required to protect physicians' professional judgment, patients' privacy and to prevent commercial exploitation of the data. The following are examples of types of restrictions that should be enumerated and articulated within such a regulation, yet are absent:

1. Names or descriptive characteristics of public and private recipient entities (i.e., healthcare-related government agencies, non-profit healthcare research organizations, etc.);
2. Permissible types of uses for the data by recipient entities;
3. Prohibitions on commercial uses or commercial gain from using the data;
4. Prohibitions on use of the data to influence physicians' prescribing patterns, including on the individual patient level;
5. Prohibitions on use of the data to influence patients' choice or acceptance of generics or certain types or brands of Part D drugs, biologics, etc.;
6. Prohibitions on transmitting the data to third parties;
7. Requirements for privacy protections within systems, policies and procedures of recipient entities; and
8. Requirements for privacy protections during the use of the data, i.e., proper use of masking of identifiers

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(a) Payment conditional upon provision of information. Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) Restriction on use of information. Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law."

CMS proposes in this rule to share Part D data with "outside entities," in addition to "other government agencies." Presumably, CMS' use of the term "outside entities" in Sec. 423.505 refers to non-governmental entities, both public and private. APA is greatly concerned that the proposed rule would allow blanket access and unrestricted usage of Part D data by any entity with which CMS shares the data. Recipients could also share the data with third parties of their choice. While the proposed rule at least requires CMS to use and share the data "in accordance with applicable Federal law" (notwithstanding that doing so in contravention to Section 1860D–15 data-use restrictions would not meet this test), there is no similar compliance clause pertaining to the recipients of the data.

Also, there is absolutely no language in the proposed rule that restricts which recipients CMS can choose to receive this Part D data or how they use the data. CMS notes in the text of the proposed rule that Part D data would be useful for public health agencies such as National Institutes of Health (NIH), Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ). CMS also believes that oversight agencies, "such as the OIG, GAO, and CBO"[32] would need access to both aggregated and non-aggregated claims data.

However, the main purpose for use of Part D data by oversight agencies would be to perform extensive data mining to detect physicians' prescribing patterns of interest. This would be likely to result in physician profiling in an attempt to proactively identify potential fraud and abuse cases or other violations. That would promote more aggressive measures by these agencies to target physicians for enforcement efforts solely on the basis of profiling, rather than concrete evidence. While APA certainly supports legitimate enforcement efforts, there is concern that this profiling could burden many innocent physicians with having to defend themselves against undue allegations of programmatic violations and investigations.

There are no prohibitions on the nature of the use or sharing of the data by recipient entities, either internally or with third-party entities of their choice. This proposed rule, on its face, would allow Part D data recipients to use the data for commercial gain, including selling or trading the data, sharing the data with the recipient's subsidiaries, business partners, etc., or transmitting it to third parties for financial or other gain. FBI, police, life insurance companies, healthcare insurers, prospective employers and all manner of entities could potentially access and use this Part D data for whatever purposes they chose, commercial or otherwise.

**Physicians' Judgment, Patients' Privacy and Commercial Exploitation**

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[32] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61452:
"We believe oversight agencies may also require access to the Part D claims data. These agencies would include the Office of the Inspector General (OIG), the Government Accountability Office (GAO), the Congressional Budget Office (CBO), and the Medicare Payment Advisory Commission (MedPAC)."

While many benign and productive uses are possible for Part D data, widespread access to such data will inevitably be prone to misuse, breaches of privacy and commercial exploitation. APA is especially concerned that pharmaceutical companies and others with a financial interest in influencing physicians' prescribing patterns will be able to do so in a more highly targeted, effective way than is now possible. This can be done through marketing efforts, incentives and other methods that direct physicians toward prescribing drugs that provide higher a financial advantage to some entity.

Targeted pressure may be directed toward brand names, generics over brands, or certain classes of drugs over others. When detailed patient-level prescribing information is accessible, it allows for pinpointed influence attempts at the micro and macro levels. Where there is political pressure on government agencies to reduce costs for drug utilization, this can translate into increased pressure on physicians participating in such programs.

Whenever physicians are highly pressured to prescribe in a given direction, it interferes with their free exercise of professional judgment in the best interests of the patient. The managed care environment in private and public sectors already encourages more of this type of activity than is optimal for physicians and their patients. This would be markedly enhanced by CMS' proposed rule, which promotes interference with, rather than protecting, the sanctity of the physician-patient relationship.

APA has ongoing privacy concerns for patients, whose intimate medical details can be gleaned directly and indirectly from Part D claims data. The more widespread the data within computerized systems, the higher the likelihood of privacy breaches. When CMS wishes to compound this problem by widening the circle of dissemination of Part D data to any entity, regardless of its relationship to the program, the privacy concerns expand logarithmically. CMS notes that the proposed rule would not affect existing HIPAA, Privacy Act or states' privacy protections.[33] Such privacy laws cover physician-patient and other healthcare interactions but can easily be averted by commercial (or other) entities that are allowed to access and use Part D data outside the umbrellas of protection.

There are other issues. Insurance companies can access and use such data to the disadvantage of patients. For psychiatric patients, once an entity discovers merely that they are prescribed certain psychotropic drugs, it is easy to extrapolate with some degree of accuracy that the patient is experiencing psychiatric illness and what type it is. Especially considering the social stigma of psychiatric illness, having such information be widely accessible can adversely affect a person's life in a substantial way.

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[33] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61453:
"The proposed revision does not affect the applicability of HIPAA to the Department or any other appropriate parties, nor does it affect the applicability of the Privacy Act (5 U.S.C. 552a and b) or the Trade Secrets Act (18 U.S.C. 1905)."

Apart from these negative consequences of Part D data dissemination, various commercial advantages can be gained when entities access and use Part D data. Patients can be subjected to highly targeted marketing efforts to request or accept certain prescription drugs. While some may find this only a minor annoyance, marketing mailings can reflect that a person has a certain disorder or is on certain types of medication. This can prove highly intrusive and disruptive to their lives. For instance, a loved one may not be aware that a patient was prescribed a certain anti-depressant, but accidentally opens a mailing that indicates this. Such marketing can also influence a patient's willingness to accept a physician's recommendation to take a certain prescription drug that may work better for that patient.

The most CMS says in the proposed rule about patient privacy protections is that data release to external researchers would be subject to CMS' "standard data use agreement protocols" and that each research request would be evaluated to determine whether "(t)he confidentiality of beneficiary information is protected."[34] These statements are less than reassuring, especially absent any privacy protection language in the proposed regulation itself.

## CONCLUSION

APA supports CMS' goals such as addressing health disparities and improving Medicare services.[35] To the extent that publicly beneficial activities are genuinely precluded by current statutory language, a conclusion for which this proposed rule does not provide convincing support, APA would support CMS working with Congress to revise or amend the statute. However, APA does not support broadening the access or use of Part D data to any public or private entity that wishes to have it. APA is especially concerned about Part D data access by private commercial entities for financial gain, i.e., through pressuring physicians to alter prescribing patterns or for marketing drugs to current or prospective beneficiaries. As conceived, the proposed rule is far too liberal in its scope of intended access. Moreover, it lacks substantive privacy protections and other limitations to protect patients' welfare.

APA urges CMS to reconsider its approach to expanding access of Part D claims data. While APA agrees that public health and other benefits may be obtained from judicious sharing of Part D data with other governmental agencies and certain carefully chosen private entities, CMS must more thoroughly think through the appropriate legal and practical methods for reaching acceptable goals in this regard. The substantial privacy interests of patients and need to prevent undue intrusion into physicians' prescribing decisions must be carefully protected. Any further data sharing must account for and weigh these interests heavily against the likelihood of commercial exploitation

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[34] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61453.

[35] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61448.

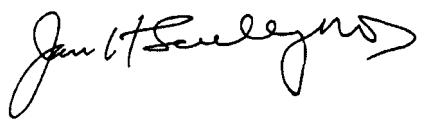
and unchecked dissemination of highly sensitive information into private and public spheres.

APA's position is that CMS's legal basis for accomplishing the goal of broader dissemination of Part D claims data is highly flawed and unsupportable. It is improper for a federal agency to deliberately design and implement a regulation specifically to avoid a federal statutory provision that protects the privacy and sanctity of Medicare beneficiaries' medical information. In addition, even if CMS' proposed method were appropriate, the language of the proposed rule is not tailored to provide any protection from patient privacy intrusions or breaches, undue influence upon prescribers, commercial exploitation, dissemination to third parties or other protections that should be required. APA believes that there is a more legally appropriate, highly tailored way to achieve most, if not all, of CMS's goals for enhancement of the Part D program by very selectively choosing certain other government agencies and researchers with which to share Part D data.

APA strongly urges CMS to weigh privacy and other interests against potential benefits, then determine with precision which government agencies and external entities truly would provide sufficient benefits to the public, if CMS were to share Part D data with them. There must be clearly delineated, specific parameters for access, use and dissemination of Part D data that comports with existing federal statutes, including Section 1860D–15 data-use restrictions, and protects patients' privacy to the utmost degree possible.

Thank you for allowing APA the opportunity to communicate its concerns.

Sincerely,



James H. Scully Jr., M.D.
Medical Director and C.E.O., American Psychiatric Association

**Submitter :** **Dr. Terrence Cronin Jr.** **Date: 12/26/2006**

**Organization :** **American Society for Mohs Surgery**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

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.

**Interim Relative Value Units**

Interim Relative Value Units

Leslie V. Norwalk
Acting Administrator

CMS-1321-FC-22-Attach-1.DOC

December 26, 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:

The American Society for Mohs Surgery is dedicated to the treatment and cure of patients suffering with skin cancer through the use of Mohs Surgery. The ASMS currently has almost nine hundred members and represents a majority of the dermatologic surgeons in the United States performing Mohs micrographic surgery.

Recently, the 2007 American Medical Association Current Procedural Terminology (CPT) manual has been changed such that the Mohs micrographic surgery codes (17311-17315) have been removed from 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 would be a departure from a longstanding exemption agreed to by CMS since 1992. We are concerned that the Centers for Medicare and Medicaid Services may have changed a reimbursement policy 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 Mohs codes 17311-17315 include both excision of cancer and the precise pathologic examination of tissue margins by the operating surgeon. Following determination of clear margins, reconstructive procedures are then undertaken, if necessary. The 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 questioned nor reviewed 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.

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 did CMS suggest it was considering such a change. As such, the ASMS, 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 change in 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 is to take effect.

Should you require additional information, please do not hesitate to contact me at tcronin2@aol.com or 800-616-2767. I appreciate your attention to this important matter.

Sincerely,

Terence Cronin, M.D.
President,
American Society for Mohs Surgery

Cc: Herb Kuhn, Deputy Administrator CMS
Liz Richter, Director Hospital Ambulatory Policy Group, CMS
Terrance Kay, Deputy Director, Hospital and Ambulatory Policy Group, CMS
Amy Basonno, Directory 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
Georgeanne Dixon, Executive Director, ACMMSCO
John Zitelli, M.D., FAAD, Chair, ACMMSCO CPT Coding Task Force
Novella Rodgers, Executive Director, ASMS
Sharon Tiefenbrunn, President-elect, ASMS .

**Submitter :** **Dr. Terrence Cronin Jr.** **Date: 12/26/2006**

**Organization :** **American Society for Mohs Surgery**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

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Leslie V. Norwalk
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CMS-1321-FC-23-Attach-1.DOC

December 26, 2006

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Sincerely,

Terence Cronin, M.D.
President,
American Society for Mohs Surgery

Cc: Herb Kuhn, Deputy Administrator CMS
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John Zitelli, M.D., FAAD, Chair, ACMMSCO CPT Coding Task Force
Novella Rodgers, Executive Director, ASMS
Sharon Tiefenbrunn, President-elect, ASMS .

**Submitter :** **Dr. Anir Dhir** **Date: 12/27/2006**

**Organization :** **Dermatology Associates of Kentucky, PSC**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Dear CMS,

I am a Mohs surgeon practicing with Dermatology Associates of Kentucky in Lexington. Established in 1951, our practice is one of the oldest and most comprehensive dermatologic practices in the country. Our nine board-certified dermatologists include 2 fellowship-trained Mohs surgeons, as well as a dermatopathologist, the state's only immunodermatologist, and four dermatologists with additional board-certification in either internal medicine or pediatrics.

We are proud of our 50+ year history of service to our community, but remain concerned about ongoing decisions by CMS that are affecting our ability to continue to deliver the highest-quality care to our patients. Just this year, the Mohs surgeons in our practice were forced to discontinue participation with Medicaid due to increasing administrative burdens and inadequate reimbursement. Our analysis revealed that CMS was paying between 20-33% of our charges for Mohs surgery, and inaccurately bundling Mohs stages and surgeries for multiple cancers. Simply put, we were losing money on each and every Mohs surgery performed for a Medicaid beneficiary.

We want to thank the CMS for formally recognizing the increased RVU's associated with Mohs surgery of facial lesions (or those involving deep structures such as muscle, bone, or cartilage) by transitioning from the current 17304 code to the new 17311 and 17313 codes. Unfortunately, we were shocked to learn that the CMS had changed the status of 17311 and 17313 to stage one codes subject to the MSRR (multiple surgery reduction rule). In the 1992 Medicare Fee Schedule Final Rule (published 11/25/91), the Mohs codes were exempted from the MSRR, based on the fact that the act of physically removing the cancer and microscopically ensuring its complete removal (via pathology examination by the Mohs surgeon) is a definable and separate act from any subsequent reconstruction.

With Mohs surgery, the surgeon also acts as the pathologist - avoiding any additional charges from a pathologist. Also, the Mohs surgeon must delay any needed repair for possibly several hours while processing the tissue for microscopic analysis. This is quite different from the traditional surgical approach in which the tissue is sent to an outside laboratory for analysis by a separate pathologist, and the wound is closed immediately without knowledge of whether the cancer has been completely removed.

Our practice has been safely and effectively performing Mohs surgery since 1987, with a cure rate well over 99%. This compares to a cure rate of 92-94% with traditional (non-Mohs) surgery. Studies have shown that Mohs surgery is cost effective for CMS, because of increased cure rates as well as reduced costs by avoiding an outside pathologist, anesthesiologist, and hospitalization in most cases. With respect to the removal of Mohs codes from MSRR exemption, we are concerned that (1) CMS did not comply with its own public notice and comment period requirements, and (2) CMS may create a situation in which the costs of providing high-quality Mohs surgical care to Medicare beneficiaries are greater than the reimbursement provided by CMS. This may force us to discontinue or reduce our Mohs surgical services, and this would be detrimental to the quality of care we have tried to provide at Dermatology Associates of Kentucky for over 50 years.

We ask that CMS continue to exempt Mohs codes from MSRR. Thank you for your time and consideration.

Respectfully yours,

Anir Dhir, MD
Dermatology Associates of Kentucky, PSC
250 Fountain Court
Lexington, KY 40509

**Interim Relative Value Units**

Interim Relative Value Units

Removal of Multiple Surgery Reduction Rule (MSRR) exemption for new Mohs micrographic surgery codes 17311 and 17313

**Submitter :** **Dr. Timothy Mate** **Date: 12/27/2006**

**Organization :** **Swedish Cancer Institute**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1321-FC-25-Attach-1.DOC

CMS-1321-FC-25-Attach-2.DOC

**SWEDISH** CANCER INSTITUTE

*December 12, 2006*



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

**ATTN: FILE CODE CMS-1321-FC**

**Re: 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:

I am writing on behalf of Swedish Cancer Institute to address an issue of great importance to Medicare beneficiaries with cancer. Swedish Cancer Institute is a radiation therapy center, which provides radiation therapy for cancer patients. We serve approximately 600 prostate cancer patients annually, many of whom are treated with external beam radiation therapy and would benefit from accurate and precise radiation therapy treatment by having fiducial markers implanted into the prostate to indicate the position and relative motion of the prostate during radiation therapy.

I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. The new CPT Code, 55876, covers placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial marker, dosimeter) for the prostate (via needle or any approach) whether single or multiple. It is understood that the intent of this new code was established to a new procedure code for implant of fiducial markers in the prostate – during the Final Rule review process a question was raised about whether fiducial markers should be included in the payment.

It should be recognized that there are a variety of types of devices that may be implanted in the prostate, each having very different functionality and costs associated. For example, some types of devices (gold fiducials and electromagnetic transponders), may be implanted in the prostate to locate the prostate, align it with the radiation beam at initial radiation setup every day for 40 or more days. Other devices such as electromagnetic transponders not only provide an initial setup function but also continuously monitor the three-dimensional position of the prostate during radiation beam delivery. Based on my literature review, the benefits of continuous, real-time tracking during radiation with electromagnetic transponders over simple gold fiducials (setup only) are potentially more significant. Real-time continuous tracking I expect will ultimately improve disease control and reduce the number of complications - such as rectal bleeding, incontinence, sexual dysfunction—that may occur during radiation therapy treatment or in the years subsequent to the treatment.

Thus, it is important to realize that there are a variety of fiducial marker types of very different complexity and functionality ranging from simple gold markers ($200) to implantable dosimeters ($900) to electromagnetic transponders ($1200). If the cost of the devices implanted were bundled there would be a significant discrepancy in payment for devices, which does not account for the range in complexity and functionality and potential benefit to the patient.

The physician final rule proposal does not recognize the importance between the various types of fiducial markers, particularly the difference between gold markers, implantable dosimeters or electromagnetic transponders. In fact, the costs to Swedish Cancer Institute of acquiring, maintaining, and utilizing the electromagnetic transponders and the technology to monitor them is costly. The payment rate for implanting markers in the prostate should not incorporate dollars for the fiducial markers, as there is a range of device types and those at either end of the cost scale with is inappropriate.

Many cancer patients benefit from more accurate radiation therapy delivery requiring implantation of fiducial markers to guide treatment setup and delivery. The proposed payment rate for 55876, Placement of Device for Radiation Therapy Guidance, would seriously underpay clinicians using electromagnetic transponders, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the proposed rate be reviewed ***without*** bundling the cost of the fiducial markers into the final payment. In addition, the procedure for implanting fiducial markers is very similar to the prostate insertion procedure and should be compensated based on the skills required for the procedure reflected in the New Technology APC 1511: Level XI or APC 1512: Level XII, identified by the American Society for Therapeutic Radiology and Oncology in their letter to CMS dated October 9, 2006.

Medicare payment rates are being established in 2007 for the new CPT code 55876. The Final Rule from CMS on November 1, 2006 highlights a comment period ending on January 2, 2007 to address what is included in the payment rate for this code. It had been proposed by professional societies that the payment bundle in the cost of fiducial markers, estimated by CMS to cost $119.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Timothy P. Mate, M.D.
*tmate@seanet.com*
*206-386-2323*

**Submitter :** **Date: 12/27/2006**

**Organization :** **American Academy of Neurology**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attached. Thank you.

CMS-1321-FC-26-Attach-1.DOC


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December 27, 2006

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

*RE: file code CMS-1321-FC*

Dear Acting Administrator Norwalk:

The American Academy of Neurology (AAN) is proud to represent more than 20,000 neurologists and neuroscience professionals worldwide. The AAN would like to take this opportunity to comment on the CMS final rule entitled: *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* [CMS-1321-FC] Federal Register, December 1, 2006. Specifically, the AAN would like to offer comment on the CMS decision to bundle newly created anticoagulation management codes (99363 & 99364) into existing evaluation and management (E/M) service codes.

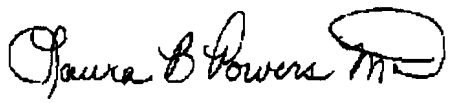
The anticoagulation management codes were developed in response to the poor quality of care that many patients on warfarin therapy receive; due at least in part to the failure of the payment system to recognize the physician work involved in monitoring use of the drug. In developing language for the codes, the CPT editorial panel, working closely with the Relative Value Update Committee (RUC), was careful to incorporate protections that would prevent anticoagulation management work from being included in selecting the level of evaluation and management services. The consensus at many of the meetings to discuss the new codes was that they can both reduce unnecessary utilization and improve care. By bundling the codes, Medicare patients may be forced to continue to take needless trips to see their physician and CMS, in turn, may actually see costs *rise*.

To our knowledge, CMS did not offer any explanation for its decision to bundle these codes. If there is to be no reimbursement for the work that physicians do in managing the very sick, there will likely be few physicians interested in managing those patients. The new CPT codes encourage

recognition of the important work of managing serious disease. The decision by CMS to bundle the codes, and effectively hide the recognition the codes work hard to achieve, could have an undesirable impact. Thus, the AAN urges CMS to reconsider and change its decision.

Thank you for your consideration of our comments. If you have questions, please contact Katie Kuechenmeister, AAN Staff, at kkuechenmeister@aan.com or 651-695-2783.

Regards,



Laura B. Powers, MD, FAAN
Chair, Medical Economics and Management Committee, AAN

**Submitter :** **Date: 12/28/2006**

**Organization :** **American Academy of Orthopaedic Surgeons**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

**Submitter :** Ms. Mary Essling **Date:** 12/28/2006

**Organization :** American Society of Plastic Surgeons

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-FC-28-Attach-1.PDF

CMS-1321-FC-28-Attach-2.PDF

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December 28, 2006

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

SUBMITTED ELECTRONICALLY: http://www.cms.hhs.gov/eRulemaking

**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; Final Rule**

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Final Rule for "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'' that was displayed on the CMS Web site November 1, 2006 and published in the December 1, 2006 Federal Register. As requested in the final rule, the relevant "issue identifier" that precedes the section we are commenting on is used as a sub-heading throughout this letter to assist the Agency in reviewing these comments.

The ASPS is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports the education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Final Rule.

***Budget Neutrality***

ASPS understands that CMS is required by law to ensure that increases or decreases in RVUs do not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from

what spending levels would have been in the absence of these changes. We disagree with CMS' rationale that it is more equitable to apply the budget neutrality adjustment across services that have work RVUs due to the changes that occurred as a result of the Five-Year Review of work RVUs. The RUC reaffirmed its position that applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward. Despite the Agency's plan to maintain transparency by listing the work RVUs without applying the budget neutrality adjuster, the adjustment to the work relative units will cause confusion among the many non-Medicare payers, as well as physician practices, that adopt the RBRVS payment system. We strongly urge CMS to reverse its decision and apply any necessary adjustment to the conversion factor, only.

***Anesthesia and Physician Fee Schedule Conversion Factors for CY 2007***

The ASPS is pleased and appreciative that CMS has worked with Congress to enact legislature to prevent a five percent cut in 2007 Medicare physician rates by freezing the Medicare conversion factor at its 2006 level. This decision will encourage our members to participate as Medicare providers and, consequently, ensure that Medicare beneficiaries receive quality medical care that they deserve.

***Addendum B***

Addendum B in the proposed rule reflected practice expense relative values that were computed using adjusted work RVUs. The application of budget neutrality to the work RVUs was applied and utilized in the indirect practice expense allocation, despite CMS clear written statement that this would not occur. ASPS is pleased that CMS corrected this error in its correction notice by applying the unadjusted work RVUs as the appropriate allocator in the methodology, however we maintain our position that the adjustment to the work relative units will cause confusion among the many non-Medicare payers, as well as physician practices, that adopt the RBRVS payment system. As stated previously, we strongly urge CMS to reverse its decision and apply any necessary adjustment to the conversion factor, only.

***Status indicator***

Rationale for why code 15830 should be changed from R status to A status.

CMS reviewed the summary of recommendations in which the RUC and specialty society recommended that CPT code 15847, *Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication (List separately in addition to code for primary procedure)*, an add-on procedure to 15830, be carrier priced in order to reduce the potential for abuse. Based on this recommendation, CMS inaccurately applied the same rationale (to reduce the potential for abuse) when assigning a status indicator of "R" (Restricted) to the base code 15830 (Panniculectomy). CMS stated that medical necessity should be established prior to payment on code 15830 thus qualifying it as "restricted" status. ASPS believes that all physicians should demonstrate medical necessity prior to performing this type of procedure just as they would do for active status procedures. Medical necessity is inherent when performing a panniculectomy for insurance purposes, thus our confusion. These two procedures are performed for very different reasons. An abdominoplasty is almost always performed for cosmetic reasons whereas a panniculectomy can be performed for functional reasons.

ASPS and other relevant societies were opposed to creating an abdominoplasty code because they believed that there wasn't a "typical patient or service" that describes 51% or more of patients undergoing the procedure described by the new add-on code 15847 (abdominoplasty). However, the CPT Editorial Panel believed the code was necessary for tracking purposes.

Unlike a panniculectomy, an abdominoplasty can include a whole host of secondary nonfunctional procedures in *varying* combinations that are determined by individual patient parameters and surgeon preferences. Most of the surgical components of an abdominoplasty are cosmetic; not functional and, therefore, should be treated like other cosmetic procedures in CPT.

A panniculectomy can be a functional, reconstructive procedure performed to eliminate/reduce intertrigo, skin abscesses, lymphedema and lower back pain. In many respects this code can be compared to code 19318 (*Reduction mammaplasty),* which has an Active status. ASPS urges CMS to change the Restrictive status indicator for code 15830 to Active status to facilitate payment to physicians and to avoid confusion for beneficiaries who may be apprehensive about having a procedure if unsure of coverage.

**19340 – Global Period**

In a November 20, 2006 letter to Dr. Simon, we requested a change in global period for code 19340 from its current ZZZ to a 90 day global period. Although not specifically tied to recommendations in this final rule, we want to reiterate our request for the Agency's consideration. Code 19340 (Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction) is currently assigned a ZZZ global period, however, there is no + denotation preceding it in the *CPT manual* to identify it as an *add-on* code. It is somewhat of an anomaly and, therefore, has the potential to cause confusion among Medicare and other payers.

ASPS Payment Policy Committee members were surveyed on their practice patterns when performing this procedure. The general consensus is that 19340 can be a stand-alone code for immediate reconstruction at the time of the mastectomy or performed in addition to the primary procedure. Regardless, 19340 *is always* performed at the same operative session as another procedure though the other procedure is usually performed by a different surgeon (e.g. the general surgeon performs the mastectomy and the plastic surgeon performs the reconstruction). Therefore, the ASPS has requested that CMS change the global period for 19340 from a ZZZ to a 90 day global. If CMS agrees to this change, we further request that code 19340 be referred to the AMA/Specialty Society Relative Value Update Committee (RUC) to be re-valued to reflect pre-service and post-service physician work in addition to intra-service physician work.

As always, we greatly appreciate your consideration of these comments. We will continue to carefully monitor future correspondence on these and other relevant health care issues.

Sincerely,

Deborah S. Bash, MD
Chair, ASPS Payment Policy Committee

**Submitter :** **Mr. Robert Knorr** **Date: 12/28/2006**

**Organization :** **Tapestry Medical, Inc.**

**Category :** **Other Health Care Professional**

**Issue Areas/Comments**

**Interim Relative Value Units**

Interim Relative Value Units

We believe that the proposed reductions of 40-50% for G-0248 and G-0249 included in the proposed Fully Implemented PE RVUs are unreasonable and do not reflect the true cost of providing these atypical services. In fact, for G-0249 the cost of the Medical Supplies alone are greater that the entire Fully Implemented PE RVU of 2.42 for this code. The CMS data file shows Direct Practice Expense Values for G-0249 equivalent to 2.44 RVUs (i.e. $87.70 in cost elements divided by the 2007 conversion factor of 35.9848). At this rate the proposed Fully Implemented PE RVUs for G-0249 will not even cover the direct cost of Supplies let alone other direct Clinical Labor and Medical Equipment costs or any provision for Indirect Costs.

We believe that a major reason that the proposed Fully Implemented PE RVUs for both G-0248 and G-0249 are understated is due to the method that CMS uses for determining the Direct PE RVUs for the Medical Equipment. Specifically, we believe that the cost of the Home INR equipment should be determined by amortizing the cost of equipment over the total number of posible INR tests performed on this dedicated-use equipment. For example, for G-0249 the RVUs for the INR monitor alone should be at least 1.07 based on the cost elements in the CMS data file (i.e. $2,000 over the 4 year useful life divided by 13 units of allowable G-0249 services per year divided by a 35.9848 conversion factor). We believe that true cost of providing G-0249 services will be more accurately reflected by using this alternate method.

As a result of these and other recommendations outlined in our previously submitted comment letter of October 5, 2006 (CMS Temporary Comment # 92511) the total Fully Implemented RVU for G-0248 should be no less than 8.20 and for G0249 be no less than 4.79. These recommendations are based on our experience as one of the few providers of Home INR Monitoring services in the country.

CMS-1321-FC-29-Attach-1.PDF

CMS-1321-FC-29-Attach-2.PDF

TAPESTRY MEDICAL

1404 Concannon Blvd., Livermore, CA 94550

October 6, 2006

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

COMMENT TO: "Provisions Issues"

**File Code CMS-1321-P: Comments Related to Proposed Rulemaking re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B**

**SUMMARY**: We believe that the proposed reductions of 40-50% for G-0248 and G-0249 are unreasonable and do not reflect the true cost of providing these atypical services. We are requesting that CMS increase the Direct PE RVUs for G-0248 by at least 1.57 and for G-0249 by at least 0.82 over current RVUs in order to more accurately reflect the actual cost of these services. We recommend the total Fully Implemented RUV for G-0248 be no less than 8.20 and for G0249 be no less than 4.79. These recommendations are based on our experience as one of the few providers of Home INR Monitoring services in the country.

Dear Ms. Norwalk:

Tapestry Medical is pleased to provide this comment letter to the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" ("Proposed Rule"). We wish to comment specifically on proposed § II.A.5.(k) as it relates to the Resource-Based Practice Expense (PE) RVU Proposals for CMS Billing Codes G-0248 and G-0249. Tapestry Medical is an approved Medicare provider focused exclusively on providing Home INR Monitoring services (G-0248 and G-0249). Several years, I was personally involved in the original estimation of resources requirements when the Home INR Monitoring Program was first implemented. At the time, we provided CMS with a comprehensive analysis of our good faith estimate of the resource requirements for these atypical services. Our comments today are based on the experience and data that we have collected while providing over 2,500 G-0249 services to hundreds of eligible beneficiaries over the past two years.

We are concerned that the substantial proposed reductions in PE RVUs for these two codes do not accurately reflect the true cost of providing these unique services. Based on our updated analysis and experience, we recommend that CMS increase the Direct PE RVUs:

1. for G-0248 by at least 1.57 over current levels resulting in a Fully Implemented PE RVU of no less than 8.20 and
2. for G-0249 by at least 0.82 over current levels resulting in a Fully Implemented PE RVU of no less than 4.79.

Typically, we would also ask for a corresponding increase in Indirect PE RVUs based on a typical ratio of direct to indirect expenses. However, we recognize that the significant general operating costs associated with our initial Medicare enrollment was atypical. However, we reserve the right to revisit this assumption if this level of indirect costs continues in the future.

Home INR Monitoring is a unique benefit that involves providing beneficiaries with dedicated capital equipment and ancillary supplies to enable self-testing. In addition, providers such as Tapestry Medical educate new users in the care and use the INR monitoring equipment and facilitate the documentation and transfer of patient-generated testing results to the beneficiary's treating physician. Non-physician providers such as Tapestry Medical play an important role in providing access to this unique service because treating physicians have expressed strong reluctance to provide either G-0248 or G-0249 themselves.[1,2] Considering physician's reluctance to provide G-0248 or G-0249 services, CMS should expect that access to Home INR Monitoring will be seriously compromised if the substantial proposed RVU reductions are implemented.

Companies such as Tapestry Medical underwrite the risk associated with purchasing expensive capital equipment by providing the INR monitor to the beneficiaries and ensuring that patients test in accordance with their physician's instructions. Equipment can be lost, stolen, misused or patients can discontinue using the equipment for any reason. Retrieving and recertifying unused equipment from beneficiaries can be extremely difficult, time-consuming and costly. Nonetheless, we undertake this risk based on the assumptions that:

1. the cost of the equipment will be recouped over time as G-0249 services are provided,
2. beneficiaries will require (on average) 8 units of G-0249 services per year[3], and
3. RVUs for G-0248 and G-0249 will be sufficient to cover the value of the equipment and inadvertent equipment and supply wastage/spoilage by the beneficiary.

I am very concerned that the Direct Practice Expense Values used to create Resource-Based Practice Expense Relative Value Units in the Proposed Rule have resulted in substantial

[1] See CMS-1321-P Public Comment (#92425) submitted by Dr. Jack Ansell – Chairman of Anticoagulation Forum on October 5, 2006.

[2] See also, the August 2002 of "CAP TODAY" (www.cap.org) which highlights concerns expressed by the American College of Cardiology and other stakeholders.

[3] One unit of service supports 4 self-tests over a maximum frequency of four tests every 28 days

proposed reductions in the Non-Facility PE RVUs for G-0248 and G-0249. If fully implemented, these proposed reductions would result in a 50% decrease in G-0248 RVUs and a 40% decrease in G-0249 RVUs. We believe that such reductions are unreasonable and are substantially less than the true cost of providing these services. Furthermore, such reductions do not adequately consider the substantial risk that providers such as Tapestry Medical have already borne with beneficiaries have who have been provided with one of our INR monitors.

Based on meetings that I with CMS several years ago, I suspect that the methodology being used by CMS to calculate the per unit cost of the INR monitor in the Proposed Rule may be contributing to the unreasonable RVUs reductions that are now being proposed. It should be remembered that each INR monitor is provided to beneficiaries for their exclusive use over the estimated useful life of the equipment. Given that beneficiaries perform (on average) 32 tests or 8 units of G-0249 services per year, we reasonably expect that they will perform 40 units of G-0249 services over the expected useful life of the equipment. Therefore, the $1,975 price of the INR monitor should be amortized over 40 units of service at a rate of ~$50 per G-0249. I recommend that CMS review its methodology to ensure that the final calculation used in the Fully Implemented PE RVUs support this amortization rate for the INR monitor.

I recommend that CMS implement the following changes to the NPRM Direct Practice Expense Inputs for G-0248 and G-0249. These recommended changes have been incorporated in the attached three separate worksheets in the excel workbook. These files follow the same format as CMS' NPRM Direct Practice Expense Inputs included in the Proposed Rule.

| **Direct Practice Expense Input** | **Applicable Code** | **Recommended Change** |
|---|---|---|
| Clinical Labor | | |
| | G-0248 | 1. RATE should change in future years to reflect increases in Social Security Cost of Living Allowance.<br>2. Increase G1_I from 50 to 120 minutes to reflect the minimum amount of time required for clinical staff to perform demonstrate and document use and care of INR monitor in accordance with protocol used by manufacturer to obtain FDA approval.<br>3. Decrease G1X_I from 20 to 10 minutes to reflect the minimum time required for clinical staff to confirm patient's ability to perform testing after initial demonstration.<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs over current levels for this item by** |

| | | |
|---|---|---|
| | | **approximately 0.59.** |
| | G-0249 | 1. DESC should change to reflect Medical/Technical Assistant used to provide testing supplies and report test results to treating physician.<br>2. RATE should decrease in 2007 from 0.37 to 0.26 to reflect the lower level clinical staff required.<br>3. RATE should change in future years to reflect increases in Social Security Cost of Living Allowance.<br>**4.** Increase GO_I from 13 to 40 minutes to reflect the actual time required for clinical staff to provide testing supplies on a monthly basis and collect, document and report 4 test results to treating physician. **[NOTE: This time of 40 minutes per 1 unit of service (i.e. 4 tests) is based on the actual time required to provide over 2,500 G-0249 services over the past two years.]**<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs for this item by approximately 0.15.** |
| Medical Equipment | | |
| | G-0248 | 1. PRICE should decrease from $2000 to $1975 to reflect the current price for the market-leading CoaguChek® PST Monitor manufactured by Roche Diagnostics. It is estimated that Roche's market share is over 80%.<br>2. EQTI should be changed from 50 to 120 to be consistent with the above comment #2 related to Clinical Labor – G-0248.<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs for this item by approximately 0.52.** |
| | G-0249 | 1. LIFE should be changed from 5 to 3 to reflect the fact that beneficiaries require (on average) only 8 units of G-0249 services per year rather than the 13 unit maximum allowance. **[NOTE: It appears that CMS currently amortizes the full price of the monitor over 65 units of G-0249 (i.e. 5 year life times the 13 unit maximum allowed). Since our experience over the past two years is that (on average) patients only require 8 units of G-0249 per year (i.e. 40% less than the 13 unit maximum), we are recommending that the LIFE be reduced by 40% in order to adjust the amortization** |

| | | |
|---|---|---|
| | | **rate to a level that enables providers such as us to recover the full price of the equipment over the 40 G-0249 units that we expect to provide over a five year period.]**<br>2. PRICE should decrease from $2000 to $1975 to reflect the current price for the market-leading CoaguChek® PST Monitor manufactured by Roche Diagnostics. It is estimated that Roche's market share is over 80%.<br>3. The following items which are dedicated to the collecting, documenting, and reporting of INR test data (and not part of our general overhread) should be added to the list of equipment required to provide G-0249 services.<br>• Customized INR Monitoring Computer System (ED011) at $75,000<br>• Computer Desktop (ED021) at $2,501<br>• Computer Server (ED022) at $22,567<br>• Laser Printer (ED032) at $1,199<br>4. The LIFE for this additional dedicated equipment should be 5 years.<br>5. The EQTI for these additional items should be 12 minutes. This time is based on a calculation of 10,000 minutes of monthly operating time divided by our expected average installed base of customers over the next 5 years (~800).<br><br>**We estimate that the above changes will increase the Non-Facility Direct PE RVUs for this item by approximately 0.58.** |
| Supplies | | |
| | G-0248 | 1. PRICE of test strip INR (SJ055) should increase from $21 to $21.875 to reflect the current price for the market-leading CoaguChek® PST strip manufactured by Roche Diagnostics. It is estimated that Roche's market share is over 80%.<br>2. The following items should be added to the list of supplies required to provide G-0248 services.<br>a. Video Tape (SK086) at $2.049<br>b. Device Shipping Cost (SK106) at $12.00<br><br>**We estimate that the above changes will increase the Non-Facility PE RVUs for this item by approximately 0.46.** |

**Submitter :** Dr. Harvey Neiman **Date:** 12/29/2006

**Organization :** American College of Radiology

**Category :** Other Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-FC-30-Attach-1.PDF

ACR™
AMERICAN COLLEGE OF RADIOLOGY

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.

**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.***

**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
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**Submitter :** **Mr. Jonathan Linkous** **Date: 12/30/2006**

**Organization :** **American Telemedicine Association**

**Category :** **Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Submission of request for additions to the services defined as Medicare telehealth services - See Attachment

CMS-1321-FC-31-Attach-1.DOC

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| | |
|---|---|
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## CPT CODE REQUESTS

The American Telemedicine Association requests the following Current Procedural Terminology (CPT) codes be added to the approved list of telehealth-related CPT codes for 2008. This request is being submitted prior to December 31, 2006 for consideration in the 2007 physician fee schedule process.

In accordance with the requirements for submitting requests for additions of telehealth CPT codes, as initially published in the December 31, 2002 **Federal Register** (67 FR 79988) and via http://www.cms.hhs.gov/Telehealth/03_Addition.asp#TopOfPage, ATA requests the addition of Subsequent Inpatient and Neuro-developmental codes.

Effective October 1, 2001, coverage and payment for Medicare telehealth included consultation, office visits, individual psychotherapy, and pharmacologic management delivered via a telecommunications system (BIPA 2000, Section 223). BIPA amended Section 1834 of the Social Security Act to provide for an expansion of Medicare payment for telehealth services. Approved CPT codes included 99241-99275, 99201-99215, 90804-90809 and 90862. As a result of requests to CMS through the process for adding or deleting telehealth services, additional CPT codes of Medical Nutrition Therapy G0270-G0271, 97802-97804 and Medical Nutrition Therapy Self-Management G0108-G0109 were added. Dialysis codes of G0308-G0309, G0311-G0312, G0314-G0315 and G0317-G0318 were added by CMS in November 2004 without scientific justification (69 FR 66276). CMS also added code 90801 in 2002 as a private request and not as a part of the Physician Fee Schedule process.

### Subsequent Inpatient – 99231, 99232, 99233

The Evaluation and Management codes of 99261-99263 (hospital inpatient follow-up consultations) were for established patients, which included counseling and/or coordination of care with other providers or agencies consistent with the nature of the problem(s) and the patient's and/or family's needs (AMA, *CPT 2006 Professional Edition*). As a result of the inclusion of the Inpatient codes, eligible practitioners were able to provide consultation services to inpatients. Services were provided to inpatients who already were established with the consultative practitioner, referred by the attending physician, or were established as a patient with the practitioner during an in-person visit.

Two scenarios exist in which these codes are used to bill for services. The first scenario includes patients admitted to a rural or remote inpatient hospital or critical access hospital -- both eligible originating sites -- by an attending physician and followed by the same attending physician, who subsequently consulted with a specialist for the care of the patient. The specialist sees the patient

initially via telemedicine and follows the specific problem of the patient for any necessary subsequent visits via telemedicine. Without telemedicine, the specialist would not be available to the attending physician or the patient. The specialist is not the attending or admitting physician.

The second scenario involves an attending or admitting physician who sees the patient in-person for the initial visit, and provides subsequent care via telemedicine, including after-hours and weekend unscheduled visits. Many outreach physicians, particularly psychiatrists, are providing services to hospitals at a distance from where the provider lives or conducts office visits. To be able to provide services on demand, or as scheduled visits when the practitioner is not on-site, is critical to the survival of many rural and critical access hospitals, as well as for the preservation of services in a market with declining specialty practitioner resources, especially mental health providers.

In 2004, CMS denied the request to add Inpatient codes 99221 – 99223 and 99231-99233 as requested by the American Telemedicine Association, citing in the August 5, 2004 **Federal Register** "the current list of Medicare telehealth services is appropriate for hospital inpatients . . . If guidance or advice is needed in these settings, a consultation could be requested from an appropriate source" (69 FR 47511). The current list of services in 2004 included Inpatient CPT codes 99251-99255, which, upon the recommendation of CMS in the **Federal Register**, were subsequently used for services for inpatients delivered via telehealth.

In 2006, the American Medical Association (AMA) deleted the Inpatient codes 99261-99263 Follow-up Inpatient Consultation and replaced the deleted codes with 99231-99233 Subsequent Hospital Care (AMA, *CPT 2006 Professional Edition*, and http://www.cms.hhs.gov/transmittals/downloads/R788CP.pdf). The deletion of the Inpatient codes 99261-99263 Follow-up Inpatient Consultation and subsequent oversight of not adding the replacement codes 99231-99233 Subsequent Hospital Care to the approved telehealth list has significant detrimental impact on the health care needs of rural and remote populations with no access to some specialists. A clear example exists in South Dakota where the Avera McKennan Telemedicine Network provides services in three states. In South Dakota, there are eight infectious disease specialists, six located in Sioux Falls and two in Rapid City, separated by a distance of 350 miles. In order to receive services for inpatients from an ID specialist, hospitalized patients would need to be transported an average of 200 miles roundtrip at significant cost and risk to the patient. With the use of telehealth, the ID specialists in Sioux Falls have been able to serve approximately 27 locations in South Dakota, Minnesota, and Iowa. Twenty-one of those locations are hospitals, including 17 critical access hospitals; two physician clinics; three FQHCs and one prison. In the last fiscal year, 548 consults were provided (July through June 2006). This year, July through November, 431 consults were provided. Of those 431 consults, 102 were inpatient initial consults and 83 were subsequent inpatient consults. The top diagnoses are fever/MRSA, osteomyelitis/cellulitis, and chronic illnesses including Hepatitis C and HIV.

With the deletion of codes 99261-99263, the ID specialist in Sioux Falls must now provide 50 percent of the care needed to stabilize an inpatient's condition without payment or not provide the service at all. This same scenario will play out repeatedly for many different specialties. For those specialties where there is a critical shortage, such as psychiatrists, dermatologists, etc., the

Medicare beneficiaries simply will have to go without care. With declining reimbursement at all levels and increasing Medicare and Medicaid burden on physician practices, it would be unreasonable to expect that physicians will be able to provide 50 percent of their care for free.

In another scenario, an admitting psychiatrist requests a referral from a specialist in psychiatry who would see the inpatient initially in-person or via telehealth, and then would follow the patient as needed, in collaboration with the generalist. With the shortage of mental health practitioners, many psychiatric providers are available only as outreach one or two days a month, and never for inpatient consultations. The use of telehealth in these situations would improve access to the specialist at the time needed by the referring psychiatrist and patient. In the event of crisis, the specialist could be imminently available to the generalist for consultation via telehealth. In very limited situations, particularly in facilities that house persons detained by law enforcement through emergency commitment orders, a psychiatrist could be available immediately to assess the security and well-being of the patient via telehealth, and then see the patient in-person during the next scheduled day.

These scenarios could occur in every rural area, every critical access hospital, and every state. The ability to stabilize and provide continuity of care to inpatients by consulting physicians is critical to the safety of patients and to the preservation of rural health care systems, particularly critical access hospitals (CAH), a federally funded program created to retain essential services in rural and remote areas.

For the purposes of this request, to correct the technical error in deleting approved codes without adding the replacement codes to the approved list of telehealth CPT codes, we are treating the request as a Category 1 service in that the services are similar to the currently approved codes for Initial Inpatient Consultations 99251-99255. Initial consultations are more complex than subsequent hospital care and are currently reimbursed via telehealth by Medicare. The use of telehealth for subsequent hospital care (99231-99233) would provide consistency in care and support the position of the Institute of Medicine on patient safety, efficiency, efficacy, timeliness, and equity, as well as providing patient-centered care.

**Neuro-developmental – 96116, 96118, 96119, 96120**

We are requesting Central Nervous System Assessments/Tests (e.g., Neuro-Cognitive, Mental Status, Speech Testing) as defined in the American Medical Association's *CPT 2006 Professional Edition* (2006, p.398). The codes are used to report "the services provided during testing of the cognitive function of the central nervous system. The testing of cognitive processes, visual motor responses, and abstractive abilities is accomplished by the combination of several types of testing procedures" (p.398). Testing includes administering such tests as the MMPI and WAIS, Developmental Screening Test II, Early Language Milestone Screen, etc. (p. 398). Services are provided in one of the following sites currently on the list of originating sites for the purposes of telehealth services (office of a physician or practitioner; critical access hospital (as described in section 1861(mm)(1) of the Act); rural health clinic (as described in section 1861(aa)(2) of the Act); or a Federally qualified health center (as defined in section 1861(aa)(4) of the Act) (42CFR410.78, p.294-295).

**Medical Professional Providing the Service:** The practitioner administering the requested services are psychiatrists and clinical psychologists, both of whom are on the list of eligible practitioners who may bill Medicare for telehealth services (42CFR410.78, p.294-295, 70 FR, 70156-8).

**Explanation of Why Current HCPCs Codes for Telehealth Cannot Be Used:** There are currently no CPT codes on the list of approved telehealth CPT codes that may be used for neuro-developmental services as described above where testing, reporting, and evaluation of the patient are conducted. The current list of approved CPT codes for telehealth do not include the appropriate codes and cannot substitute for the appropriate codes, as defined in the American Medical Association's *CPT 2006 Professional Edition.*

**Reasons for Addition of the Proposed Services:** The process for submitting and justifying requests for additional CPT codes, as set forth by CMS, specifically outlines a method for quantifying whether a request for additional CPT codes meets the definition of telehealth services (Section 1834(m)(4)(F) of the Act) as professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000 by CPT codes 99241-99275, 99201-99215, 90804-90809 and 90862) and any additional service specified by the Secretary (71 FR 48994). The requests are assigned to either Category 1 or Category 2 services. Category 1 services are those that are similar to office and other outpatient visits, consultation, and office psychiatry services. In reviewing requests, CMS looks for similarities between the proposed and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, as well as similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment (71 FR 48994). Category 2 Services are considered "not similar to the current list of telehealth services". CMS' review of Category 2 requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face "hands on" delivery of the same service. Category 2 requests require a substantive scientific justification for approval. ATA believes its request to be similar to Category 1 services, thus not requiring a substantive scientific justification for approval. However, ATA has provided documentation as to the safety and efficacy, as well as clinical outcomes, of the use of telehealth to provide neuro-developmental services.

In a case reported in *Telemedicine Journal and e-Health* (2002, Vol. 8 [1], p.139-141), a child in a rural health care setting, 200 miles away from the nearest neuro-development specialist, and 50 miles away from the nearest psychiatrist, was referred to a medical center child psychiatrist for testing and evaluation. The consulting psychologist and child psychiatrist provided clinical services via telehealth. The child, nine years old, was diagnosed with emotional-behavioral disabilities and ADHD, and was placed on three medications, a selective serotonin re-uptake inhibitor, a stimulant and an appetite suppressant. In addition, due to difficulty sleeping associated with the side effects of the medication, the patient also was given a mild sedative each night. Behavioral problems included self-abuse; verbal and physical threats toward family members, peers and other adults; stealing, lying, and destruction of property (p.140). Neurological/physiological and psychological evaluation to rule out organic or other medically related diagnoses beyond ADHD was conducted. A treatment plan was recommended to the referring pediatrician and psychiatrist. The telehealth consultation resulted in an evaluation of

medications and recommended treatment strategies with specific attention to a modification of the medications that eventually led to reduced symptoms and improved attention (p. 140).

In a study conducted by Meyers et al. (*Telemedicine Journal and e-Health*, 2004, Vol. 10[3], p.278-285), two child and adolescent psychiatrists and a licensed clinical child psychologist provided telehealth services to 369 patients, aged 3-19 years, in two rural sites. The clinical model included initial evaluation with treatment planning regarding subsequent care and interaction with other relevant providers or agencies (p.280). Initial evaluations were 60-90 minutes and comprised a typical initial child and adolescent psychiatric evaluation. In addition to patients with mood disorders, anxiety disorders, psychotic disorders and tic disorders, developmental disorders were evaluated in the areas of learning, communication, and motor skills (p.281). Pervasive developmental disorders and autism spectrum disorders were also evaluated. One hundred and fifty-nine patients were evaluated and treated by telemedicine and 210 patients were seen in-person. The study concluded that the similarity in diagnosis between the telemedicine group and the in-person group, as also compared to national statistics, indicates that telemedicine for neuro-developmental and neuro-psychiatric specialties was suitable for assessing the spectrum of juvenile psychopathology. Telemedicine provided adequate technical resolution and interpersonal rapport to detect the psychopathology of juveniles and adolescents.

**Data Showing that Telecommunications Technologies Do Not Change the Diagnosis or Treatment as Compared to In-Person Care:** There have been considerable studies in the areas of mental and behavioral health services that use telehealth in the practice setting. Several recent studies have continued to explore and demonstrate that the use of telemedicine technologies to provide clinical care does not change the diagnosis or treatment as compared to in-person care. In a study by Meyers, Sulzbacher, and Sanford (2004, *Telemedicine Journal and e-Health*, Vol. 10[3], p.278-285), telepsychiatry patients were comparable to the group of patients evaluated in person. Samples were evaluated with respect to demographics, payer source, and diagnostic profiles. Results indicated "the similarity of diagnoses further suggests that telepsychiatry provides adequate technical resolution and doctor-patient rapport to detect psychopathology of youths" (p.278).

Integris Health Systems, Oklahoma City, Oklahoma, conducted an unpublished pilot study to compare mental health outcomes among stroke patients, randomized to receive either telerehabilitation (TR) or home health (HH) services following rehab discharge (Forducey, 2006). The hypothesis that pre- and post-scores from the Beck Depression Inventory-II (BECK) and Mental Component Summary (MCS) Scale from the Short-Form 12 would not be significantly different between treatment groups was tested. Sixteen patients were recruited; eleven agreed to participate. Two dropped out after the first visit, which left five HH and four TR participants. The mean age of the population was 60 years. The groups did not differ with respect to key demographic factors. The mean MCS scores at discharge were 38.2 for HH and 38.3 for TR groups, respectively, while the post treatment scores were 47.6 for HH and 45.5 for TR. BDI-II scores were 12.0 for HH and 14.5 TR at discharge and 12.6 for HH and 12.5 TR post treatment. Pre- and post-test scores were compared using non-parametric tests for independent samples. The results suggest that scores on standard mental health instruments do not differ between those receiving TR and HH treatment.

**Patient Satisfaction:** Historically, patient satisfaction is one of the most highly studied aspects of telehealth/telemedicine. Patient satisfaction with telehealth has always been very high, even in the earliest studies. In the areas of neuro-development, which includes mental health as well, similar results in patient satisfaction have been found.

In a study by Dobscha et al. (Use of Videoconferencing for Depression Research: Enrollment, Retention, and Patient Satisfaction, *Telemedicine Journal and e-Health,* Feb 2005, Vol. 11, No. 1: 84–89), 400 patients from the Portland Veterans Affairs Primary Care Clinics were randomized in a clinical trial of care management intervention for depression. The goal of this study was to describe the effects of using videoconferencing on participant enrollment, research measure administration and responses, study retention, and satisfaction. Patients recruited from distant clinic sites had the option of traveling to Portland, Oregon, for initial interviews, or being interviewed using videoconferencing. There were no significant problems with the process of interviewing and obtaining informed consent by videoconferencing, as reported by patients and clinic staff. Twenty of the 31 participants interviewed by videoconferencing returned the satisfaction questionnaire. Participants indicated a high degree of satisfaction with these interviews, and expressed willingness to recommend videoconferencing to others. No differences were observed between the Patient Health Questionnaire depression scores of videoconferencing and in-person participants, and there was no significant difference in the 6-month rate of loss to follow-up in the randomized trial.

In a similar study conducted by Shore and Manson (Telepsychiatric Care of American Indian Veterans with Post-Traumatic Stress Disorder: Bridging Gaps in Geography, Organizations, and Culture, *Telemedicine Journal and e-Health*, Nov 2004, Vol. 10, No. Supplement 2: S-64-S-69), a weekly telepsychiatry clinic was conducted treating post-traumatic stress disorder (PTSD) among Northern Plains American Indian Veterans. A total of 50 telehealth clinic interactions occurred during the first 7 months, consisting of ongoing group psychotherapy, individual therapy, and medication management. Quality control measures exhibited a high degree of patient satisfaction and comfort with the clinic. Results indicated that the clinic represents a viable model for the delivery of telepsychiatric services. Future research is needed regarding the process and outcomes of delivering psychiatric care by this means for rural, isolated American Indians, as well as for the treatment of PTSD via real-time, interactive videoconferencing.

Special needs children were evaluated by telemedicine in a study by Robinson et al. (Use of Telemedicine to Follow Special Needs Children, *Telemedicine Journal and e-Health*, Mar 2003, Vol. 9, No.1:57–61). Two remote telemedicine clinics were established linked to a tertiary care center to improve access for special health care needs children (SHCNC). The remote clinics were established at Lamar University's School of Nursing (1996) and Stephen F. Austin University's School of Nursing (1997), and they were linked to the pediatric interdisciplinary team at the University of Texas Medical Branch. These clinics were evaluated to determine if the tertiary interdisciplinary team could effectively assess and plan interventions for SHCNC and to assess patient and caregiver satisfaction with this intervention. The interdisciplinary team and the patients and their families were highly satisfied with this arrangement.

**Submitter :** Mr. Eric Muehlbauer **Date:** 12/31/2006

**Organization :** North American Spine Society

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

The North American Spine Society wishes to comment on two sets of CPT codes (Total disc arthoplasty and intradiscal electothermal annuloplasty) which are new for 2007 and scheduled to begin payment on January 1, 2007 under the Medicare Physician Fee Schedule. our comments are attached

**Interim Relative Value Units**

Interim Relative Value Units

The North American Spine Society wishes to comment on two sets of CPT codes (Total disc arthoplasty and intradiscal electothermal annuloplasty) which are new for 2007 and scheduled to begin payment on January 1, 2007 under the Medicare Physician Fee Schedule. our comments are attached

CMS-1321-FC-32-Attach-1.DOC

# NORTH AMERICAN SPINE SOCIETY

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December 31, 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 North American Spine Society (NASS) is a multidisciplinary society dedicated to providing the best quality spine care for patients around the world. We appreciate the opportunity to provide comment on the notice of Final Rule for the 2007 Medicare Physician Payment Schedule, published in the December 1, 2006 *Federal Register*.

We wish to comment on two sets of CPT codes which are new for 2007 and scheduled to begin payment on January 1, 2007 under the Medicare Physician Fee Schedule.

**TDA- Total Disc Arthroplasty (22857, 22862 and 22865)**

- 22857- Total disc arthroplasty (artificial disc), anterior approach, including diskectomy to prepare interspace (other than for decompression), lumbar, single interspace

- 22862 - Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, lumbar, single interspace

- 22865 - Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace

We believe there is an error in the practice expense (PE) component of the RVU's for the three total disc arthroplasty (TDA) codes. The societies presenting to the RUC recommended, based on an unsupported guess (not survey data) that the utilization of these

codes would be equally split between orthopedic surgeons and neurosurgeons (50% - 50%). The RUC accepted this guess without critical analysis or debate. Those present did not anticipate the profound effect that an error in this ratio would generate when the final PE RVU's were calculated. There is substantial data available to demonstrate that this assumption (50-50 split) is incorrect. We will present below four different sources of data which all support the need for a change in the specialty mix for TDA.

1. When the societies presented the TDA codes to the RUC, 22558- Arthrodesis, anterior interbody technique, including minimal diskectomy to prepare interspace (other than for decompression); lumbar, was selected as the reference code for primary total disc arthroplasty, the most commonly done of the three TDA codes. The table below shows a comparison between primary TDA and 22558. The survey times (pre, intra and post) and office visits are very similar. The specialty mix for 22558, according to the RUC database, however shows that it is done two times more commonly by orthopedic surgeons than by neurosurgeons.

   The RUC recommended, and CMS accepted, a higher work RVU for primary TDA-22857 compared to the reference code 22558 (26.93 vs. 23.33) based upon the slightly higher survey times coupled with a higher intensity of work for TDA. The practice liability RVU (PLI) recommended and accepted was also higher for TDA (3.56 vs. 3.16).

   The PE RVU calculated by CMS, however, was lower for primary TDA than 22558 (8.8 vs. 12.86). This lower value is secondary to a lower indirect practice cost index (IPCI) assigned to TDA (0.73 vs. 1.06) and is linked to the incorrect (50-50) or (1:1) specialty mix recommended for the TDA codes.

   The practice expense cost per hour assigned by CMS to each specialty is one factor used to calculate the IPCI. When several specialties perform the same procedure, a blend of per hour costs adjusted according to frequency is utilized. Orthopedic surgery has a higher cost per hour cost assigned compared to neurosurgery ($138/hr. vs. $105/hr.). Therefore, a procedure done more commonly by orthopedic surgeons would have higher per hour costs and a higher IPCI than a procedure done with equal frequency or a procedure done more commonly by neurosurgeons.

   Spinal fusion is a treatment option for a select group of patients with degenerative disc disease (DDD) who have failed conservative therapy. Anterior interbody fusion (22558) is one commonly performed method of performing such a fusion. TDA is an alternative to spinal fusion, performed by the same surgeons who perform fusion, but in a smaller more highly selected (younger with less advanced disc degeneration) subset of patients considered for fusion. The surgical approach required for the two procedures are identical.

   Given the similarities in survey times, surgical approach and patient population it is an error that the societies and RUC recommended a (1:1) specialty mix and did not recommend the same specialty mix (2:1) for TDA for PE calculation as is used for

22558. In addition we present new data that supports a greater than (4:1) ratio of orthopedic to neurosurgery for TDA (see item #4).

| | TDA-22857 | Ant Lum Fusion- 22558 |
|---|---|---|
| **RUC Survey Data** | | |
| pre time | 95 | 80 |
| intra time | 180 | 180 |
| post time | 160 | 150 |
| office visits (4-99213) | 92 | 92 |
| **Total time** | **527** | **502** |
| | | |
| | **TDA-22857** | **Ant Lum Fusion- 22558** |
| **2007 Final Rule values** | | |
| Work RVU | 26.93 | 23.33 |
| PE RVU | | |
| PLI-RVU | 3.56 | 3.16 |
| **Total RVU** | **39.29** | **39.35** |
| | | |
| **Specialty Provider** | | |
| orthopedics | 44% | 50% |
| neurosurgery | 22% | 50% |
| general surgery | 21% | |
| vascular surgery | 7% | |

2. Further evidence that orthopedic surgeons would perform a higher percentage of TDA's than neurosurgeons is found in the CPT application to change TDA from a category III code to category I. As of the date of that application the number of surgeons who completed the required training program for TDA was 915 orthopedic surgeons and 600 neurosurgeons.

3. Analysis of the raw data of the 51 survey respondents who completed the RUC survey reveals that 73% were orthopedic surgeons and 27% neurosurgeons.

4. Finally, we have queried the DePuy company database (makers of Charite- the only FDA approved TDA in 2005). Approximately 1800 Charite TDA's were implanted in 2005. Based upon a market analysis of the top 60 surgeons, who represent 40% of sales and 750 procedures for that year, 83% were performed by orthopedic surgeons and 17% by neurosurgeons.

We believe this last piece of evidence represents the most current and most accurate information on specialty mix for TDA and strongly supports that the IPCI for TDA should be recalculated. In addition the DePuy data suggests that for TDA performed in 2005 the ratio of orthopedic surgeon/neurosurgeon is even greater (83% vs. 17%) (4.88:1) than for 22558 (44% vs. 22%) (2:1).

**IDET- Intra Discal Electrothermal Therapy (22526, 22527)**

- 22526 Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral, including fluoroscopy guidance; single level

- 22527 one or more additional levels (list separately in addition to code for primary level)

It is our belief that IDET is the subject of significant controversy among experts and that the scientific evidence demonstrating efficacy for IDET is inconsistent. At best, there is a small subset of younger, highly selected patients who obtain temporary benefit. At worst the procedure is no better than placebo. In addition, there have not been studies done demonstrating efficacy in patients over the age of 60.

We are writing to suggest that CMS review the currently available literature and science for Percutaneous Intradiscal Annuloplasty (IDET) and determine whether the procedure should be reimbursed by CMS when performed on Medicare patients.

Scientific Evidence-
Although there are a number of prospective studies evaluating the safety and efficacy of IDET that have been published including prospective studies with two-year outcome data that previously appeared promising, [1, 2], two more rigorously designed and recently published randomized, prospective double-blind placebo controlled trials on IDET appear to reach conclusions that question the positive results noted in those early studies and/or dispute the clinical efficacy of the procedure.[3, 4]

In the study by Pauza, et al,[4] the authors applied very strict inclusion/exclusion criteria, screening 4,235 respondents down to 1,360 individuals who were prepared to submit to randomization; only 64 (4.7%) of whom were found eligible for the study procedure and subsequently randomized. Only patients with less than 20% reduction in disc height were considered. The results of this small, highly selected group of patients were interpreted as showing that 22% of those subjects who underwent the procedure had a substantial benefit (i.e. relief of pain > 75%). Thus, the number needed to treat (NNT) was 5, meaning that five patients had to undergo the procedure in order to have one individual achieve 75-100% pain

relief. However, only two of five patients undergoing IDET achieved >50% relief, which when compared to the control group of whom 33% experienced a 50% reduction in pain, does not appear to be a statistically significant difference. Additionally, approximately half of those in the treatment group experienced no appreciable benefit. Further complicating the results is the fact that there was no true long-term follow-up as patients were "un-blinded" as to which group (treatment vs. sham/placebo) they had been assigned to at approximately six months post-procedure. Based on the natural course of discogenic low back pain, of the only 20% of patients that initially experienced a significant reduction or relief in pain, one would be concerned that a certain percent of those patients, on a two year follow-up, would likely report more pain than what was experienced on earlier follow-up.

In a more recently published study by Freeman, et al,[3] 57 patients were randomized to percutaneous intradiscal electrothermal therapy versus placebo using somewhat less stringent inclusion criteria than that used for the Pauza study.[4] The results, either for the overall study group or for any subgroups tested (including those with more stringent criteria applied), were interpreted as showing no significant benefit from the procedure over placebo. Interestingly, the Freeman study showed that even the placebo patients showed no improvement, which is at odds with known placebo response patterns.

These two prospective double-blind randomized placebo controlled trials on IDET have some differences with respect to their methodology and patient selection, and are therefore not directly comparable. However these types of randomized placebo controlled studies are the gold standard in demonstrating clinical efficacy. Although there are a number of earlier studies that indicated more positive and optimistic results, these more recent studies by Freeman, et al, [3] and Pauza, et al, [4] appear to contradict the positive results of earlier studies. Although the Pauza study indicates that rigorous patient selection may represent a key factor in determining outcomes in a small number (approximately 20% of highly selected patients at best), the remainder of that study's results along with the recently published study by Freeman, et al, appear to indicate that IDET has little to no statistically significant effect at improving discogenic low back pain in a vast majority of patients (perhaps over 80%) when compared to placebo controls.

IDET Conclusions

At this time, the available scientific literature evaluating the clinical efficacy of IDET is conflicting. NASS does not believe this procedure has been well studied or its efficacy established in the Medicare population. If performed, NASS strongly recommends strict adherence to the selection criteria utilized in the Pauza study.[4] Even in the best clinical practice, when these criteria are rigidly applied, only a relatively small number of patients obtain near complete relief. Because many people experience low back pain, the procedure could become quite costly without a demonstrated improvement in health benefit if it is applied indiscriminately and for improper indications.

References

1. Bogduk, N. and M. Karasek, *Two-year follow-up of a controlled trial of intradiscal electrothermal annuloplasty for chronic low back pain resulting from internal disc disruption.* Spine J, 2002. **2**(5): p. 343-50.
2. Saal, J.A. and J.S. Saal, Intradiscal electrothermal treatment for chronic discogenic low back pain: prospective outcome study with a minimum 2-year follow-up. Spine, 2002. 27(9): p. 966-73; discussion 973-4.

3. Freeman, B.J., et al., A randomized, double-blind, controlled trial: intradiscal electrothermal therapy versus placebo for the treatment of chronic discogenic low back pain. Spine, 2005. 30(21): p. 2369-77; discussion 2378.

4. Pauza, K.J., et al., A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. Spine J, 2004. 4(1): p. 27-35.

The North American Spine Society appreciates the opportunity to offer these comments to CMS. We look forward to our continued relationship to further improve the RBRVS.

Sincerely,

Sincerely,
*Eric J. Muehlbauer*
Eric Muehlbauer, MJ, CAE
Executive Director
North American Spine Society

Richard Guyer, MD
President
North American Spine Society

**Submitter :** Mr. Larry Cohen **Date:** 01/01/2007

**Organization :** Prothrombin-time Self Testing Coalition

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-FC-33-Attach-1.PDF

December 29, 2006

Via electronic submission at http://www.cms.hhs.gov/eRulemaking
Leslie V. Norwalk, J.D.
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
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; Final Rule with Comment Period**
**Payment for home PT/INR monitoring (codes G0248 and G0249)**

Dear Ms. Norwalk:

On behalf of the Prothrombin-time Self Testing (PST) Coalition comprising HemoSense, Inc., International Technidyne Corporation and Roche Diagnostics Corporation, we are pleased to submit comments on the above-captioned Final Rule with Comment Period regarding Prothrombin Time (PT)/International Normalized Ratio (INR) home monitoring for anticoagulation management. The PST Companies are medical device manufacturers who have developed the technologies used in home PT/INR monitoring. Our companies have put significant resources into the clinical development of these technologies, which have been shown to reduce the incidence of serious adverse events (strokes and bleeding) among patients requiring anticoagulation with warfarin.

We appreciate Medicare's having provided coverage for home PT/INR monitoring beginning July 2002, and we were pleased to see clarifications on billing for these services published in several Program Transmittals and codified in the Medicare Claims Processing Manual, Chapter 32, Section 60. Medicare's allowed payments for home PT/INR monitoring under the Physician Fee Schedule in 2006 are adequate to cover physician and Independent Diagnostic Testing Facility (IDTF) costs for furnishing home PT/INR monitoring equipment, supplies, clinical staff support and physician interpretation and reporting of results.

By contrast, the Final Rule payments reflect reductions in the relative values for the non-physician-work services of training for and ongoing provision of home PT/INR monitoring of approximately 10 to 13-percent for codes G0248 and G0249. Fully implemented changes to the relative values as published in the Final Rule would result in reductions of 39 to 49-percent by 2010 for codes G0248 and G0249. Reductions of this magnitude would result in payments well below physician and IDTF costs for furnishing home PT/INR monitoring and would likely shut down access to home PT/INR monitoring for Medicare beneficiaries.

We urge CMS to meet with us and other interested stakeholders during 2007 to review the data on the input costs for home PT/INR monitoring to assure that the payment rate does not drop to levels that would limit or close off access to this important service.

## I. Coding and Practice Expense Inputs for Home PT/INR Monitoring

Home PT/INR monitoring involves the furnishing, by a physician or IDTF, of a PT/INR monitor (a prothrombin time test monitor), test strips to run in the monitor, lancets for collecting blood samples, and alcohol swabs for preparing the skin for the self-testing of prothrombin time by patients or their

caregivers at home (or otherwise outside the physician's office setting) on a weekly basis[1]. Home PT/INR monitoring is reported under the following three HCPCS codes to include the technical component service described above as well as an initial training session and physician review and interpretation of the test results:

| Code | Descriptor |
|---|---|
| G0248 | Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing |
| G0249 | Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per 4 tests |
| G0250 | Physician review, interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service) |

## II. Concern about the Practice Expense Relative Values for the Technical Component Services (G0248 and G0249) in the Final Rule with Comment Period

Home PT/INR monitoring is an unusual service under the Physician Fee Schedule because it involves the furnishing of equipment and supplies by physicians or IDTFs for use by patients in their homes. Each PT/INR monitor is dedicated for use by one patient only. Therefore, although the 2007 Physician Fee Schedule Final Rule practice expense input files show the monitors to be in use for only 32 minutes for each 4-test payment unit under code G0249, the monitors are effectively in use continuously by each patient. CMS staff recognized this when the practice expense relative values for home PT/INR monitoring were developed and initially refined in 2002. The staff acknowledged that the "standard" model for assigning per-minute input costs for equipment should not be used for home PT/INR monitoring. The practice expense equipment model assumes that equipment can be used by multiple patients for up to 25 hours per-week. This assumption does not apply to home PT/INR monitoring. Therefore, staff did not apply the standard practice expense model, but rather, applied the equipment costs by considering a straight line amortization over the useful life of the monitor.[2]

We were pleased to see that, in the Proposed Rule, CMS acknowledged that home PT/INR monitoring does not fit well under the direct practice expense model applied to typical physician services. CMS

[1] The National Coverage Determination on home PT/INR monitoring limits coverage to testing no more than once per-week. The 4-test payment units under codes G0249 and G0250 may reflect weekly testing over a 4 week period or less frequent testing over a longer period.

[2] Through 2004, the equipment was assigned a price of $2,000 and a useful life of 4 years. In the 2005 and 2006 practice expense input databases, the equipment was assigned a price of $2,000 and a useful life of 5 years. In the 2007 Final Rule database, the equipment is assigned a price of $2,000 and a useful life of 4 years.

sought comments on the home PT/INR monitoring codes together with a group of remote cardiac monitoring services principally performed by independent diagnostic testing facilities (IDTFs).[3] In the Final Rule, CMS indicated that it received input on the practice expenses from a survey of 7 IDTFs:

> *"One commenter submitted the requested information after conducting a survey of 7 large IDTFs specializing in these remote cardiac monitoring services. For each of the 11 CPT/HCPCS codes referenced above in this section, the commenter provided recommendations for the direct PE inputs, including the type of clinical labor and the related minutes for their service, the needed disposable supplies and the equipment costs, the number of minutes in use, and the respective life of each piece of equipment."* (71 Fed. Reg. 69,623, 69,647 (Dec. 1, 2006).)

We are not familiar with this survey and do not know which IDTFs were surveyed to obtain the data submitted to CMS. We would note, however, that the practice expense input file values supporting the 2007 Final Rule differ in only minor ways from the values shown in the input files supporting the 2006 Final Rule: (1) the clinical staff performing the training and ongoing monitoring service was changed from RN/LPN/MTA (for G0248 and G0249) in 2006 to RN for the training service (G0248) and electrodiagnostic technologist for the ongoing monitoring service (G0249) in 2007, (2) the clinical staff time for the ongoing monitoring service increased from 13 minutes to 32 minutes, (3) the equipment time-in-use for the ongoing monitoring service increased from 20 minutes to 32 minutes, and (4) the useful life of the PT/INR monitor decreased from 5 years to 4 years. Although these changes are minor, they should result in an increase in the total practice expense inputs—not a dramatic decrease in these values. We would also note that the change in the staff performing the ongoing monitoring to an "electrodiagnostic technologist" is clearly an error—home PT/INR monitoring is not an electrodiagnostic test and does not involve the services of an electrodiagnostic technologist.

It would appear that one important reason for the dramatic reduction in practice expense relative values is the application of the standard fee schedule equipment input cost model to the home PT/INR device. Using CMS's standard equipment input cost model, a $2,000 device with a 4 year useful life would have a $0.0099 input cost on a per-minute basis. If 32 minutes are used as the time that the device is in use for each 4-test set of services under G0249, this would yield equipment cost inputs of $0.3177. If the testing is performed weekly (consistent with the coverage determination limit), this would result in 13 units of G0249 per-year and an equipment input cost of $4.13 per-year. **At such rate, it would take nearly 500 years for an IDTF (or physician) to recoup the cost of the equipment!**

By contrast, if the equipment is considered to be in use full-time,[4] this would yield an input cost of $59.57, which would result in recoupment of the equipment cost in approximately 2.6 years (without considering interest on capital).

Alternatively, if CMS maintained a straight-line amortization of the $2,000 device cost of the 4-year useful life, this would yield an input cost of approximately $38.46 per-service. This is nearly 10-times the input cost resulting from application of the standard practice expense equipment cost model—a model CMS staff rejected in 2002 as not being appropriate for home PT/INR monitoring.

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[3] The other services include: cardiac event monitoring (codes 93271, 93012 and 93270); pacemaker monitoring (codes 93733 and 93736) and Holter monitoring (codes 93232, 93226, 93231 and 93225).

[4] Considering full-time to be 50 hours per-week with a 50-percent usage rate consistent with the CMS practice expense standard equipment model.

At this point in time, we do not have data from a survey of providers to furnish to CMS, but we would welcome the opportunity to meet with your staff together with other stakeholders to determine what type of data CMS would need re-evaluate the practice expenses for home PT/INR monitoring and to discuss the most appropriate model to apply to this at-home service, which is paid under the Physician Fee Schedule.

When we met with CMS staff in 2002 prior to the implementation of coverage for home PT/INR monitoring, we expressed our serious concerns about access to home PT/INR monitoring by Medicare beneficiaries if the benefit were structured as a physician or diagnostic testing service paid under the Physician Fee Schedule rather than as home medical equipment paid under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule. CMS staff assured us that they would monitor access to this new technology and would make changes to the payment policies to assure appropriate patient access. Although utilization of this benefit under Medicare remains relatively low, the payment rates for this technology under the Physician Fee Schedule in effect in 2006 appear adequate to support access to the technology. The practice expense values in the Final Rule for 2007, however, would result in such drastic reductions in payments for home PT/INR monitoring that access likely would shut down for Medicare beneficiaries—especially when considering the nearly 40- to 50-percent reductions expected by 2010.

## III. Recommendation

Therefore, we urge CMS to maintain the practice expense values for home PT/INR monitoring under codes G0248 and G0249 consistent with the values that were "hard coded" into the payment system since late 2002.[5] We would welcome an opportunity to meet with your staff to discuss their needs for additional input survey information as well as to identify the most appropriate model to account for home PT/INR monitoring equipment costs.

* * * *

We appreciate the opportunity to comment on this Final Rule with Comment Period. Please contact our reimbursement counsel, Paul Radensky, M.D., J.D., at 305.347.6557 or by e-mail at pradensky@mwe.com if you have any questions about our comments or would like to discuss these further. Thank you for your consideration of our comments.

Sincerely,

*/s/ Larry Cohen*

Larry Cohen
President
International Technidyne Corporation

*/s/ David Phillips*

David Phillips

[5] We would note that the payments for the professional service fee for review and interpretation of the PT/INR results (code G0250) do not include direct practice expenses and so are not negatively affected by the proposed change in practice expense methodology.

Vice President, Marketing
HemoSense, Inc.

*/s/ John Ridge*

John Ridge
Director, Reimbursement Affairs
Roche Diagnostics Corporation

Cc: Denise Garris, American College of Cardiology
Paul Radensky, M.D., J.D., McDermott, Will & Emery LLP

**Submitter :** Dr. Robert Zwolak **Date:** 01/01/2007

**Organization :** Society for Vascular Surgery

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

2. Abdominal Aortic Aneurysm (AAA) Screening Benefit

SVS thanks CMS for positive regulations in the Final Rule for the new AAA screening benefit, including adequate reimbursement at the same rate as CPT code 76775 ultrasound, retroperitoneal (e.g., renal, aorta, nodes), B-scan and/or real time with image documentation; limited.

However, SVS is concerned about how few Medicare beneficiaries have taken advantage of the initial preventive physical examination (IPPE) and the fact that this will limit access to AAA screening. We appreciate CMS s commitment to educating Medicare beneficiaries and practitioners about the IPPE and AAA screening. We again urge the Agency to publicize the AAA screening benefit among enrollees and primary care providers. To support CMS efforts, SVS is reaching out to appropriate physician, PA and Nurse Practitioner groups to request that they publicize AAA screening along with the IPPE.

SVS further appreciates the Agency s verbal clarification of the term referral in the setting of the new Medicare AAA screening benefit. According to clarification from Dr. William Rogers at CMS, the phrase referral for AAA screening means that a provider may order a screening ultrasound test after having confirmed the beneficiary as appropriately qualified (patient has undergone an IPPE and has either a positive family history of AAA or is a male-ever smoker).

SVS is disappointed that CMS interpreted Congressional language narrowly in the Agency s decision to limit ordering of the AAA screening test to the IPPE provider. While the common sequence will be the IPPE provider ordering the AAA screening ultrasound on appropriately selected beneficiaries, SVS encourages CMS to allow any qualified provider to order the AAA screening as long as the beneficiary has undergone the IPPE and meets clinical criteria.

Finally, SVS supports the expansion of the AAA screening benefit in the future. We would welcome the opportunity to bring forth additional evidence, as it accrues, to support coverage of other population cohorts who may be at significant risk for AAA. We are also open to establishing new regulatory pathways that will facilitate appropriate utilization of this screening benefit.

3. Non-imaging Vascular Diagnostic Studies and the DRA

SVS appreciates CMS removal of five non-imaging vascular diagnostic procedures in the Final Rule (CPT 93875, 93922, 93923, 93924 and 93965) from the list of codes subject to the OPPS cap in the Deficit Reduction Act of 2005. The stated reason was the following: these do not involve the generation of an image , and we agree that this is totally accurate.

Using the above logic in the Final Rule, SVS believes that duplex transcranial Doppler studies (93886, 93888, 93890, 93892 and 93893) should also be removed from the OPPS cap. These are Doppler velocity analyses that include either no imaging at all or just enough imaging to identify vessel location.

4. Noninvasive Arterial Duplex Vascular Diagnostic Studies and the DRA

Duplex ultrasound is the combination of Doppler blood flow velocity analysis and B-mode ultrasound imaging. In the arterial duplex codes the B-mode imaging is used primarily to identify the artery to allow Doppler sampling to take place. Virtually every scientific article published since 1980 in this arena concludes that the Doppler velocity measurements carry the accuracy and therefore create the value of these exams. Doppler is not an imaging modality. Therefore, arterial duplex ultrasound vascular diagnostic studies (93880, 93882, 93925, 93926, 93975, 93976, 93978, 93979 and 93990) should be exempt from the DRA OPPS cap. Again, the goal of arterial duplex ultrasound studies is to identify whether blood is flowing in an artery and how fast the flow is, because the velocity of flow correlates accurately with vessel narrowing.

NOTE: Our submission was truncated here. Please see ATTACHMENT.

**Interim Relative Value Units**

Interim Relative Value Units

CMS rejected RUC and/or SVS recommendations for six of vascular surgery s most complex and labor-intensive open aortic aneurysm and bypass operations (35102, 35081, 35556, 35566, 35583, and 35585). Following our comment to the work RVUs published in the NPRM, CMS referred these codes to a Refinement Panel. At Refinement, SVS supported the recommended RVUs with an enormous amount of objective time and intensity data, including very detailed tables demonstrating where these procedures fit in work relativity among the family of RUC-reviewed and CMS-approved vascular codes, plus comparisons to relevant aneurysm codes from neurosurgery and other codes from general surgery. The issue was that we justified work RVUs above the RUC median survey values, and although the RUC itself agreed that values above median survey were appropriate for most, the Refinement Panel rejected our submission without asking a question. SVS believes that the 2007 CMS work RVUs for these six services 1) fail to reflect the true physician work required for these complex operations in multiply co-morbid patients, 2) create rank order anomalies within our specialty, and 3) create rank order anomalies with regard to other specialties including general surgery. We request reconsideration.

CMS assigned a work RVU less than recommended by SVS and the RUC for these codes:

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)
SVS recommended 39.80
RUC recommended 36.28
CMS assigned 34.00

35556 Bypass graft, with vein; femoral-popliteal
SVS recommended 31.58
RUC recommended 27.25
CMS assigned 25.00

35566 Bypass graft, with vein; femoral-anterior tibial, posterior tibial, peroneal artery or other distal vessels
SVS recommended 39.20
RUC recommended 32.00
CMS assigned 30.00

35585 In-situ vein bypass; femoral-anterior tibial, posterior tibial, or peroneal artery
SVS recommended 39.42
RUC recommended 32.00
CMS assigned 30.00

CMS assigned a work RVU less than that recommended by SVS for these codes:

35081 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.
SVS recommended 34.55
RUC recommended 31.00
CMS assigned 31.00

35583 In-situ vein bypass; femoral-popliteal
SVS recommended 32.26
RUC recommended 26.00
CMS assigned 26.00

The CMS work RVUs for these codes create rank order anomalies of physician work, both within the family of vascular codes and when considered in light of complex procedures from other specialties. Please see Appendix 1 for extensive details in this regard.

Appendix 1.

Detailed Time, Intensity and Relatively Justification for Six Vascular Codes

NOTE: The work RVUs discussed below are those used during the five-year review process. These RVUs do not include the adjustment made in the Final Rule for revalued E&Ms packaged in the global period.

CPT 35102 Open Repair of abdominal aortic aneurysm requiring bifurcated graft

CPT 35102 is open repair of an infrarenal abdominal aortic aneurysm using a bifurcated graft. The operation is used to prevent death from aneurysm. This service was submitted to the five-year review because the work has changed. Since endovascular AAA repair requires at least 15 mm of normal aorta below the renal artery origins, those aneurysms with short, angulated and calcified infrarenal necks require open aneurysm repair. All of these factors increase the intensity and complexity of the open surgery. The net result is that this service is more complex and time consuming than it was five years ago.

NOTE: Our submission is truncated at this point. Please see the ATTACHED document.

**Submitter :** **Dr. Robert Zwolak** **Date: 01/01/2007**

**Organization :** **Society for Vascular Surgery**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**Interim Relative Value Units**

Interim Relative Value Units

SVS submitted a comment, but we believe the attached full comment letter failed to transmit. This is a second attempt at sending the full Microsoft Word document.

**Submitter :** **Dr. Robert Zwolak** **Date: 01/01/2007**

**Organization :** **Society for Vascular Surgery**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Third attempt to send you the completed Attachment comment letter from SVS.

CMS-1321-FC-36-Attach-1.DOC

SOCIETY FOR VASCULAR SURGERY

December 30, 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

***RE: 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 Physicians Fee Schedule, and Other Changes to Payment Under Part B***

Dear Ms. Norwalk,

The Society for Vascular Surgery (SVS) provides the following comments on the Final Rule for the 2007 Medicare Physician Payment Schedule published in the *Federal Register* on December 1, 2006.

The SVS comments are provided in the following order:

1. Five-Year Review codes 35081, 35102, 35556, 35566, 35583 and 35585
2. AAA screening benefit
3. Non-imaging vascular diagnostic codes removed from the DRA and other that should be removed
4. Remaining noninvasive vascular diagnostic codes should be removed from the DRA

## 1. Five-Year Review of Work for Vascular Surgery Codes

CMS rejected RUC and/or SVS recommendations for six of vascular surgery's most complex and labor-intensive open aortic aneurysm and bypass operations (35102, 35081, 35556, 35566, 35583, and 35585). Following our comment to the work RVUs published in the NPRM, CMS referred these codes to a Refinement Panel. At Refinement, SVS supported the recommended RVUs with an enormous amount of objective time and intensity data, including very detailed tables demonstrating where these procedures fit in work relativity among the family of RUC-reviewed and CMS-approved vascular codes,

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However, SVS is concerned about how few Medicare beneficiaries have taken advantage of the initial preventive physical examination (IPPE) and the fact that this will limit access to AAA screening. We appreciate CMS's commitment to educating Medicare beneficiaries and practitioners about the IPPE and AAA screening. We again urge the Agency to publicize the AAA screening benefit among enrollees and primary care providers. To support CMS efforts, SVS is reaching out to appropriate physician, PA and Nurse Practitioner groups to request that they publicize AAA screening along with the IPPE.

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In addition, we wish to reiterate the negative consequences these cuts will have on Medicare beneficiaries. If duplex studies remain under the cap, the reduction in reimbursement, ranging up to 45 percent, is at such extreme levels that some facilities will be forced to close or reduce services to Medicare beneficiaries, particularly in rural and underserved areas. This could create an unintended consequence – Medicare beneficiaries with vascular disease would be shifted back to the hospital setting where more expensive and invasive tests such as contrast arteriograms, contrast-enhanced CT scans or contrast-enhanced MR scans would be ordered.

Non-invasive vascular diagnostic studies are by far the least expensive for the Medicare program and have years of published literature supporting their accuracy and reliability. Until the proposed rule was published, ultrasound was never the target of over-utilization

by Congress, CMS and MedPAC. SVS urges CMS to reconsider and exclude all non-invasive diagnostic vascular studies from DRA cuts.

As always, we appreciate the work of CMS staff in the very complex realm of the Medicare Physicians Fee Schedule.

Yours truly,

K. Craig Kent, M.D.
President
Society for Vascular Surgery

Robert M. Zwolak, M.D.
Chair, Health Policy Committee
Society for Vascular Surgery

## Appendix 1.

## Detailed Time, Intensity and Relatively Justification for Six Vascular Codes

**NOTE:** The work RVUs discussed below are those used during the five-year review process. These RVUs do not include the adjustment made in the Final Rule for revalued E&Ms packaged in the global period.

### CPT 35102 Open Repair of abdominal aortic aneurysm requiring bifurcated graft

CPT 35102 is open repair of an infrarenal abdominal aortic aneurysm using a bifurcated graft. The operation is used to prevent death from aneurysm. This service was submitted to the five-year review because the work has changed. Since endovascular AAA repair requires at least 15 mm of normal aorta below the renal artery origins, those aneurysms with short, angulated and calcified infrarenal necks require open aneurysm repair. All of these factors increase the intensity and complexity of the open surgery. The net result is that this service is more complex and time consuming than it was five years ago.

| Source | Work RVU | IWPUT (using RUC time/visit) |
|---|---|---|
| SVS Recommendation: | 39.80 | 0.096 |
| RUC Recommendation: | 36.28 | 0.083 |
| CMS Value : | 34.00 | 0.074 |

### Service Components and IWPUT for 35102, SVS recommendation vs. CMS value. The CMS value results in an inappropriately low IWPUT intensity.

| SVS Rec RVU with RUC time & Visits | | RVW: | 39.80 |
|---|---|---|---|
| | RUC time | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 75 | 0.0224 | 1.68 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.80** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 1 | 4.00 | 4.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 99232 | 3 | 1.06 | 3.18 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **12.57** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 265 | 0.096 | 25.43 |
| ***Total Time:*** | 688 | | |

| CMS Rec RVU with RUC time & visits | | RVW: | 34.00 |
|---|---|---|---|
| | RUC Time | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positi | 75 | 0.0224 | 1.68 |
| Pre-service scrub, dress, | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.80** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 1 | 4.00 | 4.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 99232 | 3 | 1.06 | 3.18 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **12.57** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 265 | 0.074 | 19.63 |
| ***Total Time:*** | 688 | | |

SVS recommended an RVW of 39.80 based on an iterative process including survey data, NSQIP data, intensity analysis, building block analysis and extensive comparisons with open surgical procedures within and outside the specialty. The IWPUT analysis demonstrates an appropriate value of 0.096 even after applying the RUC's reductions in pre-service time. An IWPUT of 0.096 places 35102 at the mid-point of the established IWPUT range for aneurysms and aortic surgery (see table below). Anything less creates a rank order anomaly. The RUC recommendation of 36.28 would have resulted in a low IWPUT of 0.083, at the bottom of the established IWPUT range for aneurysm repairs and aortic surgery. The 2007 CMS recommendation of 34.00 RVUs established a totally inappropriate new low benchmark of calculated intensity for open aneurysm services at an IWPUT of 0.074.

The following Table demonstrates IWPUTs that have been established by the RUC and CMS processes for aneurysm repairs and aortic surgery over the past 7 years. Open aortic aneurysm repair is a complex operation with an established 30-day mortality of 4-6% in the best surgical hands. The 2007 CMS RVW calculates to an IWPUT of 0.074, failing to approximate the true intensity and complexity of this service. The Table demonstrates conclusively that CMS created a rank order anomaly with this 2007 work RVU.

**RUC/CMS IWPUT Intensity Measure for Aneurysm Repairs and Aortic Surgery**

| Code | Short Descriptor | Year Implemented | IWPUT |
|---|---|---|---|
| ****CMS placed 35102 AAA Repair here** | | | **0.074** |
| 35141 | Repair femoral aneurysm | 2002 5Yr | 0.082 |
| 34900 | Endovasc rep iliac aneurysm | 2003 new | 0.088 |
| 35646 | Aorto-bifemoral bypass synth | 2002 new | 0.093 |
| 35151 | Rep popliteal aneurysm | 2002 5 Yr | 0.094 |
| 33881 | Endovasc rep thoracic aorta | 2006 new | 0.095 |
| ****SVS recommended 35102 AAA Repair here** | | | **0.096** |
| 35011 | Rep axillary/brach aneurysm | 2002 5 Yr | 0.099 |
| 35131 | Rep Iliac aneurysm | 2002 5 Yr | 0.101 |
| 34802 | Endo rep abd AAA 2-piece | 2001 new | 0.101 |
| 34805 | Endo rep Abd AAA aorto-uni | 2001 new | 0.101 |
| 35647 | Aorto-fem bypass synth | 2002 new | 0.102 |
| 35045 | Rep radial/ulnar aneurysm | 2002 5 Yr | 0.102 |
| 34803 | Endo rep abd AAA 3-piece | 2005 new | 0.104 |
| 35121 | Rep mesenteric aneurysm | 2002 5 Yr | 0.105 |
| 33880 | Endovasc rep thoracic | 2006 new | 0.105 |
| 35111 | Rep splenic aneurysm | 2002 5 Yr | 0.109 |
| 34800 | Endovasc rep abd AAA | 2001 new | 0.109 |

**Comparison of 35102 to Other Vascular Surgery Services, MPC "A" List 35631**

CPT 35631 is "Bypass graft, with other than vein; aortoceliac, aortomesenteric, aortorenal". It serves as a RUC MPC "A" list standard service. 35631 is a 90-day global intra-abdominal operation that was analyzed by the RUC during the 2nd five-year review. 35631 had an RVW of 33.95. Pre-service time of 35631 (110 minutes) is very slightly more than 35102, which has 90 RUC-approved pre-service minutes (reduced from survey time). This accounts for only a 0.2 rvu difference. Intra-service work for 35102 at the SVS recommended RVW of 39.40 is 265 min x 0.096 = 25.43 rvus. Intra-service work for 35631 is 225 min x 0.102 = 23.00 rvus. Thus, 35102 has 2.43 rvus more intra-service than 35631. Post-service work is greater for 35102 (12.57 rvus) compared to 35631 (8.77 rvus) because the patients are generally older and sicker.

Based on this analysis, 35102 should be 0.2 rvus less than 35631 for pre-service work, 2.43 rvus more for intra-service work and 3.80 rvus more for post-service work. 35631 has a work RVU of 33.95. If appropriately valued in comparison to 35631, 35102 should have a work RVU of 33.95 - 0.2 +2.43 + 3.80 = 39.98. Thus, based on this comparison with an MPC "A" list vascular service, the SVS recommended work RVU of 39.80 is totally appropriate.

## Comparison of aortic aneurysm repair CPT 35102 to simple intracranial aneurysm repair CPT 61702

CPT 61702 is "Surgery of simple intracranial aneurysm, intracranial approach; vertebrobasilar circulation." 61702 was granted 25 minutes more pre-service time than 35102 by the RUC. CPT 61702 has 280 minutes of intra-service time compared to 265 for CPT 35102. CPT 61702 has a longer length of stay, but the cerebral aneurysm patient is less ill (typical patient has single-system disease without overt hemodynamic instability) than the one recovering from open abdominal aneurysm repair. The typical 61702 patient does not require critical care service. The two procedures have an identical office visit pattern. Overall, 61702 has 20.83 post-service RVUs compared to 12.57 for 35102, a difference of 8.26.

SVS agrees that the CMS proposal of 54.28 work RVUs for 61702. An appropriate work RVU for 35102 may then be constructed from 61702 by subtracting 0.56 RVUs for pre-service, 5.66 RVUs for intra-service and 8.26 RVUs for post-service work from 54.28, with the resultant RVU of 39.80 for 35102. The building blocks of these two services are listed here, assuming 35102 is valued at the SVS recommended 39.80.

**Since 61702 simple intracranial aneurysm repair is correctly valued at 54.28, 35102 abdominal aortic aneurysm should be valued at 39.80:**

| SVS Rec RVU | | RVW: | 39.80 | CMS Rec RVU | | RVW: | 54.28 |
|---|---|---|---|---|---|---|---|
| with RUC time & Visits | RUC time | RUC Std. | RVW | with RUC time & Visits | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) | ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 75 | 0.0224 | 1.68 | Pre-service eval & positi | 100 | 0.0224 | 2.24 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 | Pre-service scrub, dress, | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | 1.80 | **Pre-service total** | | | 2.36 |
| ***Post-service:*** | Time | Intensity | (=time x intensity) | ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 | Immediate post | 50 | 0.0224 | 1.12 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) | Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 1 | 4.00 | 4.00 | ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 | ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 | NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 | NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 | 99233 | 5 | 1.51 | 7.55 |
| 99232 | 3 | 1.06 | 3.18 | 99232 | 5 | 1.06 | 5.30 |
| 99231 | 2 | 0.64 | 1.28 | 99231 | 5 | 0.64 | 3.20 |
| Discharge 99238 | 1 | 1.28 | 1.28 | Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 | Discharge 99239 | | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 | 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 | 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 | 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 | 99212 | 0 | 0.43 | 0.00 |
| 99211 | | 0.17 | 0.00 | 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | 12.57 | **Post-service total** | | | 20.83 |
| | Time | IWPUT | INTRA-RVW | | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 265 | 0.096 | 25.43 | ***Intra-service:*** | 280 | 0.111 | 31.09 |
| ***Total Time:*** | 688 | | | ***Total Time:*** | 1015 | | |

**Hospital Visits for 35102**

An important aspect of the RUC process involves expert consensus panel evaluation of the survey data. SVS believes that CMS and the RUC failed to take into account the fact that our expert consensus panel provided a very conservative interpretation of the hospital visit pattern compared to the raw survey data to provide what we felt was a balanced package that still easily justified the recommended work value.

SVS submitted only one 99291 in this package, when in fact, 65% of survey respondents included two or more 99291 critical care visits, some recommending as many as five. Similarly, we provided a conservative interpretation of the other hospital visits and the office visits compared to the array of survey responses. Even with this conservative visit pattern, a building block analysis easily justifies a work RVU of 39.80.

**Summary**

For CPT 35102, the wide range of analyses provided by SVS indicates that survey respondents undervalued the true relative value of this procedure. We would like to remind CMS that in several situations where SVS felt the survey median was too high, our society voluntarily reduced the recommended work RVU. In addition, we believe that adhering to the RUC survey median while ignoring extensive additional data is not consistent with the spirit of the relative value system. We submit that these extensive additional rationale analyses should lead the Agency to conclude that the survey median was too low in this case. **SVS requests reconsideration of this service because the weight of the data supports a work RVU of 39.80.**

**CPT 35081 Open Repair of abdominal aortic aneurysm requiring tube graft**

CPT 35081 is open repair of an infrarenal abdominal aortic aneurysm performed to prevent death from AAA. This service was submitted to the five-year review because the work has changed. Since endovascular aortic aneurysm repair requires at least 15 mm of normal aorta below the renal artery origins, this leaves aneurysms with short, angulated and calcified infrarenal necks for open aneurysm repair. All of these factors increase the intensity and complexity of this service. The net result is that open AAA repair is more complex and time consuming than it was five years ago.

CMS rejected the SVS and RUC recommendations based on concerns regarding NSQIP data. The fact is that NSQIP and SVS Survey hospital length of stay were identical at 7 days. In addition, NSQIP and SVS Survey data for intra-service time varied by only three minutes. Early on during workgroup negotiations, SVS relinquished those 3 minutes of intra-service time such that NSQIP data plays no part in our recommendation for this service.

SVS believes that CMS failed to fully consider the extensive "Additional Rationale" submitted to support a work relative value of 34.55 RVUs for this service.

SVS recommended 34.55 RVUs for open AAA repair based on an iterative process including a building block analysis, comparison with many other RUC-reviewed open aneurysm repairs, and comparison with other major procedures from related surgical disciplines. This is an operation with high complexity, long duration (210 minutes skin-to-skin) and a slow recovery (633 total minutes of physician time). It is performed on patients who typically carry multiple medical comorbidities.

Our recommended work RVU lies between the median and 75$^{th}$ percentile of the survey values. SVS believes the survey respondents undervalued the total service based on our Expert panel's analysis of the pre-, intra-, and post-service work. In addition, a wide range of supplemental analyses indicates that survey respondents undervalued the true worth of this procedure. We would like to remind CMS that in several situations where SVS felt the survey median was too high, our society voluntarily reduced the recommended work RVU. For this code, we are convinced that survey respondents undervalued the work, and we would hope that in fairness, CMS would reconsider the extensive data provided to prove our position.

At the CMS 2007 work RVU, the IWPUT for this aortic reconstruction is only 0.079, a value inconsistent with aortic reconstruction. At the SVS recommended value of 34.55, IWPUT is 0.096, fully consistent with arterial surgery. Based on IWPUT analysis, the CMS-proposed RVU of 31.00 is too low for open aortic aneurysm construction 35081.

| Source | Work RVU | IWPUT (using RUC time/visit) |
|---|---|---|
| SVS Recommended: | 34.55 | 0.096 |
| 2007 CMS work RVU: | 31.00 | 0.079 |

**35081 Time, Visit & IWPUT Intensity for SVS Recommended vs. CMS 2007 (unadjusted) work RVU. The CMS Proposal results in an inappropriately low IWPUT intensity:**

| SVS 5Yr REC | | RVW | 34.55 |
|---|---|---|---|
| with RUC time & visits | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 75 | 0.0224 | 1.68 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.80** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 1 | 4.00 | 4.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 99232 | 3 | 1.06 | 3.18 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **12.57** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 210 | 0.096 | 20.18 |
| ***Total Time:*** | 633 | | |

| CMS Proposed | | | 31.00 |
|---|---|---|---|
| w RUC time & visits | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positi | 75 | 0.0224 | 1.68 |
| Pre-service scrub, dress, | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.80** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 1 | 4.00 | 4.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 99232 | 3 | 1.06 | 3.18 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **12.57** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 210 | 0.079 | 16.63 |
| ***Total Time:*** | 633 | | |

**Comparison to Other Vascular Surgery Aneurysm Repairs and Aortic Surgery**

SVS recommended a work RVU of 34.55 for 35081, a value which results in an IWPUT of 0.096, directly in the middle of the established range for these services. The 2007 CMS work RVU of 31.00, results in an IWPUT of 0.079, below the lowest value of the established range of intensities for aneurysm repairs and other aortic surgery. Note that the other IWPUT values in this table are calculated from RUC-recommended and CMS-approved aneurysm repairs and aortic surgery.

**RUC/CMS-Approved IWPUT Intensity for Aneurysm Repairs and Aortic Surgery Indicates that CMS proposed work RVU is too low based on intensity comparison:**

| Code | Short Descriptor | Year Implemented | IWPUT |
|---|---|---|---|
| ****CMS placed 35081 Open AAA Repair here** | | | **0.079** |
| 35141 | Repair femoral aneurysm | 2002 5Yr | 0.082 |
| 34900 | Endovasc rep iliac aneurysm | 2003 new | 0.088 |
| 35646 | Aorto-bifemoral bypass synth | 2002 new | 0.093 |
| 35151 | Rep popliteal aneurysm | 2002 5 Yr | 0.094 |
| 33881 | Endovasc rep thoracic aorta | 2006 new | 0.095 |
| ****SVS would put 35081 Aortic aneurysm Repair here** | | | **0.096** |
| 35011 | Rep axillary/brach aneurysm | 2002 5 Yr | 0.099 |
| 35131 | Rep Iliac aneurysm | 2002 5 Yr | 0.101 |
| 34802 | Endo rep abd AAA 2-piece | 2001 new | 0.101 |
| 34805 | Endo rep Abd AAA aorto-uni | 2001 new | 0.101 |
| 35647 | Aorto-fem bypass synth | 2002 new | 0.102 |
| 35045 | Rep radial/ulnar aneurysm | 2002 5 Yr | 0.102 |
| 34803 | Endo rep abd AAA 3-piece | 2005 new | 0.104 |
| 35121 | Rep mesenteric aneurysm | 2002 5 Yr | 0.105 |
| 33880 | Endovasc rep thoracic | 2006 new | 0.105 |
| 35111 | Rep splenic aneurysm | 2002 5 Yr | 0.109 |
| 34800 | Endovasc rep abd AAA | 2001 new | 0.109 |

**Hospital Visits for 35081**

An important aspect of the RUC process involves expert consensus panel evaluation of the survey data. SVS believes that CMS and the RUC failed to take into account the fact that our expert consensus panel provided a very conservative interpretation of the hospital visit pattern compared to the raw survey data to provide what we felt was a balanced package that still easily justified the recommended work value.

SVS submitted only one 99291 in this package, when in fact, 62% of survey respondents included two or more 99291 critical care visits, some recommending as many as five. Similarly, we provided a conservative interpretation of the other hospital visits and the office visits compared to the array of survey responses. Even with this conservative visit pattern, a building block analysis easily justifies a work RVU of 34.55.

**Summary**

For 35081, SVS provided survey data, an intensity analysis, comparison with other vascular surgery procedures, comparison with aneurysm repairs in the neurosurgical realm, all calculated using a conservative interpretation of hospital visits. We believe this information points to our originally recommended work RVU of 34.55 as the most accurate relative work value. This wide range of analyses indicates that survey respondents undervalued the true worth of this procedure. We remind CMS that in several situations where SVS felt the survey median was too high, our society voluntarily reduced the recommended work RVU. **We submit that this extensive analysis should lead the Agency to conclude that the survey median was too low in this case. The weight of the data supports a work RVU of 34.55.**

**CPT 35556 Bypass with vein, femoral-popliteal**

35556 lower extremity bypass graft is performed to prevent leg amputation due to ischemic gangrene and non-healing ischemic foot ulcers. SVS believes that this operation, in addition to three others in the same family (35566, 35583, 35585) are among the most undervalued services in the Medicare physicians fee schedule. These operations require many hours of complex surgery, and the patients are extremely ill postoperatively. The individuals who require this type of operation are elderly and almost always have coincident atherosclerotic disorders such as coronary artery disease and cerebrovascular disease. Most of these patients has smoked thousands of packs of cigarettes and have advanced COPD, comorbidities that contribute to the complexity of post-operative care in the typical patient.

These bypass grafts were undervalued by survey respondents. SVS believes this is because respondents underestimated the total package of work including skin-to-skin work and the magnitude of post-operative work. This is borne out by a variety of additional rationale calculations. For example, we believe NSQIP data provides accuracy superior to that of survey respondents. In this case, there were 1500 CPT 35556 operations in the NSQIP database. The survey respondents underestimated the actual intra-service time by 41 minutes.

Based on an iterative process involving many different analyses, SVS recommended 31.58 work RVUs. This value results in IWPUT of 0.090, consistent with major arterial surgery and many other arterial bypass grafts. The RUC reduced the recommended RVW to 27.25, a value that provides an IWPUT of only 0.073, inconsistent with major arterial reconstructions. CMS reduced the value further to 25.00, a value that results in an IWPUT of only 0.064, totally inconsistent with any major arterial reconstructions. In fact, with the new 2007 E&M RVUs, this complex arterial reconstruction is valued at an intensity less than a low level emergency visit (99282, IWPUT 0.070). SVS believes its originally recommended value of 31.58 is the most accurate work relative value.

## SVS Recommendation vs. CMS 2007 (unadjusted) work RVU:

| SVS Rec RVU | 35556 | RVW: | 31.58 |
|---|---|---|---|
| w RUC time & visits | RUC Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positio | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 1 | 1.06 | 1.06 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **7.53** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 251 | 0.090 | 22.69 |
| ***Total time:*** | 557 | | |

| CMS Rec RVU | 35556 | RVW: | 25.00 |
|---|---|---|---|
| w RUC time & visits | RUC Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | =time x intensity |
| Pre-service eval & positi | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | Time | Intensity | =time x intensity |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 1 | 1.06 | 1.06 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **7.53** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 251 | 0.064 | 16.11 |
| ***Total time:*** | 557 | | |

SVS recommended work RVU results in an appropriate IWPUT of 0.090. CMS 2007 work RVU (unadjusted for new E/M wRVUs) results in an inappropriately low IWPUT.

Thirty-two bypass grafts have undergone RUC evaluation over the past seven years. The IWPUT ranges from 0.065 for relatively straightforward bypass grafts involving medium-sized arteries to values of 0.120 for more complex procedures performed in body areas difficult to reach. This chart demonstrates the inappropriateness of the CMS 2007 RVW for CPT 35556. The SVS recommendation of 31.58 places the intensity of this code where it appropriately belongs in the middle of the range.

**CMS/RUC IWPUTs for Vascular Surgery Bypass Codes 2000-2006**

| | | |
|---|---|---|
| **35556** | **CMS Rec inappropriately places code here** | **0.064** |
| 35558 | BPG w vein femoral-femoral | 0.065 |
| 35533 | BPG w vein axillary-bi-femoral | 0.075 |
| 35656 | BPG w other than vein fem-pop | 0.075 |
| 35565 | BPG w vein ilio-femoral | 0.076 |
| 35522 | BPG w vein axillary-brachial | 0.077 |
| 35521 | BPG w vein axillary-femoral | 0.079 |
| 35665 | BPG w other than vein iliofem | 0.080 |
| 35563 | BPG w vein ilio-iliac | 0.081 |
| 35571 | BPG w vein popliteal-tibial | 0.083 |
| 35510 | BPG w vein carotid-brachial | 0.084 |
| 35671 | BPG w other than vein pop-tib | 0.084 |
| 35663 | BPG w other than vein ilioiliac | 0.084 |
| 35587 | BPG w vein insitu pop-tib | 0.085 |
| 35512 | BPG w vein subclavian-brachial | 0.085 |
| 35666 | BPG w other than vein fem-tib | 0.086 |
| 35661 | BPG w other than vein fem-fem | 0.086 |
| 35531 | BPG w vein aorto-mesenteric | 0.086 |
| 35654 | BPG w other than vein ax-bifem | 0.089 |
| **35556** | **SVS Rec Appropriately Places Code here** | **0.090** |
| 35518 | BPG w vein axillary-axillary | 0.091 |
| 35646 | BPG w other than vein aortobifem | 0.092 |
| 35525 | BPG w vein brachial-brachial | 0.093 |
| 35636 | BPG w other than vein splenorenal | 0.094 |
| 35511 | BPG w vein subclavian-subclavian | 0.096 |
| 35526 | BPG w vein aorto-subclavian | 0.098 |
| 35621 | BPG w other than vein ax-fem | 0.100 |
| 35647 | BPG w other than vein aortofem | 0.101 |
| 35631 | BPG w other than vein aorto-mes | 0.101 |
| 35626 | BPG w other than vein aorto-sub | 0.104 |
| 35560 | BPG w vein aorto-renal | 0.107 |
| 35650 | BPG w other than vein ax-ax | 0.107 |
| 35536 | BPG w vien splenorenal | 0.120 |
| 35623 | BPG w other than vein ax-pop | 0.120 |

## Comparison of 35556 with CMS-chosen Benchmark Vascular Bypass CPT 35671

In the proposed rule, CMS chose CPT code 35671 as a reference service when discussing orthopedic surgery code CPT 27447 (page 71). We therefore assume that CMS believes 35671 is a solid benchmark in the relative value scale. The following data exist for 35671, which is "Bypass graft, with other than vein; popliteal-tibial or-peroneal artery".

| **35671 CMS REF Code** | **35671** | **RVW:** | **19.30** |
|---|---|---|---|
| 2nd 5-Yeaf Rev | **Svy Data** | **RUC Std.** | **RVW** |
| ***Pre-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | **Visit n** | **E/M RVW** | **(=n x RVW)** |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 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 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **6.44** |
| | **Time** | **IWPUT** | **INTRA-RVW** |
| ***Intra-service:*** | 135 | 0.085 | 11.50 |
| ***Total Time:*** | 411 | | |

After the NPRM was published, SVS built a work RVU for 35556 based on this CMS-chosen benchmark service. Intra-service time for 35556 is 251 minutes compared to 135 minutes for 35671. Using an IWPUT of 0.085 (for 35671), this represents an additional 9.86 RVUs. The two services have equal pre-service time and pre-service work. The post-service work for 35556 is 7.53 RVUs compared to 6.44 RVUs for 35671. Therefore, a work RVU for 35556 may be calculated as 19.30 plus 9.86 plus 1.09 equals 30.25.

Working with vein conduit (35556) is more complex than working with synthetic conduit (35671). Therefore, an IWPUT of 0.090 is more appropriate for this calculation. The work RVU would then be 31.51, essentially equivalent to the SVS recommended value of 31.58.

## Comparison of 35556 to General Surgery procedure 44150

CMS created a major rank order anomaly for 35556 at only 25.00, while appropriately assigning CPT 44150 (partial removal of colon) a work RVU of 27.50. 44150 is a 180 minute skin-to-skin operation performed in patients who typically have moderate comorbidities. CPT 35556 is a 251 minute operation performed in patients who typically have advanced cardiovascular comorbidities. SVS believes 44150 is accurately valued at 27.50, and the society strongly recommends reconsideration of a more accurate work RVU for the much longer and equally complex 35556 operation at 31.58 RVUs.

**CMS valued 44150 at 27.50, while 35556 was valued at only 25.00 RVUs. 35556 has 70 more minutes of equally complex skin-to-skin time:**

| 2007 CMS Proposed RVU | 44150 | RVW: | 27.50 |
|---|---|---|---|
| Colectomy/Ileostomy | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positionin | 45 | 0.0224 | 1.01 |
| Pre-service scrub, dress, wai | 15 | 0.0081 | 0.12 |
| Pre-service total | | | 1.13 |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 3 | 1.06 | 3.18 |
| 99231 | 3 | 0.64 | 1.92 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 |
| 99212 | 2 | 0.43 | 0.86 |
| 99211 | | 0.17 | 0.00 |
| Post-service total | | | 11.15 |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 180 | 0.085 | 15.22 |
| | 585 | | |

| 2007 CMS Proposed RVU | 35556 | RVW: | 25.00 |
|---|---|---|---|
| w RUC time & visits | RUC Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| Pre-service total | | | 1.35 |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 1 | 1.06 | 1.06 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| Post-service total | | | 7.53 |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 251 | 0.064 | 16.11 |
| ***Total time:*** | 557 | | |

**Hospital Visits for 35556 Should be Reviewed**

An important aspect of the RUC process involves expert consensus panel evaluation of the survey data. SVS believes that CMS and the RUC failed to take into account the fact that our expert consensus panel provided a very conservative interpretation of the hospital visit pattern compared to the raw survey data to provide what we felt was a balanced package that still easily justified the recommended work value.

SVS submitted no 99291 critical care visits in this package, when in fact, 59% of survey respondents included one or more 99291 visits. Similarly, we provided a conservative interpretation of the other hospital visits and the office visits compared to the array of survey responses. Even with this conservative visit pattern, a building block analysis easily justifies a work RVU of 31.58

**Summary**

SVS provided a building block intensity analysis, a comparison with other vascular surgery procedures, comparison with general surgery procedures, and a review of hospital visits. We believe all of this information points to our originally recommended work RVU of 31.58 as the most accurate relative value.

This wide range of analyses indicates that survey respondents undervalued the true worth of this procedure. We remind CMS that in several situations where SVS felt the survey median was too high, our society voluntarily reduced the recommended work RVU. We submit that this extensive analysis should lead the Agency to conclude that the survey median was too low in this case. **SVS requests reconsideration of the CMS 2007 work RVU for 35556 of 25.00 because the weight of the data supports a much higher value, and the CMS value creates a myriad of rank order anomalies.**

## CPT 35566 Bypass Graft with vein, Femoral-tibial

This lower extremity bypass is performed to prevent leg amputation due to ischemic gangrene and non-healing foot ulcers. SVS believes that this bypass in addition to three others in the same family (35556, 35583, 35585) number among the most undervalued services in the Medicare physicians fee schedule.

SVS used an iterative process including review of survey data, NSQIP data, building block analysis, comparison to other RUC-reviewed bypass grafts and comparison to procedures in other specialties to arrive at a recommended work RVU of 39.20 for this complex service. Our analysis indicated that survey respondents underestimated the true relative value of work involved in this service.

First, the NSQIP data proves that survey respondents underestimated the intra-service time by 36 minutes. There were almost 1400 of these operations recorded in the NSQIP database. The NSQIP intra-time is more accurate than estimates by ~40 surgeons. The analysis provided here indicates that by using an accurate skin-to-skin time, an RVU of 39.20 results in an IWPUT appropriate for complex open lower extremity bypass surgery.

**SVS Recommendation vs. CMS unadjusted 2007 RVU for 35566 Fem-Tib Bypass with vein. The CMS RVU set a new low intensity level for bypass surgery.**

| SVS Rec RVU | 35566 | | 39.20 |
|---|---|---|---|
| RUC-approved time & visi | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positio | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 2 | 1.06 | 2.12 |
| 99231 | 3 | 0.64 | 1.92 |
| Discharge 99238 | 0 | 1.28 | 0.00 |
| Discharge 99239 | 1 | 1.75 | 1.75 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **9.70** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 306 | 0.092 | 28.14 |
| ***Total Time:*** | 670 | | |

| CMS Rec RVU | 35566 | | 30.00 |
|---|---|---|---|
| RUC-approved time & visits | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | =time x intensity |
| Pre-service eval & positionir | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wa | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | Time | Intensity | =time x intensity |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 2 | 1.06 | 2.12 |
| 99231 | 3 | 0.64 | 1.92 |
| Discharge 99238 | 0 | 1.28 | 0.00 |
| Discharge 99239 | 1 | 1.75 | 1.75 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **9.70** |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 306 | 0.062 | 18.94 |
| ***Total Time:*** | 670 | | |

At the SVS recommended work RVU of 39.20, the IWPUT of this service (0.092) is appropriate for major vascular arterial reconstructions extending to the tibial arteries. CMS valued 35566 at 30.00, resulting in an IWPUT of only 0.062. At 0.062, this complex service now has intensity less than the lowest level inpatient consult (99251, IWPUT 0.078).

SVS analyzed 32 arterial bypass grafts that have undergone RUC evaluation and CMS approval over the past seven years. The IWPUT ranges from 0.065 for relatively straightforward bypass grafts involving medium-sized arteries to values of 0.120 for more complex procedures performed in body areas that require very complex dissections. This chart demonstrates the inappropriateness of the CMS value for CPT 35566. The SVS recommendation of 39.20 places the intensity of this code appropriately in the middle of the range.

**CMS/RUC Approved IWPUTs for Vascular Surgery Bypass Codes 2000-2006**

| CPT Code | Short Descriptor | IWPUT |
|---|---|---|
| **35566** | **CMS Rec inappropriately places code here** | **0.062** |
| 35558 | BPG w vein femoral-femoral | 0.065 |
| 35533 | BPG w vein axillary-bi-femoral | 0.075 |
| 35656 | BPG w other than vein fem-pop | 0.075 |
| 35565 | BPG w vein ilio-femoral | 0.076 |
| 35522 | BPG w vein axillary-brachial | 0.077 |
| 35521 | BPG w vein axillary-femoral | 0.079 |
| 35665 | BPG w other than vein iliofem | 0.080 |
| 35563 | BPG w vein ilio-iliac | 0.081 |
| 35571 | BPG w vein popliteal-tibial | 0.083 |
| 35510 | BPG w vein carotid-brachial | 0.084 |
| 35671 | BPG w other than vein pop-tib | 0.084 |
| 35663 | BPG w other than vein ilioiliac | 0.084 |
| 35587 | BPG w vein insitu pop-tib | 0.085 |
| 35512 | BPG w vein subclavian-brachial | 0.085 |
| 35666 | BPG w other than vein fem-tib | 0.086 |
| 35661 | BPG w other than vein fem-fem | 0.086 |
| 35531 | BPG w vein aorto-mesenteric | 0.086 |
| 35654 | BPG w other than vein ax-bifem | 0.089 |
| 35518 | BPG w vein axillary-axillary | 0.091 |
| **35566** | **SVS Rec Appropriately places code here** | **0.092** |
| 35646 | BPG w other than vein aortobifem | 0.092 |
| 35525 | BPG w vein brachial-brachial | 0.093 |
| 35636 | BPG w other than vein splenorenal | 0.094 |
| 35511 | BPG w vein subclavian-subclavian | 0.096 |
| 35526 | BPG w vein aorto-subclavian | 0.098 |
| 35621 | BPG w other than vein ax-fem | 0.100 |
| 35647 | BPG w other than vein aortofem | 0.101 |
| 35631 | BPG w other than vein aorto-mes | 0.101 |
| 35626 | BPG w other than vein aorto-sub | 0.104 |
| 35560 | BPG w vein aorto-renal | 0.107 |
| 35650 | BPG w other than vein ax-ax | 0.107 |
| 35536 | BPG w vien splenorenal | 0.120 |
| 35623 | BPG w other than vein ax-pop | 0.120 |

**Comparison of 35566 with CMS-chosen Benchmark Vascular Bypass CPT 35671**

In the NPRM, CMS chose CPT code 35671 as a reference service when discussing orthopedic surgery code CPT 27447 (page 71). We therefore assume that CMS believes 35671 is a solid benchmark in the relative value scale. The following data exist for 35671, which is "Bypass graft, with other than vein; popliteal-tibial or-peroneal artery".

| **35671 CMS REF Code** | **35671** | **RVW:** | **19.30** |
|---|---|---|---|
| 2nd 5-Yeaf Rev | **Svy Data** | **RUC Std.** | **RVW** |
| ***Pre-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | **Visit n** | **E/M RVW** | **(=n x RVW)** |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 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 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **6.44** |
| | **Time** | **IWPUT** | **INTRA-RVW** |
| ***Intra-service:*** | 135 | 0.085 | 11.50 |
| ***Total Time:*** | 411 | | |

After the NPRM was published, SVS built a work RVU for 35566 based on this CMS-chosen benchmark service. 35566 has 306 minutes of intra-service time, 171 minutes more than 35671. Using the 35671 IWPUT of 0.085 and the 171 minute time increment, the intra-service work of 35566 is an additional 14.54 RVUs. The two services have equal pre-service time and pre-service work. The post-service work for 35566 is 9.70 RVUs compared to 6.44 RVUs for 35671. Therefore, a work RVU for 35566 may be calculated as 19.30 plus 14.54 plus 3.26 equals 37.10.

Since working with vein conduit (as in 35566) is more complex than working with synthetic conduit (as in 35671), the IWPUT that we actually should use in this calculation is that higher, 0.092 being a typical value. The resultant RVW would be 39.24, essentially identical to the original SVS recommended value of 39.20.

## Comparison of 35566 to 2007 CMS RVU for General Surgery service 44151

CMS created a major rank order anomaly by valuing 35566 at only 30.00, while at the same time assigning CPT 44151 removal of colon an RVW of 32.00. 44151 is a 240 minute skin-to-skin operation performed in patients with low or moderate cardiovascular comorbidities. CPT 35566 is a 306 minute operation performed in patients who typically have advanced cardiovascular comorbidities. Total time for 44151 is 683 minutes, while total time for 35566 is 670 minutes. Thus, the major difference in these two services is the 66 minute increment of complex intra-service time of 35566 over 44151. The following table demonstrates that CMS unfairly valued 35566 at 30 RVUs, assuming that 44151 is appropriately valued at 32.00.

### With 44151 valued at 32.00, a fair relative value of 35566 must be substantially > 30:

| 2007 CMS Proposed RVU | 44151 | RVW: | 32.00 |
|---|---|---|---|
| Colectomy/ileostomy | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positionin | 45 | 0.0224 | 1.01 |
| Pre-service scrub, dress, wai | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | 1.13 |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 3 | 1.06 | 3.18 |
| 99231 | 5 | 0.64 | 3.20 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 |
| 99212 | 2 | 0.43 | 0.86 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | 12.43 |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 240 | 0.077 | 18.44 |
| ***Total Time:*** | 683 | | |

| CMS Rec RVU | 35566 | | 30.00 |
|---|---|---|---|
| RUC-approved time & visits | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | 1.35 |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 2 | 1.06 | 2.12 |
| 99231 | 3 | 0.64 | 1.92 |
| Discharge 99238 | 0 | 1.28 | 0.00 |
| Discharge 99239 | 1 | 1.75 | 1.75 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | 9.70 |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 306 | 0.062 | 18.94 |
| ***Total Time:*** | 670 | | |

**Hospital Visits for 35566**

An important aspect of the RUC process involves expert consensus panel evaluation of the survey data. SVS believes that CMS and the RUC failed to take into account the fact that our expert consensus panel provided a very conservative interpretation of the hospital visit pattern compared to the raw survey data to provide what we felt was a balanced package that still easily justified the recommended work value.

SVS submitted no 99291 critical care visits in this package, when in fact, 64% of survey respondents included one or more 99291 visits. We downshifted these to 99233s. Similarly, we provided a conservative interpretation of the other hospital visits and the office visits compared to the array of survey responses. Even with this conservative visit pattern, a building block analysis easily justifies a work RVU of 39.20.

**Summary**

SVS provided RUC survey data, a building block intensity analysis, a comparison with other vascular surgery procedures, a comparison with general surgery procedures, all including a very conservative interpretation of hospital visits. This wide range of analyses indicates that survey respondents undervalued the true worth of this procedure. We remind CMS that in several situations where SVS felt the survey median was too high, our society voluntarily reduced the recommended work RVU. We submit that this extensive analysis should lead the Agency to conclude that the survey median was too low in this case. **The weight of the data supports a work RVU of 39.20. We request that CMS reconsider the 2007 work RVU for this service.**

## CPT 35583 Bypass graft with vein in-situ, femoral-popliteal:

This lower extremity bypass is performed to prevent leg amputation due to ischemic gangrene and non-healing foot ulcers. SVS believes that this bypass, in addition to three others in the same family (35556, 35566, 35585) number among the most undervalued services in the Medicare physicians fee schedule. SVS undertook an iterative process involving consideration of survey data, a building block analysis, IWPUT analysis, comparison to existing RUC-analyzed and CMS-approved bypass grafts, and comparison to general surgery procedures to conclude that a work RVU of 32.26 is accurate.

SVS believes that this wide spectrum of analyses proves that the survey respondents underestimated the true relative work of this procedure.

In this case, the NSQIP data demonstrated that survey respondents minimally underestimated the intra-service time, (253 minutes actual by NSQIP (256 accurately recorded operations) vs. 240 minutes survey median). We believe that as surgery time and post-op visit complexity increase, survey respondents have increasing difficulty estimating the true total work RVU. This is especially true when the total services lies at the upper end of work among potential references.

SVS recommended a work RVU of 32.26, which results in an IWPUT of 0.092. The IWPUT is fully consistent with many other complex major arterial bypass grafts and serves to justify the work recommendation. The table demonstrates that the CMS reduced work RVU to 26.00 provides an IWPUT of only 0.068, inconsistent with major arterial reconstructions. SVS believes its original value of 32.26 is most accurate based on this analysis.

### SVS Recommendation and CMS Proposed RVU for CPT 35583

| SVS Rec RVU | 35583 | | 32.26 |
|---|---|---|---|
| with RUC time & visits | RUC Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 1 | 1.06 | 1.06 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **7.53** |
| | Time | IWPUT | INTRA-RVW |
| *Intra-service:* | 253 | 0.092 | 23.37 |
| *Total Time:* | 559 | | |

| CMS Rec RVU | 35583 | | 26.00 |
|---|---|---|---|
| with RUC time & visits | RUC Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 1 | 1.06 | 1.06 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **7.53** |
| | Time | IWPUT | INTRA-RVW |
| *Intra-service:* | 253 | 0.068 | 17.11 |
| *Total Time:* | 559 | | |

SVS analyzed 32 arterial bypass grafts that have undergone RUC evaluation and CMS approval over the past seven years. The intra-service intensity (IWPUT) of these bypasses ranges from 0.064 for relatively straightforward operations involving medium-sized arteries to values of 0.120 for complex procedures that require extensive and risky dissection. This chart demonstrates the inappropriateness of the CMS 2007 RVU for CPT 35583. The SVS recommendation of 32.26 RVUs places the intensity of this code appropriately in the middle of the range.

**CMS/RUC IWPUTs for Vascular Surgery Bypass Codes 2000-2006**

| CPT Code | Short Descriptor | IWPUT | |
|---|---|---|---|
| 35558 | BPG w vein femoral-femoral | 0.065 | |
| **35583** | **CMS Rec inappropriately places code here** | **0.068** | ⇦ |
| 35533 | BPG w vein axillary-bi-femoral | 0.075 | |
| 35656 | BPG w other than vein fem-pop | 0.075 | |
| 35565 | BPG w vein ilio-femoral | 0.076 | |
| 35522 | BPG w vein axillary-brachial | 0.077 | |
| 35521 | BPG w vein axillary-femoral | 0.079 | |
| 35665 | BPG w other than vein iliofem | 0.080 | |
| 35563 | BPG w vein ilio-iliac | 0.081 | |
| 35571 | BPG w vein popliteal-tibial | 0.083 | |
| 35510 | BPG w vein carotid-brachial | 0.084 | |
| 35671 | BPG w other than vein pop-tib | 0.084 | |
| 35663 | BPG w other than vein ilioiliac | 0.084 | |
| 35587 | BPG w vein insitu pop-tib | 0.085 | |
| 35512 | BPG w vein subclavian-brachial | 0.085 | |
| 35666 | BPG w other than vein fem-tib | 0.086 | |
| 35661 | BPG w other than vein fem-fem | 0.086 | |
| 35531 | BPG w vein aorto-mesenteric | 0.086 | |
| 35654 | BPG w other than vein ax-bifem | 0.089 | |
| 35518 | BPG w vein axillary-axillary | 0.091 | |
| **35583** | **SVS Rec Appropriately places code here** | **0.092** | ⇦ |
| 35646 | BPG w other than vein aortobifem | 0.092 | |
| 35525 | BPG w vein brachial-brachial | 0.093 | |
| 35636 | BPG w other than vein splenorenal | 0.094 | |
| 35511 | BPG w vein subclavian-subclavian | 0.096 | |
| 35526 | BPG w vein aorto-subclavian | 0.098 | |
| 35621 | BPG w other than vein ax-fem | 0.100 | |
| 35647 | BPG w other than vein aortofem | 0.101 | |
| 35631 | BPG w other than vein aorto-mes | 0.101 | |
| 35626 | BPG w other than vein aorto-sub | 0.104 | |
| 35560 | BPG w vein aorto-renal | 0.107 | |
| 35650 | BPG w other than vein ax-ax | 0.107 | |
| 35536 | BPG w vien splenorenal | 0.120 | |
| 35623 | BPG w other than vein ax-pop | 0.120 | |

**Comparison of 35583 with CMS-chosen Benchmark Vascular Bypass CPT 35671**

In the NPRM, CMS chose CPT code 35671 as a reference service when discussing orthopedic surgery code CPT 27447 (page 71). We therefore assume that CMS believes 35671 to be a solid benchmark in the relative value scale. The following data exist for 35671, which is "Bypass graft, with other than vein; popliteal-tibial or-peroneal artery".

| **35671 CMS REF Code** | **35671** | **RVW:** | **19.30** |
|---|---|---|---|
| 2nd 5-Yeaf Rev | **Svy Data** | **RUC Std.** | **RVW** |
| ***Pre-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | **Visit n** | **E/M RVW** | **(=n x RVW)** |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 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 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **6.44** |
| | **Time** | **IWPUT** | **INTRA-RVW** |
| ***Intra-service:*** | 135 | 0.085 | 11.50 |
| ***Total Time:*** | 411 | | |

Following the NPRM, SVS built a work RVU for 35583 based on this CMS-chosen benchmark. 35583 intra-service time is 253 minutes, 118 minutes longer than 35671. At the 35671 IWPUT of 0.085, this represents an additional 10.03 RVUs. The two services have equal pre-service time and pre-service work. The post-service work for 35583 is 7.53 RVUs compared to 6.44 RVUs for 35671. Therefore, a work RVU for 35583 may be calculated as 19.30 plus 10.03 plus 1.09 equals at least 30.42.

In reality, working with vein conduit (as in 35583) is more complex than working with synthetic conduit (as in 35671), and an IWPUT higher than 0.085 is actually indicated in this calculation. SVS chose a typical IWPUT for vein conduit bypasses, a value of 0.092. This action places the calculated value at 31.89, very close to the SVS recommended value of 32.26.

## Comparison of 35583 to General Surgery procedure 44150

CMS created a major rank order anomaly by valuing 35583 at only 26.00, while at the same time appropriately assigning CPT 44150 partial removal of colon a work RVU of 27.50. Assuming 44150 is appropriately valued at 27.50, consider the following. 44150 is a 180 minute skin-to-skin operation performed in patients with low to moderate cardiovascular comorbidities. CPT 35583 is a 253 minute operation performed in patients who typically have advanced cardiovascular comorbidities. Based on the detailed element-by-element provided below, SVS believes 35583 is markedly undervalued at 26.00 RVUs when 44150 is valued at 27.50. A much more accurate work value for this service would be at the SVS recommended 32.26 RVUs.

**Since CMS valued 44150 at 27.50, 35583 is unreasonably valued at only 26.00 RVUs. 35583 has 73 more minutes of high-intensity skin-to-skin time than 44150:**

| 2007 CMS Proposed RVU | 44150 | RVW: | 27.50 |
|---|---|---|---|
| Colectomy/Ileostomy | Svy Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positioning | 45 | 0.0224 | 1.01 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | 1.13 |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 3 | 1.06 | 3.18 |
| 99231 | 3 | 0.64 | 1.92 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 1 | 1.08 | 1.08 |
| 99213 | 1 | 0.65 | 0.65 |
| 99212 | 2 | 0.43 | 0.86 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | 11.15 |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 180 | 0.085 | 15.22 |
| | 585 | | |

| CMS Rec RVU | 35583 | | 26.00 |
|---|---|---|---|
| with RUC time & visits | RUC Data | RUC Std. | RVW |
| ***Pre-service:*** | Time | Intensity | (=time x intensity) |
| Pre-service eval & positio | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | 1.35 |
| ***Post-service:*** | Time | Intensity | (=time x intensity) |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | Visit n | E/M RVW | (=n x RVW) |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 1 | 1.06 | 1.06 |
| 99231 | 2 | 0.64 | 1.28 |
| Discharge 99238 | 1 | 1.28 | 1.28 |
| Discharge 99239 | 0 | 1.75 | 0.00 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | 7.53 |
| | Time | IWPUT | INTRA-RVW |
| ***Intra-service:*** | 253 | 0.068 | 17.11 |
| ***Total Time:*** | 559 | | |

**Hospital Visits for 35583**

An important aspect of the RUC process involves expert consensus panel evaluation of the survey data. SVS believes that CMS and the RUC failed to take into account the fact that our expert consensus panel provided a very conservative interpretation of the hospital visit pattern compared to the raw survey data to provide what we felt was a balanced package that still easily justified the recommended work value.

SVS submitted no 99291 critical care visits in this package, when in fact, >50% of survey respondents included one or more 99291 visits. We downshifted these to 99233s. Similarly, we provided a conservative interpretation of the other hospital visits and the office visits compared to the array of survey responses. Even with this conservative visit pattern, a building block analysis easily justifies a work RVU of 32.26.

Even with the voluntary visit pattern reduction, a building block analysis easily justifies a work RVU of 32.26. In light of this, the CMS 2007 work RVU of 26.00 is particularly unreasonable. SVS would be happy to review the raw data with the Agency.

**Summary**

SVS undertook an iterative process involving a RUC survey, a building block intensity analysis, a comparison with other vascular surgery procedures, a comparison with general surgery procedures, all including a conservative analysis of hospital visits. We believe this information, considered in total, demonstrates that survey respondents underestimated the total work involved in this service. Our recommended work RVU of 32.26 is accurate, based on overall consideration of the data. At the same time, these analyses demonstrate that the 2007 CMS value creates a rank order anomaly with procedures within and outside of vascular surgery.

**SVS requests reconsideration of CPT code 35583 at a work RVU of 32.26.**

**CPT 35585 Bypass graft with vein in-situ, femoral-tibial or peroneal:**

This lower extremity bypass is performed to prevent leg amputation due to ischemic gangrene and non-healing foot ulcers. SVS believes that this bypass is among the most undervalued services in the Medicare physicians' fee schedule. Unfortunately, the five-year review did little to rectify that problem.

SVS undertook an iterative process involving consideration of RUC survey data, a building block analysis, IWPUT analysis, comparison of existing RUC-analyzed and CMS-approved bypass grafts, and comparison to general surgery procedures to conclude that a work RVU of 39.42 is accurate.

SVS believes that this wide spectrum of analyses proves that the survey respondents underestimated the true relative value of this procedure, and reliance on survey values while ignoring a mountain of other data is simply wrong.

In this case, the NSQIP data proves that survey respondents underestimated the intra-service time by a full 35 minutes. There were 430 of these operations recorded in the NSQIP database, and the intra-time must be more accurate than estimates of ~40 surgeons.

SVS recommended a work RVU of 39.42, which results an in IWPUT of 0.093. This IWPUT is fully consistent with many other existing arterial bypass grafts and serves to justify the work recommendation. The Table below demonstrates that the 2007 CMS work RVU of only 30.00 results in an IWPUT of only 0.069, inconsistent with major arterial reconstruction.

**SVS Recommendation vs. 2007 CMS work RVU for CPT 35585. SVS recommendation results in appropriate IWPUT intensity measure:**

| SVS Rec RVU | 35585 | | 39.42 |
|---|---|---|---|
| with RUC time & visits | RUC data | RUC Std. | RVW |
| ***Pre-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | **Visit n** | **E/M RVW** | **(=n x RVW)** |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 2 | 1.06 | 2.12 |
| 99231 | 3 | 0.64 | 1.92 |
| Discharge 99238 | 0 | 1.28 | 0.00 |
| Discharge 99239 | 1 | 1.75 | 1.75 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **9.70** |
| | **Time** | **IWPUT** | **INTRA-RVW** |
| ***Intra-service:*** | 305 | 0.093 | 28.36 |
| ***Total Time:*** | 689 | | |

| CMS Proposed RVU | 35585 | | 32.00 |
|---|---|---|---|
| with RUC time & visits | RUC data | RUC Std. | RVW |
| ***Pre-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | **Visit n** | **E/M RVW** | **(=n x RVW)** |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 1 | 1.51 | 1.51 |
| 99232 | 2 | 1.06 | 2.12 |
| 99231 | 3 | 0.64 | 1.92 |
| Discharge 99238 | 0 | 1.28 | 0.00 |
| Discharge 99239 | 1 | 1.75 | 1.75 |
| 99215 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **9.70** |
| | **Time** | **IWPUT** | **INTRA-RVW** |
| ***Intra-service:*** | 305 | 0.069 | 20.94 |
| ***Total Time:*** | 689 | | |

SVS analyzed 32 arterial bypass grafts that have undergone RUC evaluation and CMS approval over the past seven years. The IWPUT ranges from 0.064 for relatively straightforward bypass grafts involving medium-sized arteries to values of 0.120 for more complex procedures. This chart demonstrates the inappropriateness of the CMS value for CPT 35585. The SVS recommendation of 39.42 RVUs places the intensity of this code appropriately in the middle of the range.

**IWPUTs for RUC-reviewed & CMS-approved vascular surgery bypass codes 2000-2006. This table demonstrates inappropriateness of 2007 work RVU for 35585.**

| CPT Code | Short Descriptor | IWPUT |
|---|---|---|
| 35558 | BPG w vein femoral-femoral | 0.065 |
| **35585** | **CMS Rec inappropriately places code here** | **0.069** |
| 35533 | BPG w vein axillary-bi-femoral | 0.075 |
| 35656 | BPG w other than vein fem-pop | 0.075 |
| 35565 | BPG w vein ilio-femoral | 0.076 |
| 35522 | BPG w vein axillary-brachial | 0.077 |
| 35521 | BPG w vein axillary-femoral | 0.079 |
| 35665 | BPG w other than vein iliofem | 0.080 |
| 35563 | BPG w vein ilio-iliac | 0.081 |
| 35571 | BPG w vein popliteal-tibial | 0.083 |
| 35510 | BPG w vein carotid-brachial | 0.084 |
| 35671 | BPG w other than vein pop-tib | 0.084 |
| 35663 | BPG w other than vein ilioiliac | 0.084 |
| 35587 | BPG w vein insitu pop-tib | 0.085 |
| 35512 | BPG w vein subclavian-brachial | 0.085 |
| 35666 | BPG w other than vein fem-tib | 0.086 |
| 35661 | BPG w other than vein fem-fem | 0.086 |
| 35531 | BPG w vein aorto-mesenteric | 0.086 |
| 35654 | BPG w other than vein ax-bifem | 0.089 |
| 35518 | BPG w vein axillary-axillary | 0.091 |
| 35646 | BPG w other than vein aortobifem | 0.092 |
| **35585** | **SVS Rec Appropriately places code here** | **0.093** |
| 35525 | BPG w vein brachial-brachial | 0.093 |
| 35636 | BPG w other than vein splenorenal | 0.094 |
| 35511 | BPG w vein subclavian-subclavian | 0.096 |
| 35526 | BPG w vein aorto-subclavian | 0.098 |
| 35621 | BPG w other than vein ax-fem | 0.100 |
| 35647 | BPG w other than vein aortofem | 0.101 |
| 35631 | BPG w other than vein aorto-mes | 0.101 |
| 35626 | BPG w other than vein aorto-sub | 0.104 |
| 35560 | BPG w vein aorto-renal | 0.107 |
| 35650 | BPG w other than vein ax-ax | 0.107 |
| 35536 | BPG w vien splenorenal | 0.120 |
| 35623 | BPG w other than vein ax-pop | 0.120 |

## Comparison of 35585 with CMS-chosen Benchmark Vascular Bypass CPT 35671

In the NPRM, CMS chose CPT 35671 as a reference service when evaluating an orthopedic surgery code (CPT 27447, page 71). We therefore assume that CMS believes 35671 to be a solid benchmark in the relative value scale. The following data exist for 35671, which is "Bypass graft, with other than vein; popliteal-tibial or-peroneal artery".

| **35671 CMS REF Code** | **35671** | **RVW:** | **19.30** |
|---|---|---|---|
| 2nd 5-Yeaf Rev | **Svy Data** | **RUC Std.** | **RVW** |
| ***Pre-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Pre-service eval & positioning | 55 | 0.0224 | 1.23 |
| Pre-service scrub, dress, wait | 15 | 0.0081 | 0.12 |
| **Pre-service total** | | | **1.35** |
| ***Post-service:*** | **Time** | **Intensity** | **(=time x intensity)** |
| Immediate post | 30 | 0.0224 | 0.67 |
| Subsequent visits: | **Visit n** | **E/M RVW** | **(=n x RVW)** |
| ICU 99291 | 0 | 4.00 | 0.00 |
| ICU 99292 | | 2.00 | 0.00 |
| NICU 99296 | | 16.00 | 0.00 |
| NICU 99297 | | 8.00 | 0.00 |
| 99233 | 0 | 1.51 | 0.00 |
| 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 | | 1.73 | 0.00 |
| 99214 | 0 | 1.08 | 0.00 |
| 99213 | 2 | 0.65 | 1.30 |
| 99212 | 1 | 0.43 | 0.43 |
| 99211 | | 0.17 | 0.00 |
| **Post-service total** | | | **6.44** |
| | **Time** | **IWPUT** | **INTRA-RVW** |
| ***Intra-service:*** | 135 | 0.085 | 11.50 |
| ***Total Time:*** | 411 | | |

Following the NPRM, SVS built a work RVU for 35585 based on this CMS-chosen benchmark service. 35585 has 305 minutes of intra-service time, 170 minutes longer than 35671. At the 35671 IWPUT of 0.085, this represents an additional 14.45 RVUs. The two services have equal pre-service time and pre-service work. The post-service work for 35585 is 9.70 RVUs compared to 6.44 RVUs for 35671. Therefore, a work RVU for 35585 may be calculated as 19.30 plus 14.45 plus 3.26 equals 36.99, approximating the SVS recommendation of 39.42, and substantially more than the 2007 CMS work RVU.

Since working with vein conduit (as in 35585) is more complex than working with synthetic conduit (as in 35671) the correct IWPUT to calculate the adjustment should be greater than 0.085. If one uses 0.093 (typical for complex bypass surgery using vein conduit), this calculation results in a value of 39.43, essentially equal to the original SVS recommended value of 39.42.

**Comparison of 35585 to CMS proposal for General Surgery service 44151**

CMS created a major rank order anomaly by valuing 35585 at only 30.00, while at the same time appropriately assigning CPT 44151 removal of colon an RVW of 32.00. 44151 is a 240 minute skin-to-skin operation performed in patients with low to moderate cardiovascular comorbidities. CPT 35585 is a 305 minute operation performed in patients who typically have advanced cardiovascular comorbidities. Total time for 44151 is 683 minutes, while total time for 35585 is 669 minutes. The biggest difference in these two services is the 65 minute increment of complex intra-service time in 35585 above that of 44151. By valuing 44151 at 32.00 RVUs, CMS created a severe rank order anomaly with 35585 at 30.00 RVUs.

**Hospital Visits for 35585**

An important aspect of the RUC process involves expert consensus panel evaluation of the survey data. SVS believes that CMS and the RUC failed to take into account the fact that our expert consensus panel provided a very conservative interpretation of the hospital visit pattern compared to the raw survey data to provide what we felt was a balanced package that still easily justified the recommended work value.

SVS submitted no 99291 critical care visits in this package, when in fact, >60% of survey respondents included one or more 99291 visits. We downshifted these to 99233s. Similarly, we provided a conservative interpretation of the other hospital visits and the office visits compared to the array of survey responses. Even with this conservative visit pattern, a building block analysis easily justifies a work RVU of 39.42. In light of this, the CMS 2007 work RVU of 30.00 is particularly unreasonable. SVS would be happy to review the raw data with the Agency.

**Summary**

For CPT 35585, SVS undertook an iterative process involving a RUC survey, a building block intensity analysis, a comparison with other vascular ssurgery procedures, a comparison with general surgery procedures, all including a conservative pattern of hospital visits. We believe this information, considered in total, fully justifies our recommended work RVU of 39.42. In addition, we believe a global review of the data serves to indicate that survey respondents underestimated the totality of work involved in this service.

In addition, these analyses prove that the 2007 CMS value creates a rank order anomaly within vascular surgery and in comparison to general surgery.

**SVS requests reconsideration of 35585 at a work RVU of 39.42.**