DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 410 and 414

[HCFA-1120-FC]

RIN 0938-AK11

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period makes several changes affecting Medicare Part B payment. The changes include: refinement of resource-based practice expense relative value units (RVUs); the geographic practice cost indices; resource-based malpractice RVUs; critical care RVUs; care plan oversight and physician certification and recertification for home health services; observation care codes; ocular photodynamic therapy and other ophthalmological treatments; electrical bioimpedance; antigen supply, and the implantation of ventricular assist devices. This rule also addresses the comments received on the May 3, 2000 interim final rule on the supplemental survey criteria and makes modifications to the criteria for data submitted in 2001. Based on public comments we are withdrawing our proposals related to the global period for insertion, removal, and replacement of pacemakers and cardioverter

defibrillators and low intensity ultrasound. This final rule also discusses or clarifies the payment policy for incomplete medical direction, pulse oximetry services, outpatient therapy supervision, outpatient therapy caps, HCPCS "G" Codes, and the second 5-year refinement of work RVUs for services furnished beginning January 1, 2002. In addition, we are finalizing the calendar year (CY) 2000 interim physician work RVUs and are issuing interim RVUs for new and revised codes for CY 2001. We are making these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This final rule also announces the CY 2001 Medicare physician fee schedule conversion factor under the Medicare Supplementary Medical Insurance (Part B) program as required by section 1848(d) of the Social Security Act. The 2001 Medicare physician fee schedule conversion factor is $38.2581.

DATES: *Effective date:* This rule is effective January 1, 2001.

Comment date: Comments on interim RVUs for selected procedure codes identified in Addendum C and on interim practice expense RVUs and malpractice RVUs for all codes as shown in Addendum B will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on

[OFR -- Please insert date 60 days after the date of publication in the **Federal Register**].

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address only:

Health Care Financing Administration,

Department of Health and Human Services,

Attention: HCFA-1120-FC,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. If you prefer, you may deliver your written comments by courier (1 original and 3 copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201 or

Room C5-14-03,

7500 Security Boulevard,

Baltimore, MD 21244.

Comments mailed to the two above addresses may be delayed and received too late to be considered. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code

HCFA-1120-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT:

Carolyn Mullen, (410) 786-4589 or Marc Hartstein, (410) 786-4539, (for issues related to resource-based practice expense relative value units).

Kenneth Marsalek, (410) 786-4502 (for issues related to supplemental practice expense survey data).

Bob Ulikowski, (410) 786-5721 (for issues related to resource-based malpractice relative value units and geographic practice cost index changes).

Rick Ensor, (410) 786-5617 (for issues related to care plan oversight and physician certification/recertification).

Cathleen Scally, (410) 786-5714 (for issues related to observation care codes).

Jim Menas, (410) 786-4507 (for issues related to incomplete medical direction and the 5-year review).

Roberta Epps, (410) 786-4503 (for issues related to outpatient/therapy).

Marc Hartstein, (410) 786-4539 (for issues related to the physician fee schedule update, the sustainable growth rate, the conversion factor, and the regulatory impact analysis).

Diane Milstead, (410) 786-3355 (for all other issues).

SUPPLEMENTARY INFORMATION:

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Information on the physician fee schedule can be found on our homepage. You can access this data by using the following directions:

1. Go to the HCFA homepage (http://www.hcfa.gov).
2. Click on "Medicare."
3. Click on "Professional/Technical Information."
4. Select Medicare Payment Systems.
5. Select Physician Fee Schedule.

Or, you can go directly to the Physician Fee Schedule page by typing the following: http://www.hcfa.gov/medicare/pfsmain.htm.

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents. Some of the issues discussed in this preamble affect the payment

policies but do not require changes to the regulations in the Code of Federal Regulations. Information on the regulations impact appears throughout the preamble and is not exclusively in section X.

Table of Contents

In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing

these acronyms and their corresponding terms in alphabetical order below:

AMA	American Medical Association
BBA	Balanced Budget Act of 1997
BBRA	Balanced Budget Refinement Act of 1999
CF	Conversion factor
CFR	Code of Federal Regulations
CPT	[Physicians'] Current Procedural Terminology [4th Edition, 1997, copyrighted by the American Medical Association]
CPEP	Clinical Practice Expert Panel
CRNA	Certified Registered Nurse Anesthetist
E/M	Evaluation and management
EB	Electrical bioimpedance
FMR	Fair market rental
GAF	Geographic adjustment factor
GPCI	Geographic practice cost index
HCFA	Health Care Financing Administration
HCPCS	HCFA Common Procedure Coding System
HHA	Home health agency
HHS	[Department of] Health and Human Services
IDTFs	Independent Diagnostic Testing Facilities
MCM	Medicare Carrier Manual

MedPAC	Medicare Payment Advisory Commission
MEI	Medicare Economic Index
MGMA	Medical Group Management Association
MSA	Metropolitan Statistical Area
NAMCS	National Ambulatory Medical Care Survey
OBRA	Omnibus Budget Reconciliation Act
PC	Professional component
PEAC	Practice Expense Advisory Committee
PPAC	Practicing Physicians Advisory Council
PPS	Prospective payment system
RUC	[AMA's Specialty Society] Relative [Value] Update Committee
RVU	Relative value unit
SGR	Sustainable growth rate
SMS	[AMA's] Socioeconomic Monitoring System
TC	Technical component

Background

Legislative History

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), "Payment for Physicians' Services." This section contains three major elements-- (1) a fee schedule for the payment of physicians' services; (2) a sustainable growth rate for the

rates of increase in Medicare expenditures for physicians' services; and (3) limits on the amounts that nonparticipating physicians can charge beneficiaries. The Act requires that payments under the fee schedule be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense, and malpractice expense.

Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs may not cause total physician fee schedule payments to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs cause expenditures to change by more than $20 million, we must make adjustments to the conversion factors (CFs) to preserve budget neutrality.

B. Published Changes to the Fee Schedule

In the July 2000 proposed rule (65 FR 44177), we listed all of the final rules published through November 1999, relating to the updates to the RVUs and revisions to payment policies under the physician fee schedule. In the July 2000 proposed rule (65 FR 44176), we discussed several issues affecting Medicare payment for physicians' services, including:

Refinement of resource-based practice expense RVUs;

- Changes to the geographic practice cost indices;
- Resource-based malpractice RVUs;
- Critical care RVUs;
- Care plan oversight and physician certification/recertification;
- Observation care codes;
- Ocular photodynamic therapy and other ophthalmological treatments;
- Electrical bioimpedance;
- The global period for insertion, removal, and replacement of pacemakers and cardioverter defibrillators;
- Antigen supply;
- Low intensity ultrasound; and
- The implantation of ventricular assist devices.

This proposed rule also discussed or clarified the payment policy for incomplete medical direction, pulse oximetry services, outpatient therapy supervision, outpatient therapy caps, and the second 5-year refinement of work RVUs for services furnished beginning January 1, 2002.

This final rule affects the regulations set forth at Part 410, Supplementary medical insurance (SMI) benefits and Part 414, Payment for Part B medical and other services.

The information in this final rule updates information in the July 2000 proposed rule and the May 3, 2000 interim final rule with comment period (65 FR 25664) discussed later.

C. Components of the Fee Schedule Payment Amounts

Under the formula set forth in section 1848(b)(1) of the Act, the payment amount for each service paid under the physician fee schedule is the product of three factors—(1) a nationally uniform relative value for the service; (2) a geographic adjustment factor (GAF) for each physician fee schedule area; and (3) a nationally uniform CF for the service. The CF converts the relative values into payment amounts.

For each physician fee schedule service, there are three relative values—(1) an RVU for physician work; (2) an RVU for practice expense; and (3) an RVU for malpractice expense. For each of these components of the fee schedule there is a geographic practice cost index (GPCI) for each fee schedule area. The GPCIs reflect the relative costs of practice expenses, malpractice insurance, and physician work in an area compared to the national average for each component.

The general formula for calculating the Medicare fee schedule amount for a given service in a given fee schedule area can be expressed as:

Payment = [(RVU work x GPCI work) + (RVU practice expense x GPCI practice expense) + (RVU malpractice x GPCI malpractice)] x CF

The CF for CY 2001 appears in section V. The RVUs for CY 2001 are in Addendum B. The GPCIs for CY 2001 can be found in Addendum E.

Section 1848(e) of the Act requires us to develop GAFs for all physician fee schedule areas. The total GAF for a fee schedule area is equal to a weighted average of the individual GPCIs for each of the three components of the service. Thus, the GPCIs reflect the relative practice expenses, malpractice insurance, and physician work in an area compared to the national average. In accordance with the statute, however, the GAF for the physician's work reflects one-quarter of the relative cost of physician's work compared to the national average.

D. Development of the Relative Value Units

1. Work Relative Value Units

Approximately 7,500 codes represent services included in the physician fee schedule. The work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed

the original work RVUs for most codes in a cooperative agreement with us. In constructing the vignettes for the original RVUs, Harvard worked with panels of expert physicians and obtained input from physicians from numerous specialties.

The RVUs for radiology services were based on the American College of Radiology (ACR) relative value scale, which we integrated into the overall physician fee schedule. The RVUs for anesthesia services were based on RVUs from a uniform relative value guide. We established a separate CF for anesthesia services while we continue to recognize time as a factor in determining payment for these services. As a result, there is a separate payment system for anesthesia services.

2. Practice Expense and Malpractice Expense Relative Value Units

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. No. 103-432), enacted on October 31, 1994, required us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician service. As amended by the Balanced Budget Act of 1997 (BBA) (Pub. L. No. 105-33), section 1848(c) required the new payment methodology to be phased in over 4 years, effective for services furnished in 1999, with resource-based practice expense RVUs becoming fully effective in 2002. The BBA also requires us to implement

resource-based malpractice RVUs for services furnished beginning in 2000.

II. Specific Proposals for Calendar Year 2001

In response to the publication of the July 2000 proposed rule, we received approximately 600 comments. We received comments from individual physicians, health care workers, and professional associations and societies. The majority of comments addressed the proposals related to practice expense, observation care, antigen supplies, care plan oversight, and certification and recertification of home health services.

The proposed rule discussed policies that affected the number of RVUs on which payment for certain services would be based. Certain changes implemented through this final rule are subject to the $20 million limitation on annual adjustments contained in section 1848(c)(2)(B)(ii)(II) of the Act.

After reviewing the comments and determining the policies we would implement, we have estimated the costs and savings of these policies, and added those costs and savings to the estimated costs associated with any other changes in RVUs for 2001. We discuss in detail the effects of these changes in the Regulatory Impact Analysis (section X).

For the convenience of the reader, the headings for the policy issues correspond to the headings used in the July 2000

proposed rule. More detailed background information for each issue can be found in the May 2000 interim final rule with comment period and the July 2000 proposed rule.

A. Resource-Based Practice Expense Relative Value Units

1. Resource-Based Practice Expense Legislation

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. No. 103-432), enacted on October 31, 1994, required us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician's services beginning in 1998. In developing the methodology, we were to consider the staff, equipment, and supplies used in furnishing medical and surgical services in various settings. The legislation specifically required that, in implementing the new system of practice expense RVUs, we must apply the same budget-neutrality provisions that we apply to other adjustments under the physician fee schedule.

Section 4505(a) of the BBA delayed the effective date of the resource-based practice expense RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based practice expense RVUs to resource-based RVUs. The practice expense RVUs for CY 1999 were the product of 75 percent of charge-based RVUs and 25 percent of the resource-based RVUs. For CY 2000, the RVUs

were 50 percent charge-based and 50 percent resource-based. For CY 2001, the RVUs are 25 percent charge-based and 75 percent resource-based. After CY 2001, the RVUs will be totally resource-based.

Section 4505(e) of the BBA provided that, in 1998, the practice expense RVUs would be adjusted for certain services in anticipation of the implementation of resource-based practice expenses beginning in 1999. As a result, we increased practice expense RVUs for office visits. For other services in which practice expense RVUs exceeded 110 percent of the work RVUs and were furnished less than 75 percent of the time in an office setting, we reduced the 1998 practice expense RVUs to a number equal to 110 percent of the work RVUs. This limitation did not apply to services that had proposed resource-based practice expense RVUs that increased from their 1997 practice expense RVUs as reflected in the June 18, 1997 proposed rule (62 FR 33196). The services affected, and the final RVUs for 1998, were published in the October 1997 final rule (62 FR 59103).

The most recent legislation affecting resource-based practice expense was included in the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. No. 106-113). Section 212 of the BBRA stated that we must establish a process under which we accept and use, to the maximum extent practicable and consistent

with sound data practices, data collected or developed by entities and organizations. These data would supplement the data we normally collect in determining the practice expense component of the physician fee schedule for payments in CY 2001 and CY 2002.

2. Current Methodology for Computing Practice Expense Relative Value Unit System

Effective with services on or after January 1, 1999, we established a new methodology for computing resource-based practice expense RVUs that used the two significant sources of actual practice expense data we have available: the Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. The methodology is based on an assumption that current aggregate specialty practice costs are a reasonable way to establish initial estimates of relative resource costs of physicians' services across specialties. It then allocates these aggregate specialty practice costs to specific procedures and, thus, can be considered as a "top-down" approach. The methodology can be summarized as follows:

a. Practice Expense Cost Pools.

We used actual practice expense data by specialty, derived from the 1995 through 1997 SMS survey data, to create six cost pools--administrative labor, clinical labor, medical supplies,

medical equipment, office supplies, and all other expenses. There were three steps in the creation of the cost pools.

• Step (1) We used the AMA's SMS survey of actual cost data to determine practice expenses per hour by cost category. The practice expenses per hour for each physician respondent's practice was calculated as the practice expenses for the practice divided by the total number of hours spent in patient care activities. The practice expenses per hour for the specialty were an average of the practice expenses per hour for the respondent physicians in that specialty. In addition, for the CY 2000 physician fee schedule, we used data from a survey submitted by the Society of Thoracic Surgeons (STS) in calculating thoracic and cardiac surgery's practice expense per hour. (See the November 1999 final rule (64 FR 59391) for additional information concerning acceptance of this data.)

• Step (2) We determined the total number of physician hours (by specialty) spent treating Medicare patients. This was calculated from physician time data for each procedure code and from Medicare claims data.

• Step (3) We calculated the practice expense pools by specialty and by cost category by multiplying the specialty practice expenses per hour for each category by the total physician hours.

For services with work RVUs equal to zero (including the technical component (TC) of services with a TC and professional component (PC)), we created a separate practice expense pool, using the average clinical staff time from the CPEP data (since these codes by definition do not have physician time), and the "all physicians" practice expense per hour.

b. Cost Allocation Methodology.

For each specialty, we separated the six practice expense pools into two groups and used a different allocation basis for each group.

(i) Direct Costs

For direct costs (including clinical labor, medical supplies, and medical equipment), we used the CPEP data as the allocation basis. The CPEP data for clinical labor, medical supplies, and medical equipment were used to allocate the clinical labor, medical supplies, and medical equipment cost pools, respectively.

For the separate practice expense pool for services with work RVUs equal to zero, we used 1998 practice expense RVUs to allocate the direct cost pools (clinical labor, medical supplies, and medical equipment cost pools) as an interim measure. Also, for all radiology services that are assigned work RVUs, we used the 1998 practice expense relative values for

radiology services as an interim measure to allocate the direct practice expense cost pool for radiology. For all other specialties that perform radiology services, we used the CPEP data for radiology services in the allocation of that specialty's direct practice expense cost pools.

(ii) Indirect Costs

To allocate the cost pools for indirect costs, including administrative labor, office expenses, and all other expenses, we used the total direct costs, as described above, in combination with the physician fee schedule work RVUs. We converted the work RVUs to dollars using the Medicare CF (expressed in 1995 dollars for consistency with the SMS survey years).

The SMS pool was divided by the CPEP pool for each specialty to produce a scaling factor that was applied to the CPEP direct cost inputs. This was intended to match costs counted as practice expenses in the SMS survey with items counted as practice expenses in the CPEP process. When the specialty-specific scaling factor exceeds the average scaling factor by more than three standard deviations, we used the average scaling factor. (See the November 1999 final rule (64 FR 59390) for further discussion of this issue).

For procedures performed by more than one specialty, the final procedure code allocation was a weighted average of allocations for the specialties that perform the procedure, with the weights being the frequency with which each specialty performs the procedure on Medicare patients.

c. Other Methodological Issues.

(i) Global Practice Expense Relative Value Units

For services with the PC and TC paid under the physician fee schedule, the global practice expense RVUs were set equal to the sum of the PC and TC.

(ii) Practice Expenses per Hour Adjustments and Specialty Crosswalks

Since many specialties identified in our claims data did not correspond exactly to the specialties included in the practice expense tables from the SMS survey data, it was necessary to crosswalk these specialties to the most appropriate SMS specialty category. We also made the following adjustments to the practice expense per hour data. (For the rationale for these adjustments to the practice expense per hour see the November 1998 final rule (63 FR 58841).)

- We set the medical materials and supplies practice expenses per hour for the specialty of "oncology" equal to the

"all physician" medical materials and supplies practice expenses per hour.

- We based the administrative payroll, office, and other practice expenses per hour for the specialties of "physical therapy" and "occupational therapy" on data used to develop the salary equivalency guidelines for these specialties. We set the remaining practice expense per hour categories equal to the "all physician" practice expenses per hour from the SMS survey data.
- Due to uncertainty concerning the appropriate crosswalk and time data for the nonphysician specialty "audiologist," we derived the resource-based practice expense RVUs for codes performed by audiologists from the practice expenses per hour of the other specialties that perform these codes.
- For the specialty of "emergency medicine," we used the "all physician" practice expense per hour to create practice expense cost pools for the categories "clerical payroll" and "other expenses."
- For the specialty of "podiatry," we used the "all physician" practice expense per hour to create the practice expense pool.
- For the specialty of "pathology," we removed the supervision and autopsy hours reimbursed through Part A of the Medicare program from the practice expense per hour calculation.

• For the specialty "maxillofacial prosthetics," we used the "all physician" practice expense per hour to create practice expense cost pools and, as an interim measure, allocated these pools using the 1998 practice expense RVUs.

• We split the practice expenses per hour for the specialty "radiology" into "radiation oncology" and "radiology other than radiation oncology" and used this split practice expense per hour to create practice expense cost pools for these specialties.

(iii) Time Associated with the Work RVUs

The time data resulting from the refinement of the work RVUs have been, on average, 25 percent greater than the time data obtained by the Harvard study for the same services. We increased the Harvard research team's time data to ensure consistency between these data sources.

For services with no assigned physician time (such as, dialysis, physical therapy, psychology, and many radiology and other diagnostic services), we calculated estimated total physician time based on work RVUs, maximum clinical staff time for each service as shown in the CPEP data, or the judgment of our clinical staff.

We calculated the time for CPT codes 00100 through 01996, using the base and time units from the anesthesia fee schedule and the Medicare allowed claims data.

3. Refinement

a. Background

Section 4505(d)(1)(C) of the BBA required us to develop a refinement process to be used during each of the 4 years of the transition period. We did not propose a specific long-term refinement process in the June 1998 proposed rule (63 FR 30835). Rather, we set out the parameters for an acceptable refinement process for practice expense RVUs and solicited comments on our proposal. We received a large variety of comments about broad methodology issues, practice expense per hour data, and detailed code level data. We made some adjustments to our proposal when we were convinced an adjustment was appropriate. We also indicated that we would consider other comments for possible refinement and that the values of all codes would be considered interim for 1999 and for future years during the transition period.

We outlined in the November 1998 final rule (63 FR 58832) the steps we were undertaking as part of the initial refinement process. These steps included--

- Establishment of a mechanism to receive independent advice for dealing with broad practice expense RVU technical and methodological issues;
- Evaluation of any additional recommendations from the General Accounting Office, the Medicare Payment Advisory Commission (MedPAC), and the Practicing Physicians Advisory Council (PPAC); and
- Consultation with physician groups and other groups concerning these issues.

We also discussed a proposal submitted by the AMA's Specialty Society Relative Value Update Committee (RUC) for development of a new advisory committee, the Practice Expense Advisory Committee (PEAC), to review comments and recommendations on the code-specific CPEP data during the refinement period. In addition, we solicited comments and suggestions about our practice expense methodology from organizations that have a broad range of interests and expertise in practice expense and survey issues.

In the July 22, 1999 proposed rule, the November 1999 final rule, and the July 2000 proposed rule, we provided further information on refinement activities underway, including the recommendations from the PEAC and the support contract that we awarded to focus on methodologic issues. The following is an

update on activities with respect to these initiatives, as well as the status of refinement with respect to other areas of concern such as the SMS data and CPEP inputs.

b. SMS Data

We have received many comments on both our 1998 and 1999 proposed and final rules from a number of medical specialty societies expressing concerns regarding the accuracy of the SMS data. Some commenters stated their belief that the sample size for their specialty was not large enough to yield reliable data. Other specialties not represented in the SMS survey objected that the crosswalk used for their practice expense per hour was not appropriate and requested that their own data be used instead. Commenters also raised questions about whether the direct patient care hours for their specialty were overstated by the SMS to the specialty's disadvantage.

We consider dealing with these issues to be one of the major priorities of the refinement effort. Therefore, we have undertaken the following activities:

(i) Interim Final Rule on Supplemental Practice Expense Survey Data

On May 3, 2000, we published an interim final rule (65 FR 25664) that set forth the criteria for physician and non-physician specialty groups to submit supplemental practice

expense survey data for use in determining payments under the physician fee schedule. Section 212 of the BBRA amended section 1848(c) of the Act to require us to establish a process under which we will accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations. These data will supplement the data we normally collect in determining the practice expense component of the physician fee schedule for payments in CY 2001 and CY 2002.

To obtain data that could be used in computing practice expense RVUs beginning January 1, 2001, we published the criteria in the May 2000 interim final rule (65 FR 25666) that we will apply to supplemental survey data submitted to us by August 1, 2000. We also provided a 60-day period for submission of comments on the criteria that we will consider for survey data submitted between August 2, 2000 and August 1, 2001 for use in computing the practice expense RVUs for the CY 2002 physician fee schedule. (See the May 2000 interim final rule for further information on the criteria and process). We are responding to comments received on the interim final rule in this rule, and are publishing the criteria to be used for 2001 submission.

The following are specific criteria and discussion in the May 2000 interim final rule.

· Physician groups must draw their sample from the AMA Physician Masterfile to ensure a nationally representative sample that includes both members and non-members of a physician specialty group.

· Physician groups must arrange for the AMA to send the sample directly to their survey contractor to ensure confidentiality of the sample; that is, to ensure comparability in the methods and data collected, specialties must not know the names of the specific individuals in the sample.

· Non-physician specialties not included in the AMA's SMS must develop a method to draw a nationally representative sample of members and non-members. At a minimum, these groups must include former members in their survey sample. The sample must be drawn by the non-physician group's survey contractor, or another independent party, in a way that ensures the confidentiality of the sample; that is, to ensure comparability in the methods and data collected, specialties must not know the names of the specific individuals in the sample.

· A group (or its contractors) must conduct the survey based on the SMS survey instruments and protocols, including administration and follow-up efforts, and definitions of practice expense and hours in patient care. · In addition, any cover letters or other information furnished to survey sample

participants must be comparable to such information previously supplied by the SMS contractor to its sample participants.

· A group must use a contractor that has experience with the SMS or a survey firm with experience successfully conducting national multi-specialty surveys of physicians using nationally representative random samples.

· A group must submit raw survey data to us, including all complete and incomplete survey responses as well as any cover letters and instructions that accompanied the survey, by August 1, 2000 for data analysis and editing to ensure consistency. All personal identifiers in the raw data must be eliminated. (Send data to Health Care Financing Administration, Department of Health and Human Services, Attn: Kenneth Marsalek, C4-03-06, 7500 Security Boulevard, Baltimore, MD 21244-8013.)

· Raw survey data submitted to us between August 2, 2000 and August 1, 2001 will be considered for use in computing practice expense RVUs for CY 2002.

· The physician practice expense data from surveys that we use in our code-level practice expense calculations are the practice expenses per physician hour in the six practice expense categories--clinical labor, medical supplies, medical equipment, administrative labor, office overhead, and other. Supplemental survey data must include data for these categories. Ideally, we

would like to calculate practice expense values with precision; however, we recognize that we must achieve a balance. Conducting surveys is expensive, and there is a tension between achieving large sample sizes, which increases precision, and smaller ones, which conserves costs.

In addition, in the May 2000 interim final rule (65 FR 25666) we indicated that we believed an achievable level of precision is a coefficient of variation, that is, the ratio of the standard error of the mean to the mean expressed as a percent, not greater than 10 percent, for overall practice expenses or practice expenses per hour. For existing surveys the standard deviation is frequently the same magnitude as the mean. If the standard deviation equals the mean, then a usable sample size of 100 will yield a coefficient of variation of 10 percent. For small, homogeneous subspecialties, the variations in practice expenses may be lower because a smaller sample size achieves this level of precision. Other ways of expressing precision (for example, 95 percent confidence intervals) are also acceptable if they are approximately equivalent to a coefficient of variation of 10 percent or better. We indicated that will consider surveys for which the precision of the practice expenses are equal to or better than this level of precision and that meet the other survey criteria. Also, we indicated that we

will require documentation regarding how the practice expenses were calculated and we will verify the calculations. We have the statutory authority, however, to determine the final practice expense RVUs.

We also indicated that, since the physician fee schedule is a national fee schedule, we would require that the survey be representative of the target population of physicians nationwide. We can presume national representativeness if a random sample is drawn from a complete nationwide listing of the physician specialty or subspecialty and the response rate, the percent of usable responses received from the sample, is high, for example, 80 to 90 percent. If any of these conditions (random sample, complete nationwide listing, and high response rate) are not achieved, then the potential impacts of the deviations upon national representativeness must be explored and documented. For example, if the response rate is low, then justification must be furnished to demonstrate that the responders are not significantly different from non-responders with regard to factors affecting practice expense. Differential weighting of subsamples may improve the representativeness. Minor deviations from national representativeness may be acceptable.

Comments on Criteria for Submitting Supplemental Practice Expense Data

We received comments from 17 specialty groups concerning the criteria for the acceptance of supplemental data. While many of these comments contained positive feedback on aspects of our interim final rule, they all contained statements of opposition to specific requirements and/or suggestions for improving the process. Outlined below are the comments from specialty groups and our responses concerning the requirements for supplemental survey data.

Required Sampling from the AMA's Physician Masterfile

Comment: Four groups stated that the requirement for survey respondents to be drawn solely from the AMA Physician Masterfile is inappropriate for the specialties of radiology and radiation oncology. They believe that hospital-based radiologists and radiation oncologists do not encounter the same practice expenses for staff and supplies as those radiologists and radiation oncologists working in freestanding centers. According to the groups, radiologists and radiation oncologists working in a freestanding center encounter capital intensive TC services not incurred by hospital-based physicians and, often, these TC component costs are borne by non-physician entities not included in the Physician Masterfile. The groups also believe

that the small number of radiologists and radiation oncologists who own and operate a freestanding center will not be represented in a sample from the Physician Masterfile. The groups suggest that we work with the professional community to develop a list of freestanding radiation centers from which we could extract a geographically diverse sample. Alternatively, the groups suggest that, because of potential low response rates, we include all radiation practices in the survey sample and use the data for those physicians not working at freestanding centers only in the calculation of PC services.

One group expressed concern that by sampling from the AMA Physician Masterfile, a substantial number of emergency medicine practices are overlooked. The small number of physician practice owners leads to a strong possibility that these owners will not be selected in the random sample. They suggest that we permit an additional sample of large emergency medicine practice groups to supplement the current survey.

Response: The Physician Masterfile is the most extensive list of physicians in the United States, and, therefore, we believe it is the most appropriate list from which to develop a random sample of physicians within a specialty. Currently, we are not aware of a complete list of radiation and radiation oncology practices or emergency medicine practice groups that

exists that is more comprehensive than the Physician Masterfile with the information necessary to extract a representative random sample. If such a list were to exist or be developed in the future, we would consider the appropriateness and potential uses for sampling. We would welcome information from physician and other organizations on specific data sources from which representative samples of physicians could be selected, if there is concern that the AMA Masterfile is not a comprehensive list for the specialty.

Comment: One group commented that the AMA Physician Masterfile may contain "self-designated" dermatologists who do not meet the criteria for "qualified" dermatologists. They defined "qualified" dermatologists as board certified dermatologists, associates and affiliate members such as osteopathic dermatologists, physicians conducting research in dermatology, and practicing dermatologists certified by a foreign board but now practicing in the United States. According to the group, other, "self-designated" dermatologists should not be included in the sample for dermatology because their practice expense data could be unrepresentative and potentially damaging to the practice expense RVUs for dermatology.

Response: Self-designation of specialty is not unique to dermatologists. In the Physician Masterfile, all specialties are based on self-designation. The SMS survey deals with the issue of self-designation by asking respondents if their specialty designation is representative of the specialty practice from which they gain the majority of their medical income. It is important to note that if any physician who is self-designated as a dermatologist furnishes dermatological services to Medicare patients, it is appropriate for this physician to be included in the sample because this physician receives income for dermatological services.

Comment: Three groups suggested that the requirement to sample from the Physician Masterfile may not be reasonable, as it serves only to limit specialties' ability to present alternative data to us. They noted that the requirement to sample from the Physician Masterfile is based on the assumption that physicians outside of the specialty group have different costs than members of the group. One commenter maintained that the substantial variance in practice expenses within members' practices makes it unlikely that non-members' practices would extend this variance. In addition, one group suggested that societies representing a smaller proportion of specialty practitioners should be allowed to explore options for

addressing potential bias beyond sampling from the Physician Masterfile. According to the group, nonmembers of a specialty society are unlikely to respond to what they consider a time-consuming and intrusive survey about sensitive financial issues.

Response: We believe that the commenter is arguing that is should be sufficient to draw a sample from the members of a specialty society because there is unlikely to be a difference in practice expense per hour between members and nonmembers of a specialty society. Our goal in collecting practice expense data is to create practice expense values that reflect the costs of both members and non-members of a specialty society. We cannot assume that the average practice expenses of members and non-members of a specialty group are comparable without data to support this finding. The AMA Physician Masterfile is the most comprehensive list of physicians practicing in the United States. A specialty society's members are likely to include only a portion of the physicians practicing in that specialty. Thus, we believe that it is likely that a random sample selected from the AMA Physician Masterfile is going to be more representative of a specialty than a sample drawn from a specialty society's membership list. For this reason, we are

maintaining the requirement that the sample of physicians must be drawn from the AMA Physician Masterfile.

Required Use of SMS Survey Instruments and Protocol

Comment: One group expressed concern that the SMS survey does not account for care hours induced by the Emergency Treatment and Labor Act (EMTALA) in the patient care hours question, thereby overstating the hours and understating the practice expense costs. They recommend that a question be added to the SMS that asks respondents about the patient care hours they spend in an average week providing EMTALA-induced care. Each specialty's average amount of EMTALA-induced care should then be deducted from the total hours spent in patient care. The commenter recognized that this is a long-term recommendation and wished to work on an interim solution with us.

Response: We understand the group's concerns and have contracted with The Lewin Group to provide recommendations on both the modification of future surveys to account for EMTALA-induced patient care hours and the use of these data to adjust practice expense values. We have also made specific comments to the AMA requesting that this issue be addressed in any future work they may do with regard to collecting survey data. In the interim, we have made an adjustment to the practice expense per hour for emergency medicine to address this issue. We have no

reason to believe emergency medicine is being disadvantaged in the interim as a result of this adjustment. We will consider The Lewin Group's recommendations.

Comment: Six groups questioned the adequacy of the SMS survey for the purpose of accurately assessing a particular specialty's practice expenses. For example, one group believes that additional questions are needed to account for cardiology TC questions. They recommend that we revise the criteria for supplemental surveys to allow for the collection of additional data through specialty-specific questions.

Response: We consider the SMS survey to be adequate for the purpose of accurately assessing practice expenses. However, we agree that additional clarification and examples tailored to specific specialties may improve the accuracy of the data collected. Although we do not want specialties to change the basic structure of the SMS practice expense module, we have not precluded any groups from collecting additional data specific to the specialty in their supplemental surveys.

Comment: One group suggested that we adopt the AMA's practice level Practice Expense survey in place of the SMS and revise the criteria for supplemental survey data accordingly. They also suggested that our references to the SMS survey may be misunderstood by specialty groups referencing the AMA's practice

level survey instrument, and that we must clarify this distinction. Two groups recommended that the specialty groups should collect practice level data, rather than individual physician estimates. One group also suggested that a practice level survey should be developed to more appropriately capture the practice expenses.

Response: The AMA has fielded the practice expense level survey with minimal success. At this time, we understand that the AMA does not plan to continue with the practice expense level survey. We are currently using the physician level SMS as the basis for supplemental surveys, and will continue to use this survey to maintain consistency with our existing data. We cannot use the AMA's practice level survey, or any other survey, until it has been evaluated to determine if the survey data can be incorporated into our practice expense methodology. In addition, we would have to determine if it is possible to reconcile the outcomes of the physician level and practice level surveys. We have asked The Lewin Group to review the AMA's practice level survey to determine how the data collected could be used to calculate practice expenses per hour values.

Comment: Four groups requested that specialty groups be allowed to conduct the supplemental surveys by mail with follow-

up phone interviews. The groups believe this will reduce the cost of administering a survey.

Response: As explained previously, to help obtain comparable data, we believe supplemental surveys should follow the SMS methodology.

Comment: Two groups expressed concern that requiring cover letters and other information furnished to survey participants to be comparable to those supplied by the SMS contractor will hamper response rates. They believe specialty groups should be able to provide correspondence that explains the importance of the data for the benefit of the specialty without our "censorship."

Response: Although specialty-specific correspondence may increase response rates, it could potentially introduce bias into the practice expense data. We believe that it is essential to obtain unbiased data.

Comment: One group suggested we use the tax form 1120 as a foundation for validating practice expense data. They suggested that independent accountants could be used to compare the practice expense data submitted to the actual expenses on the tax form.

Response: The Lewin Group has considered this recommendation and, after discussions with the AMA and numerous

physician specialty groups, has determined that practitioners may not respond to the survey if they believe their data may be audited. However, The Lewin Group does believe that a closer link between the survey worksheet and a practice's tax forms may improve the accuracy of the data. We may consider this as a longer-term refinement issue.

Comment: One group recommended that we develop a workable alternative to the SMS survey. They noted the indefinite suspension of the SMS survey, and the lack of evidence that the SMS is the best source of obtaining practice expense data at the specialty level as reasons for their suggestion. They suggested we develop a set of core questions and standard definitions to be incorporated in each specialty's survey. If we create an alternative to the SMS, They requested that we take into account the extensive amount of time involved in designing and conducting an effective practice expense survey.

Response: The Lewin Group has already worked with specialty groups to modify the SMS survey for administration as a supplemental survey. The Lewin Group will continue to help specialty groups field supplemental surveys.

Comment: One group requested that we keep the specialty groups updated on the status of the SMS survey and any potential solutions or alternate plans we develop to account for the

absence of new SMS data. They stated that keeping the specialties current would allow them to anticipate extra spending on survey projects.

Response: The best source of current information on the status of the SMS survey would, of course, be from the AMA. Any plans on our part would be included in information provided as part of future revisions to practice expenses.

Comments on the Response Rate

Comment: Seven groups objected to the response rate of 80 to 90 percent mentioned as a criterion for the presumed national representativeness of a sample. The groups stated that the SMS has never achieved a response rate this high, and that specialty groups should not be expected to achieve a response rate higher than that achieved by the SMS. Two groups suggested an acceptable response rate of 30 to 40 percent, and the American Academy of Ophthalmology (AAO) suggested an acceptable response rate of 30 percent. The ACR requested an acceptable response rate of no higher than 65 percent. Three groups objected to our response rate but did not suggest an alternative rate.

Response: The 80 to 90 percent response rate was presented as a rate at which we can presume that the sample is nationally representative, but not as an absolute requirement for the acceptance of data. As we stated in the May 3, 2000 interim

final rule (65 FR 25666), we are attempting to be as reasonable as possible. However, surveys with a response rate lower than 80 percent cannot be assumed to be nationally representative, and, for us to accept these data, a specialty group must demonstrate that the survey respondents are not significantly different from non-respondents. In addition, based on our review of the supplemental surveys submitted, we are modifying our criteria concerning an acceptable level of precision for surveys. We now believe a reasonable level of precision for surveys to be used for supplementing current data is a 90-percent confidence interval with a range of plus or minus 10 percent of the mean (that is, 1.645 times the standard error of the mean, divided by the mean, should be equal to or less than 10 percent of the mean).

Comment: One group commented that it is highly unlikely that small specialties will be able to achieve the coefficient of variation of less than 10 percent for overall practice expenses or practice expenses per hour that we require for the acceptance of supplemental data. They note that the original SMS survey did not achieve this threshold for many small specialties and, therefore, question the application of the requirement to supplemental surveys.

Response: In developing the resource-based practice expense RVUs, we consulted widely with physician groups, researchers, and others to identify possible data sources. Nearly all commenters agreed that the SMS data, while not specifically designed for the purpose of establishing practice expense RVUs, was the best available data for this purpose. We believe our criteria, as discussed above, help assure that any data used to supplement the SMS data are statistically valid and representative. Further, we believe these criteria are reasonable and achievable. For example, a specialty society for thoracic surgeons submitted supplemental data that we incorporated last year. These data from the STS achieve our statistical criteria for supplemental surveys. We also note that the 90-percent confidence interval requirement seems very reasonable in that, in general, a 95-percent confidence interval is a more typical statistical standard value.

Comment: One group requested that we provide the specialty groups "with a comprehensive definition of 'complete' and 'incomplete' data in addition to an explanation of the extent to which incomplete data will be excluded or utilized in practice expense calculations." At a minimum, the group requested indicators for required and non-required data fields on the survey instrument.

Response: The required data fields for the survey instrument are available from our contractor, The Lewin Group, and from the protocols and guidelines we have created for the supplemental surveys. The original SMS survey data obtained from the AMA was accepted only for surveys with complete practice expense and patient care per-hour information. We will continue to use these criteria for the acceptance of data. (A copy of the guidelines and procedures may be obtained by contracting Lane Koeing at The Lewin Group at (703) 269-5659.)

Data Adjustment

Comment: Three groups commented on our use of the 1995 through 1997 specialty practice expense per-hour data from the SMS and our deflation of supplemental survey data to 1995 practice costs. The groups stated that we should use the most current data available for all specialties rather than earlier data of questionable relevance.

Response: We indicated in the July 2000 proposed rule (65 FR 44181) that, based on a recommendation by The Lewin Group, we have incorporated the 1998 SMS data into our practice expense per-hour calculations and that we are now basing our practice expense per-hour calculations on a 4-year average. Regarding the deflation of the practice costs to 1995, as long as the same deflator is used across specialties, the particular year to

which the specialties are deflated is insignificant. The base year of 1995 was chosen to be consistent with the data we have already.

Comment: One group commented on our decision to weight average the supplemental data with the existing SMS data already being used. According to the group, this decision is flawed because it erroneously assumes that the SMS data currently in use is correct. In addition, they believe that the SMS sample size for emergency physicians has been too small to provide valid data for the calculation of practice expenses. The group suggested that it is inappropriate for us to weight average data from this unrepresentative sample with supplemental survey data for emergency physicians.

Response: The SMS data is the best data currently available for the calculation of practice expenses. As refinements of the practice expense methodology are identified and included, we will extrapolate and apply them to past SMS data to the extent possible. Weight averaging the supplemental survey data with the existing SMS data would be used to increase the sample size. We also established the criteria for supplemental surveys in the May 3, 2000 interim final rule (65 FR 25666) as a guideline for those specialties seeking to increase their sample size.

Short Time Frame for Data Submission

Comment: Three groups expressed concern with the short time frame we have provided for specialty groups to develop the survey methodologies, find a contractor, and provide the data for computation of RVUs.

Response: Section 212 of the BBRA required that we establish, through regulation, a process for any organization to collect and submit supplemental survey data for use in establishing payments for the calendar years 2001 and 2002 physician fee schedules. Thus, the amount of work required to be accomplished in a short time was largely due to the requirements of the statute itself.

Cost Burden of the Supplemental Surveys

Comment: Two groups commented that we should share the cost burden for the supplemental surveys. According to the groups, the supplemental surveys will be filling in the data gap left by the SMS and, therefore, we should subsidize the cost of completing the surveys. In addition, one group commented that the efforts needed to meet the supplemental survey requirements may be prohibitively costly for many specialties without subsidization from us. One group also commented that we should take into account the AMA’s problems with the expense of administering the SMS before fully adopting the survey protocol.

Specifically, they suggested that we look for less costly, and more cost-effective, ways of validating the data than telephone interviews.

Response: We have no funding for supplemental surveys, and we are not currently considering such approaches. As we have previously explained, we believe the SMS data are currently the best available source of practice cost information. We believe there are significant, methodological advantages to obtaining practice cost information through multi-specialty surveys such as SMS, rather than through surveys of more limited groups of specialties. The supplemental survey process allows specialties the option to provide additional information.

Comment: Two groups suggested that we should eliminate some of the criteria for the acceptance of outside survey data if a specialty can demonstrate that the collected data are valid practice expense data for the specialty. According to one commenter, some specialty groups may have valid data that does not exactly meet the criteria we outlined, but nevertheless could be a valuable data source.

Response: In the May 3, 2000 interim final rule (65 FR 25666), we presented the criteria for specialty societies seeking to collect new practice expense data through supplemental surveys. The process established by these

criteria, as amended by this final rule, should be followed by specialty societies to collect future supplemental practice expense data.

Survey Contractor Requirements

Comment: One group expressed concern about contracting for survey research. According to the group, many specialties have staff capable of analyzing the survey data. Requiring specialties to contract for the surveys could eliminate certain subspecialties from administering a supplemental survey due to cost burden.

Response: We recognize the cost burden of contracting for the supplemental survey administration; however, to ensure the integrity of the practice expense data, we are requiring that a disinterested third party administer supplemental surveys.

Comment: One group questioned our requirement for specialties to use a survey contractor with experience in conducting national multi-specialty surveys of physicians using random samples. They believe that a contractor with experience surveying health care professionals and using random sample techniques should be sufficient.

Response: We believe our initial requirements represent a preferred way to collect valid and reliable data. We will, however, consider survey contractors with experience surveying

health care professionals, collecting financial information, and using random samples.

Comment: Two groups are concerned with our requirement for raw survey data to be submitted to us. One group believes that we should outsource the analysis of the survey responses. The other group opposes the submission of raw data to us because they believe physicians will be unlikely to respond to sensitive financial questions if they are informed that their individual responses will be sent directly to the government.

Response: The raw survey data have been submitted to The Lewin Group, and they have provided us with only aggregate practice expense values.

HCFA's Use of the Supplemental Survey Data

Comment: One group expressed concern about our use of the supplemental survey data. Before administering an expensive survey, they want assurance from us that the supplemental data will be used. Alternatively, the group believes we should conduct a survey across all specialties. They commented that we must adopt one of these options to remove flawed data that does not account for the unique practice expenses related to emergency medicine.

Response: The criteria for the consideration of supplemental survey data are described in this final rule. We

anticipate incorporating data that meet these criteria in the practice expense methodology.

Comment: One group requested that we provide specialty groups with the criteria for determining if data supplied between August 2, 2000 and August 1, 2001 is usable. We state in the interim final rule that submitted data will be considered, but we do not state whether the criteria for acceptance will be the same as the criteria for data supplied by August 1, 2000.

Response: The criteria for accepting supplemental survey data were presented in the May 3, 2000 interim final rule. These criteria were subject to public comment, and any modification we have made to these criteria, as a result of the comments, are part of this final rule.

Result of Evaluation of Comments

The criteria published May 3, 2000 will be used for surveys submitted in 2001 with the following modifications.

· We had proposed that specialty groups use a contractor that has experience with the SMS or a survey firm with experience successfully conducting national multi-specialty surveys of physicians using nationally representative random samples. We have modified the criteria to provide for using a contractor

that has experience surveying health care professionals, collecting financial information and using random samples.

· In addition, based on our review of the supplemental surveys submitted, we are modifying our criteria concerning an acceptable level of precision for surveys. We now believe a reasonable level of precision for surveys to be used for supplementing current data is a 90 percent confidence interval with a range of plus or minus 10 percent of the mean; (that is, 1.645 times the standard error of the mean, divided by the mean, should be equal to or less than 10 percent of the mean).

With respect to response rates, we are concerned about the low response rates received from supplemental surveys submitted to us in 2000. While we acknowledge that the timing of the surveys (that is, short-field time and time of year) contributed to the low response rates, we believe that groups will have more time to conduct surveys and, thus, are likely to obtain better response rates in future surveys. While we continue to believe that it is impossible and impractical to set rigid cutoffs, we are expecting higher response rates than were achieved in the supplemental surveys submitted to us in 2000. We would like to see detailed analyses that indicate the sample is representative of the population. While The Lewin Group was able to perform some limited analyses of response bias for the supplemental

surveys received in 2000, we expect that these supplemental surveys received in 2001 will provide detailed analyses with respect to possible response bias on factors that could affect practice expenses. Such analyses should consider variables such as specialty society membership, years in practice, board certification, gender, geographic distribution of respondents, and practice arrangements (for example, solo practitioners or large group practices). We will not consider supplemental data in the practice expense methodology unless we receive detailed analyses that give us confidence that survey respondents are representative of the profession on items that affect practice expense. In addition, the data must appear reasonable and consistent with other data used to determine practice expense RVUs.

Submission of Supplemental Surveys

In response to the May 3, 2000 interim final rule, three organizations submitted supplemental survey data for consideration. One survey was submitted by the American Physical Therapy Association (APTA), and a joint survey was submitted by the American Association of Vascular Surgery (AAVS) and the Society for Vascular Surgery (SVS). Our contractor, The Lewin Group, has evaluated the data submitted by each organization and recommended that we use these data. The full

recommendation and discussion will be made available on the HCFA website. We have decided to use the data submitted by the AAVS and SVS to supplement the information we are currently using. However, we have decided not to use the data submitted by the APTA. The revised practice expense per hour figures that we are using for vascular surgery are:

Clinical Staff	Admin Staff	Office Expense	Supplies	Equipment	Other	Total
20.2	18.1	17.7	3.2	4.5	11.4	75.1

These figures are from the supplemental survey information provided to us from the Lewin Group adjusted by the MEI so the figures reflect 1995 data. That is, we divided the 1999 practice expense per hour data by the cumulative MEI for 1996-1999 (1.0877).

Both supplemental surveys have extremely low response rates (about 14 percent for vascular surgeons and 11 percent for physical therapists). We specified the criteria we would apply for supplemental surveys in the May 2000 interim final rule (65 FR 25666). While we did not establish a precise minimum response rate, we did indicate that surveys with response rates less than 80 percent to 90 percent require an analysis to determine to what extent the sample is representative of the population. The extremely low response rates achieved by these

two supplemental surveys and the relatively small number of responses make it extremely difficult, and very subjective, to determine whether the data are representative of each specialty. Our contractor was able to make very limited assessments of this issue based on the data provided.

However, in our May 2000 interim final rule, we indicated that, based on our review of existing physician practice expense surveys, we believe that an achievable level of precision is a coefficient of variation, that is, the ratio of the standard error of the mean to the mean expressed as a percent, not greater than 10 percent, for overall practice expenses or practice expenses per hour. For existing surveys, the standard deviation is frequently the same magnitude as the mean. We indicated in the May 2000 interim final rule that we would consider practice expenses for which the precision of the practice expenses is equal to or better than this level of precision and that meet the other survey criteria.

The data submitted by the AAVS and the SVS met the level of precision. The data submitted by the APTA did not rise to this level of precision; they did not meet this objective criterion set out in the May 2000 interim final rule. Thus, we do not have, in the survey data submitted by the APTA, data that convince us of both the representativeness or the precision of

the surveys. For that reason, we are unable to incorporate the supplemental survey data submitted by the APTA in the practice expense system.

We note, however, that we have made an adjustment to the practice expense data for physical and occupational therapy services based on other comments received. These comments and adjustments are described elsewhere in this regulation.

In addition, one specialty society also submitted data concerning clinical staff in the hospital setting. The data submitted were not in the context of supplemental survey data. We discuss the issues addressed by these data elsewhere in this preamble.

(ii) Proposals for SMS Refinement

In the July 2000 proposed rule (65 FR 44180), we discussed the tasks that our contractor, The Lewin Group, was undertaking to assist us with broad practice expense technical and methodological issues. We also highlighted the recommendations that were contained in the first draft report that the contractor submitted, "Practice Expense Methodology," dated September 24, 1999. This report is on our homepage under the title "Practice Expense Methodology Report." (Access to our homepage is discussed under the "Supplementary Information" section above.)

The report contained various recommendations aimed at increasing the validity and reliability of the AMA's SMS survey. Although the Lewin Group's recommendations were made specifically to address improving the SMS survey for calculating practice expense RVUs, we believe the recommendations will be useful in making refinements to any other survey instrument that may be used in calculating practice expense RVUs. The recommendations fell into the three following areas:

- The use of data supplementary to the SMS survey.
- Suggested changes to the survey instrument.
- Recommendations for using the data in calculating the specialty-specific practice expense per hour.

In response to the report's recommendations on the use of the SMS data, we proposed to incorporate data from the 1998 SMS survey, which is the latest data available, into our practice expense per-hour calculations. In addition, we proposed basing the practice expense per hour calculations on a 4-year average, rather than the 3-year average recommended in the contractor's report. We published a table that contained the practice expense per-hour calculations for CY 2001 that resulted from the above proposals. We also proposed standardizing the practice expense data to reflect a 1995 cost year consistent with the pricing information we are using for the estimates of practice expense inputs for individual procedures. To standardize costs, we proposed inflating 1995 cost data by the MEI and deflating 1996 and 1997 costs data. This proposal has virtually no impact on the practice expense per-hour calculations.

After discussions with the AMA's SMS staff, we did not propose, as recommended by our contractor, to revise edits and trims to the SMS survey data to exclude data that fall outside set acceptable ranges.

In the July 2000 proposed rule (65 FR 44184), we also discussed the suggestions we made to the AMA for including additional questions in the SMS survey that would make it more useful for calculating specialty-specific practice expenses more

precisely. It now appears that the AMA may no longer undertake a multi-specialty survey to collect practice expense information. While we will continue our discussion with the AMA regarding any future plans for practice expense data collection, as stated above, we believe these recommendations will be useful in the design of any other survey used in developing practice expense RVUs.

As we indicated earlier, we proposed to use data from the 1998 SMS to develop the 2001 practice expense RVUs. Furthermore, data from the 1999 SMS will become available later this year for use in developing the 2002 practice expense RVUs. In addition, section 1848(c)(2)(B) of the Act requires that not less often than every 5 years, we review and make adjustments to RVUs. Thus, we are required by the statute to review and make adjustments to the practice expense RVUs 5 years after the end of the transition period, that is, no later than 2007. Regardless of whether the AMA continues to collect data on practice expenses, we will be developing plans for making refinements to practice expense RVUs beyond 2002.

Comment: One specialty society indicated that SMS data from 1998 and 1999 is available and we have not used this data in the past because of fears that the data may be tainted now that some physicians know that the responses could affect

Medicare fees. The commenter recommended that we use data from 1996 through 1999, rather than the 1995 through 1998 data we have proposed using.

Response: In the November 2, 1998 final rule (63 FR 58821), we expressed concern about the potential biases that may exist in surveys collected by individual specialties and in any survey data collected in the SMS survey process subsequent to our June 5, 1998 proposed rule. There is no relationship between this concern and any decisions that we have made with respect to incorporating available data from the SMS survey process into the practice expense methodology. Since SMS survey data from 1998 was collected more than 1 year before the June 1998 proposed rule announcing the "top down" methodology, any implication that we did not previously propose use of the data because of a concern about bias in the data is inaccurate. Rather, we have not previously proposed using the data because it was unavailable to us before this year's proposed rule. In addition, we did not propose using SMS data from 1999 because it was unavailable to us at the time of the proposed rule. We will consider using 1999 data from the SMS for setting 2002 physician fee schedule rates. As we stated in our July 2000 proposed rule (65 FR 44184), we welcome comments on long term strategies for collecting practice expense data in the future.

Comment: We received two comments that indicated that the SMS sample for gastroenterology is small and inadequate, that the response rate in the SMS is the lowest among any specialty, and that the practice expense calculations are probably inaccurate. One of these commenters also urged us to work with the AMA and the medical community to improve the aggregate specialty-specific data. A specialty society representing pediatrics reiterated the concern that the pediatric specialties are not adequately represented in the SMS, and a society representing geriatrics also believed that the sample size of geriatricians is not large enough to yield reliable data. Another commenter was concerned about the inadequate sample size of radiation oncologists in the SMS and believed that the use of the Physician Masterfile under-samples non-hospital based radiation oncologists and over-samples hospital-based radiation oncologists, who do not incur the same practice expenses for equipment and staff. Several imaging specialties stated that the SMS does not capture the practice expenses for TC services, probably because the SMS sample is skewed toward professional-component only providers. These commenters argued that, even if the sample of TC providers were adequate, the higher TC costs would be diluted by the lower PC costs, and thus it is necessary

to perform a survey of only TC providers to use in the practice expense calculations.

Response: Since concerns regarding the representation of various specialty societies in the SMS data were raised previously, we are reiterating our general response that can be found in more detail in the November 2, 1998 final rule (63 FR 58821). As we indicated in that rule, many of the criticisms of the SMS data could well be made about any other practice expense survey. At the time, we proposed use of the SMS data for developing the practice expense RVUs, we indicated that it was the best available data source on aggregate practice expenses. Since we are continuing to rely on the SMS data in the process for determining practice expense RVUs, we believe that the specialty-specific representation in the data is now improved by incorporating an additional year of data. The practice expense per hour will be based on a larger number of survey responses that will likely result in improved representativeness of the data.

Comment: One commenter contended that the data in the practice expense per-hour table in the July 2000 proposed rule do not appear logical, objective, or consistent. There is an unexplained range of clerical payroll per hour among similar specialties, and the ranking of the practice expenses among

specialties appears to be untenable; for example, the total practice expense per hour for dermatology is almost two times greater than for gastroenterology.

Response: We believe that different specialties are likely to have differences in practice expense per-hour for indirect types of costs depending upon the nature of the practice. With respect to the examples identified, dermatologists are generally in office-based practices, while gastroenterologists provide most services in hospitals. The nature of these types of practices may result in very different expenses for administrative personnel. Without disaggregating the costs and describing the different administrative activities that are performed by employees of the different types of specialties, it is difficult to explain deviations in the practice expense per hour among specialties. Nevertheless, we reviewed data on administrative practice expenses per hour across specialties for each individual SMS data year and found, with some exceptions, that there is stability among the relative practice expense per hour for this item across years. For instance, for 3 of the 4 years that there is survey data, the administrative practice expense per hour for gastroenterology is between 61 and 63 percent of dermatology (in the remaining year, it is 53 percent). We believe that the apparent stability of the

relative practice expense per hour across specialties provides assurance of the data's reliability.

Comment: We received a number of comments expressing concern about our decision to incorporate 1998 SMS data into the practice expense methodology. Several commenters noted that there were a small number of usable responses for some specialties to calculate the practice expense per hour using the 1998 SMS data, citing that cardiac and thoracic surgeons and radiation oncologists had only three responses. Another commenter stated that, in the past, we have been unwilling to use SMS data if the number of survey respondents is low. Other commenters expressed concern that for some specialties, the small sample of physicians would mean that the practice expense per hour could not be calculated accurately and such unstable data would produce some substantial changes. These commenters suggested that we not incorporate additional data, including the 1998 SMS data, until a representative practice expense sample can be performed with an adequate number of respondents for all specialties.

One specialty commented that inclusion of the 1998 SMS data is premature because of questions regarding its validity, since AMA is redeveloping the SMS with the possibility of seeking specialty-society input, and there are questions regarding the

validity of the 1998 SMS data. While some commenters agreed with the general principle of using the most current data, they argued that the quality of the 1998 SMS data does not merit inclusion into our practice expense per-hour calculations. One commenter stated that the SMS survey does not recognize the unique nature of emergency medicine.

Alternatively, there were many comments that supported our use of the 1998 SMS data. These commenters generally indicated that we should use the most current data because practice expenses may change over time. In addition, these commenters indicated that there is no evidence that the 1998 SMS data is tainted or otherwise objectionable. Other commenters indicated that including more survey responses from later SMS years will result in practice expense values that are more representative of physicians' costs. Some commenters indicated that practice expense data based on a 4-year sample provides greater assurance of its quality. Many of the commenters that suggested incorporating the 1998 SMS data also indicated that we should use the 1999 data from the SMS when it becomes available. Other commenters supported our proposal to base the practice expense per-hour calculation on a 4-year average of SMS data as opposed to a 3-year average, because it will help to compensate for the

low number of survey responses from some specialties in the prior years' SMS surveys.

One commenter believed that we should follow our contractor's recommendation and use a rolling 3-year average, because using 4 years results in older data completed by persons less familiar with the SMS. Other commenters supported using only the latest 3 years of data to eliminate the oldest practice expense data from the methodology.

Response: While the lower response rates in the 1998 SMS data are a concern, we continue to believe it is appropriate to incorporate these additional data into the practice expense methodology. In general, even though there are fewer responses in the 1998 SMS data, it is unclear to us why this alone indicates that we should reject incorporating the data. Generally, the inclusion of more survey data will improve the data's representativeness and lead to more stability in the practice expense methodology. Furthermore, to the extent that there are fewer responses to the 1998 SMS survey, there will be less impact on a given specialty because the practice expense per-hour calculation is weighted by the number of respondents from each respective year. With respect to the stability of the data, the AMA indicated that a statistical test of the data "revealed only marginal evidence of a statistically significant

change in PE-HR across specialties when all specialty-level changes were considered jointly. In other words, the combined set of changes in relative PE-HR were with the range of what could be expected by sampling error." Thus, although there may have been some large changes in practice expense per hour across years for some specialties, there appears to be overall stability across years among all physicians.

In general, use of the 1998 SMS improves the stability of the practice expense per hour and results in little specialty level impact. For the 35 specialties listed in our impact table in the July 2000 proposed rule (65 FR 44203), 21 specialties will experience an impact that is near zero. There are nine specialties that will experience an impact of approximately 1 percent as a result of inclusion of the data. For two (cardiac and thoracic surgery) of the four specialties that show a payment impact of approximately 2 percent, the data were affected by more than just the inclusion of the 1998 SMS data. In the November 1999 final rule (64 FR 59391), we indicated that supplemental data would be incorporated in the practice expense per hour and we would not include data from the 1995 SMS. We are now adding the 1995 SMS data as well as the 1998 SMS data to the calculation of practice expense per hour and increased the likelihood that there would be a larger impact on the practice

expense per hour. For one specialty (physical and occupational therapy, included in the nonphysician practitioner category), we made an error in the practice expense per hour calculation in the July 2000 proposed rule. After correcting this error, there is only approximately a 1-percent increase in the nonphysician practitioner category from incorporating the additional SMS data. We believe that these results support the argument that the practice expense per hour is generally stable and that it is appropriate to include 1998 SMS data in the practice expense methodology.

With respect to the comment that it is premature to incorporate 1998 SMS data into the practice expense methodology because of AMA efforts to redesign the survey and include specialty society input, we are unsure of the AMA's efforts in this regard. Nevertheless, while we would welcome multispecialty involvement in an effort to collect practice expense data specifically for the purpose of determining relative value units, we believe that such efforts should not have any bearing on our decision to incorporate later SMS data into the practice expense methodology at this time. If new data were to be collected under a redesigned survey process, it could be at least 2 years before such data is available to us. In the

interim, we believe it is appropriate to include the latest SMS data into our methodology.

We disagree with the commenter who suggested that the older SMS data should be eliminated from the practice expense per hour calculations because the surveys were completed by respondents less familiar with the SMS. The SMS is a longstanding survey that was originally developed by the AMA in 1981. There is no evidence that data from earlier SMS surveys is less reliable than later survey information.

Comment: A commenter representing urologists stated that, if we are not going to accept our contractor's recommendation to revise the edits and trims to the SMS survey data, the use of median values, rather than means, would produce the most fair relative ranking of the practice expense per hour among medical specialties.

Response: We believe it is appropriate and consistent with the statute to use the mean practice expense per hour rather than the median. Under the practice expense methodology, the practice expense per hour for each specialty is multiplied by the physician time per procedure and number of Medicare allowed services and summed at the specialty level to produce aggregate specialty cost pools. In theory, the aggregate practice expense pools would reflect actual physicians' costs if the utilization

data for all payers, not just Medicare payers, were used. (In reality, however, the data is potentially biased by the inclusion of mid-level practitioners. See the June 5, 1998 proposed rule (63 FR 30832) for a more detailed discussion of this issue). If the median practice expense per hour were used, however, the aggregate cost pools would not be reflective of physicians' actual expenses, because very high-cost or low-cost practice data would be excluded. Since the statute indicates that we should "recognize all staff, equipment, supplies and expenses," we believe use of the mean rather than the median practice expense per hour will result in the practice expense RVUs being more reflective of all physician practice costs.

Comment: We received several comments that were concerned about the AMA's decision to no longer collect practice expense data from the SMS. One commenter noted that the Lewin Group recommendations described in the proposed rule were aimed at improving the SMS surveys and/or practice level surveys that the AMA no longer intends to perform. Other commenters expressed concern about plans for gathering practice expense data for years after 1999, particularly if the AMA will not continue the SMS survey. Two commenters recommended that we initiate a dialogue with specialty societies to develop a workable alternative and another that we consider creating and funding a

survey to collect practice expense data in the future. One organization commented that the AMA's decision to no longer collect practice expense data means that issues related to uncompensated care in the practice expense methodology will not be addressed. This commenter stated that we should continue to work with emergency physicians to ensure that what the society feels are flawed practice expense data are no longer used to determine payment amounts for emergency physicians.

Response: We share these commenters' concerns about the AMA's decision to no longer collect practice expense data. However, we continue to believe that the recommendations of the Lewin Group and our suggestions to the AMA regarding improvements that could be made to the SMS and practice level survey will be helpful in future practice expense data collection efforts. As the AMA indicated in a letter to us (see 63 FR 30829 for the AMA's more detailed comments), the SMS data were never collected for the purpose of developing relative values. The Lewin Group recommendations and our suggestions to the AMA were intended to tailor the SMS or a practice level survey to be more suitable for this purpose. While our comments were addressed specifically to improving the ability of the SMS or a practice level survey to be used for developing practice expense RVUs, there is no reason that these suggestions would

not be equally valid for any alternative practice expense survey instrument that may be developed. Thus, we continue to believe that there is merit in the work of the Lewin Group and in our suggestions on improvements to the AMA survey.

With respect to the concerns expressed about gathering practice expense data beyond 1999, we have published criteria that specialties must follow to submit supplementary practice expense survey data that can be included in the practice expense calculations. Thus, there is a process for specialties to collect representative data on practice expenses for a specialty that can be used to influence the calculation of practice expense RVUs. Furthermore, we are currently planning to use 1999 SMS data to determine the practice expense per hour for calculating practice expense RVUs for 2002. Thus, the fully implemented resource-based practice expense RVUs will be based on a weighted 5-year average of the latest SMS survey data.

Regardless of whether the AMA were to continue the SMS survey, it is unclear whether it would be necessary or even desirable to incorporate more recent practice expense per hour data into the methodology on an annual basis. While the practice expense may increase or decrease over time, the important variable for the practice expense methodology is whether there is a relative change among specialties in practice

expense per hour. Again, with exceptions for some specialties, there generally appears to be stability in the relative practice expense per hour among specialties in the SMS data we are using. Indeed, there generally was little redistribution in payment resulting from use of the latest SMS data. For 21 of the 35 specialties listed in Table 1 of the July 2000 proposed rule (65 FR 44203), the percent change in practice expense from using the latest SMS data was near zero. For nine of the remaining 14 specialties, the impact on payments was only 1 percent. For only five of 35 specialties listed was the impact on payments 2 percent or greater. Thus, if there is year to year stability in the relative practice expense per hour among specialties, it will likely make little difference whether we incorporate additional practice expense data into the methodology.

However, it is possible that there were will be more significant changes in relative practice expense per hour over time among specialties. The statute requires that we make refinements in the practice expense RVUs at least every 5 years. While we expect to continue making refinements to the inputs for individual codes on an annual basis, it could be several years before we might require practice expense data from a multi-specialty survey after the initial refinement period ends in 2002. While we consider how to approach this issue, we welcome

the comments that suggested that we seek input from the medical community in developing a mutually satisfactory and equitable approach to obtaining the needed information on practice expenses for future refinement efforts.

Comment: A society representing vascular surgeons commented that separately billable income should be deducted from practice expenses as part of the practice expense per hour calculations, because the inclusion of this income may account for the inexplicably wide range in the practice expense calculations among specialties.

Response: We agree that it is desirable to identify separately billable services. As explained elsewhere, this is an issue for future SMS revisions.

Comment: One commenter suggested that we move the SMS clinical labor expenses to the indirect expense category, as was done with the administrative labor cost. The commenter stated that with the inclusion of high administrative costs, the indirect costs will vary considerably among specialties and expressed their concern that the determination of the scaling factor is not an equitable means to distribute these indirect costs. The commenter encouraged us, along with our contractor, to examine this issue in detail.

Response: We are reviewing issues related to indirect expenses with our contractor.

Comment: A commenter stated that separately billable income of mid-level practitioners should be deducted from practice expenses as part of the practice expense per hour calculations. The commenter suggested that the total practice expense pools should be adjusted by the Medicare income received by physicians for the work of physician assistants and other mid-level practitioners. The commenter indicated that the pools can be adjusted easily for cardiac and thoracic surgery because the data on billing for these mid-level practitioners are easily available from our data files.

Response: We believe that the numerator of the practice expense per hour calculation should exclude any costs associated with mid-level practitioners and the denominator should include their patient care hours. Unfortunately, the data from the SMS do not permit the calculations to be performed in this way. We believe that this issue should be addressed in any multispecialty survey instrument that will be used in the future to collect practice expense data and determine practice expense RVUs. We disagree with the commenter that there is a feasible way of making an adjustment to the aggregate practice expense pools themselves to address this issue. While it is unclear

from the comment about how such an adjustment would be made, it is possible that the commenter believed that we can use Medicare utilization data to determine the proportion of total allowed services for cardiac thoracic surgery procedures, where the specialty data indicates that the service is performed by a mid-level practitioner assisting at surgery; perhaps the commenter assumes that we would use this proportion to reduce the size of the aggregate cost pool. We believe that it is not possible to make an equitable adjustment in this way. First, the aggregate cost pools are constructed using a total practice per hour figure, and the proportional adjustment would reflect only Medicare data. Second, it is not clear to us how such a calculation would be made. An assumption would have to be made that where a mid-level practitioner is performing a given type of service, the work is being furnished for a given type of physician specialist. For instance, if a physician assistant is assisting at surgery for a heart procedure, we would have to assume that practitioner is working for a cardiac or thoracic surgeon. Even this simplified example presents a dilemma, because it would be unclear whether to adjust the pool of the cardiac or thoracic surgeon in this instance. We believe that, even if these assumptions could be made for some services, it would be difficult to make similar assumptions, for example, for

evaluation and management services when the mid-level practitioner could be working for one of many different specialists. For these reasons, we are not making an adjustment to the practice expense pools at this time.

(iii) Direct Patient Care Hours

In our July 2000 proposed rule (65 FR 44184), we discussed the many concerns that have been raised from various specialty societies concerning our calculation of direct patient care hours. Several previous commenters representing surgical specialty societies have raised concern that the hours computed for their specialties have been overstated, because non-billable hours, such as stand-by time, have been included. In addition, commenters representing emergency room physicians raised the issue that the hours spent on uncompensated care were probably also included in the survey responses to the detriment of this specialty.

We then discussed the steps we were taking to improve the future accuracy of these data. We recommended more precise wording for future survey questions so that only the appropriate practitioner hours are included.

We also discussed the second draft report issued by our contractor, entitled "Validating Patient Care Hours Used in HCFA's Practice Expense Methodology." This report, which is on

our homepage under the title "Validating Patient Care Hours," explores alternative methods that we might use to validate the time data collected by the SMS survey. We have extended The Lewin Group's contract so that, among other refinement tasks, the above validations can be performed. We also solicited comments and suggestions as to other steps we could take to verify and improve the accuracy of the specialty-specific patient care hours.

Comment: We received several comments, primarily from surgical specialty societies, reiterating the concerns about patient care hours discussed in the July 2000 proposed rule. In particular, commenters urged that we find a way to identify non-billable hours, such as down-time between surgeries, stand-by time, phone calls, "curbstone" consultations, and uncompensated care, so that these non-billable hours can be subtracted from the specialties' direct patient care hours. In addition, several commenters raised the concern that the SMS survey data on patient care hours varies considerably by specialty.

The comments also contained a number of recommendations. One commenter suggested that we could use a blend of the all-physician and the specialty-specific hours. A specialty society, citing concerns about the variability between the SMS and the Harvard/RUC time data, recommended that we collect

information on the Medicare share of practice hours in the SMS to produce a check of the meaningfulness of the pool allocations. Another specialty society, claiming that the SMS data on patient care hours are sure to be imprecise, urged us to use a standardized number of hours in the practice expense calculation or to statistically limit the impact of this variable. While one commenter recommended that we use the average number of hours per week that physicians' offices are open to calculate the practice expense per hour, another commenter argued that the assumption of a 40-hour work week for all specialties would result in a significant distortion of practice expenses per hour.

Response: We do agree that the patient care hours data would be more precise if we could ensure that there is a standard definition understood across specialties, so that non-billable hours would not be included in the data. As discussed in the July 2000 proposed rule (65 FR 44185), we suggested adding a clarifying definition of hours to be included to any future multi-specialty practice expense surveys. In addition, we referred to the work our contractor is doing to validate the patient care hours; one of the tasks will be a comparison between the SMS hours data and the Harvard/RUC physician time data. Once this analysis is completed, it could form a basis

for deciding whether any adjustment to the SMS data is either advisable or workable. As for the recommendations that we use either a standard time for all specialties or the actual time the physicians' offices are open, we believe these recommendations stem from the mistaken impression that a specialty that actually works longer billable hours is somehow disadvantaged by our methodology. First, we believe that some specialties do put in more billable hours per week than other specialties, and using a standard number of hours for all specialties would thus be inaccurate and inequitable. Second, while it can be argued, as some commenters claimed, that most practice expense costs are generally incurred during the hours the physician's office is open, we do not have a two-tiered system of payment in which we pay less for surgeries performed at 6:00 a.m. than we do for those performed during office hours on the grounds that the earlier procedure somehow incurs less practice expense. Rather, we average the payments across each service, regardless of the time it is performed. Likewise, the practice expense per hour calculation is an average of the costs per hour, in which some hours would have higher costs and some lower. In addition, the direct patient care that takes place outside of office hours should be reflected in increases in the

utilization data for that specialty that, in turn, increases the practice expense cost pools for the same specialty.

Comment: One commenter urged that any uncompensated care adjustment be allowed only for emergency department services that are furnished by practices in areas that have a disproportionate share of uncompensated care.

Response: If we were to propose any further adjustments for uncompensated care, we would publish them in a proposed rule, subject to comment by all interested parties.

Comment: A specialty society expressed concern that, because podiatrists are not surveyed by SMS, any validation of patient care hours performed by our contractor would not apply to podiatry. This commenter also stated that the specialty society has shared with us two of the society's own surveys containing patient care hour data, and requested that we either validate and use this data or take responsibility for collecting this data.

Response: We understand the points that are made by this commenter and will consider this further if we make adjustments to the patient care hours. In addition, now that a process and criteria have been spelled out for the submission of supplementary practice expense data, the specialty society can

also submit additional survey data that should include information on podiatrists' patient care hours.

(c) CPEP Data

(i) Relative Value Update Committee's Practice Expense Advisory Committee (PEAC)

1999 RUC recommendations on CPEP inputs

The PEAC, a subcommittee of the RUC, held its initial meetings last year to begin to refine the clinical staff, supply and equipment inputs for physician fee schedule services. In the November 1999 final rule (64 FR 59394), we responded to the RUC recommendations for the refinement of the direct inputs for 65 codes originally reviewed by the PEAC and subsequently approved by the RUC and noted that our actions on all of the recommended inputs were subject to comment. We received the following comments on our revisions to the RUC recommendations:

Comment: One specialty society questioned the removal of lysol, tissues, and biohazard bags from the supply list for all codes, since these items represent costs that physicians must pay. Additionally, one organization objected to our removal of self-administered drugs from all codes, and another society, as well as the RUC, objected to the removal of betadine from the supplies recommended for the post-procedure period.

Response: We believe that the removal of such items as tissues, lysol, and biohazard bags will help simplify the refinement of the CPEP supply data without having a noticeable impact on the payment for any service. We removed the costs of these minor supplies from the overall CPEP supply list either because of the difficulty in measuring their use or because the supplies were not fully used up during a single procedure. Throughout the supply data, the quantities for biohazard bags and tissues were reported incorrectly; for example, codes were assigned 5 boxes of tissues or 250 tissues when the intention was to assign 5 single tissues at a cost of 5 cents. The PEAC/RUC has since extended this simplification by eliminating paper towels and room disinfectant from their recent recommendations. We proposed to eliminate the very few self-administered drugs on our supply list from the CPEP data because we believe that it is reasonable to exclude non-covered items in the allocation of the specialty-specific cost pools. With respect to betadine, we note that it is included in the recommendations for the post-surgical supply package that we have accepted in this rule, which can be used by any surgical specialty for its codes. Therefore, we will not be adding back any of these individual supplies at this time.

CPT Code 17003, Destruction by any method, second through 14 lesions

CPT Code 17004, Destruction by any method, 15 or more lesions

Comment: One organization commented that we should have corrected the obvious and egregious anomaly in these codes whereby the payment for destruction of 14 lesions is considerably higher than the payment for 15 lesions.

Response: We agree that the values for these two codes appear anomalous. However, we do not assign practice expense RVUs to services. Rather, these RVUs are allocated based on the inputs that are associated with each service. Both of the above codes, along with CPT Code 17001, *Destruction by any method, first lesion*, were presented by the dermatology specialty societies to the PEAC, but we received recommendations only on the supplies for these services. We accepted these recommendations in general, but deleted many specific supplies from CPT Code 17003 because it is an add-on code. We have re-examined the current CPEP inputs for CPT Code 17001, 17003, and 17004, and believe that the inputs for labor and equipment appear to be appropriate. The source of the anomaly seems to be in the supply inputs for these services. To ensure that the appropriate revisions are made to the supply lists, we need

specific recommendations from the RUC or the relevant specialty societies.

CPT Code 17304 through 17310, Chemo surgery (Mohs' micrographic technique) [first and subsequent stages]

Comment: A commenter representing Mohs surgeons, while acknowledging the revisions made in the final rule to the lists of supplies, indicated that we erroneously omitted some supplies from the updated list. The commenter provided information on the supplies omitted, as well as the rationale for why these supplies need to be included.

Response: We appreciate the detailed explanation regarding the use of these supplies. After review, we note that, with few exceptions, all the supplies the commenter claimed were omitted are in fact already included in our CPEP database as originally recommended. We explained in the November 1999 final rule that we were deleting Valium, which is separately billable, and Tylenol, which is self-administrable from all codes; therefore, these drugs will not be included for any of these services. In addition, we are not convinced that it is typical to suture the wound after each stage of surgery, and the commenter stated that the wound is not closed until it is determined that no further procedures are necessary. Therefore, we believe that only one set of sutures and suture kit are typically needed, which we are

including in the supplies only for CPT code 17304. We also note that the tincture benzoin swab requested by the commenter was not included in the original RUC recommendation, though we are adding it at this time.

CPT Code 56340, laparoscopy, surgical; cholecystectomy (any method)

Comment: A specialty society representing surgeons and the RUC objected to the decreases we made to the PEAC/RUC recommendations for the pre- and post-service times for this CPT code. They indicated that there were extensive discussions about this code at the PEAC/RUC meeting, and that adequate information was provided to support this change for pre-service time. The commenters also objected to our elimination of the time for the second registered nurse in the post-service period and requested that we provide the basis for determining that this is not typical practice.

Response: There was insufficient rationale for the PEAC recommendations transmitted to us. Moreover, the PEAC is currently working on establishing a standardized methodology for refining the pre- and post-procedure clinical staff times. This code, like all other surgical codes involving pre- and post-procedure staff time will undergo further refinement. We are not changing the clinical staff times now, but will review them

upon receipt of the PEAC recommendations for pre- and post-procedure time for surgical procedures in general.

CPT ophthalmology codes 65855, 66170, 66172, 66821, 66984, 67036, 67038, 67039, and 67040

Comment: Three specialty societies representing ophthalmologists and the RUC expressed concern that we did not accept the RUC recommendation to increase the pre-service period to 42 minutes for the above CPT codes, but rather deleted all pre-service clinical staff time. The commenters also noted that the statement in the November 1998 final rule that we were retaining the original CPEP value of zero minutes was in error for CPT codes 66170, 66172, 66984, 67036, 67038, 67039, and 67040 because the CPEP panel had assigned 24 minutes of clinical staff pre-service times to these codes. Commenters requested that we accept RUC recommendations for 42 minutes of clinical staff time in the pre-service period for all these codes because facility-based surgical procedures require significant pre-service clinical staff work.

Response: We thank the commenters for pointing out our inadvertent error regarding the pre-service time in the original CPEP data for seven of the above ophthalmology codes. Although we are not convinced that each of the codes would have as much as 42 minutes of pre-service clinical staff time, we will use

this as an interim value for pre-service time. We understand that the PEAC and RUC are planning to develop standardized approaches to assign the pre- and post-surgical clinical staff times, as well as coordination of care times, across wide ranges of codes for the different global periods. These pre-service times can then be revisited in light of future recommendations.

Comment: Several ophthalmic societies opposed our decision to decrease the post-service clinical staff time approved by the PEAC/RUC for ophthalmic surgical procedures. The commenter representing three ophthalmic sub-specialties also stated that we did not consider the consensus agreement to replace the Ophthalmic Medical Personnel (OMP) staff type with the Certified Ophthalmic Technician (COMT) staff type for ophthalmic procedures. Another specialty society believed we should have collapsed the two staff types into the OMP staff type, because this was agreed upon at the 1997 validation panels.

Response: At the time that the November 1999 final rule was developed, we had received a comment from the specialty society that had presented these codes to the PEAC. This comment described the building-block approach that was used to arrive at the post-service clinical times. Unfortunately, there was a miscommunication regarding the specific building blocks that were used to arrive at the total times, and our total times were

different from those of the RUC. We have since received a clarification from the specialty society, and we are restoring the clinical post-service times to their recommended values.

There appears not be a consensus among the ophthalmic specialty societies regarding which staff type to use for ophthalmology codes. In addition, we have not used any of the decisions from the 1997 validation panels in refining the practice expense inputs, but have accepted the RUC recommendations for the use of the OMP staff types for the codes that have been refined to date. We have not received from the RUC any recommendation regarding a global change in the staff type for ophthalmology services, but would certainly consider any future recommendation from the RUC on this issue.

CPT Code 85060 Blood smear, peripheral, interpretation by physician with written report and CPT Code 85097 Bone marrow; smear interpretation only, with or without differential cell count

In the November 1999 rule (64 FR 59397), we stated that these were professional services and, if any practice expenses were incurred, they could be reported using other applicable codes. Therefore, we removed all practice expense inputs for these two codes.

Comment: Two specialty societies and the RUC requested that we use the recommendations of the RUC to establish a TC for CPT Code 85060, even though we would not use the RVUs for payment purposes, because other payers are increasingly using our RVUs to establish fees. The commenters also stated that the interpretation of blood smears can require additional slides and services. Commenters did not agree that the activity associated with the technical portion of CPT Code 85097 is included in payment for other services when this service is performed outside a hospital, as is increasingly occurring. They indicated that creation of a TC component for CPT Code 85097, using the RUC recommendations, would allow the laboratory that receives the specimen to bill for the technical costs in preparing the slide for examination by the physician, and recommended this TC component be paid under the physician fee schedule.

Response: We do not want, at this time, to create a TC for a code that we do not cover, such as CPT Code 85060. However, as mentioned elsewhere in this final rule, we are further considering the issue of valuing non-covered services. We will publish practice expense RVUs for CPT Code 85097, so that it can be paid when furnished in a nonfacility setting. We will use

the RUC recommended inputs to calculate the practice expense RVUs.

CPT 88104 Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation

Comment: Several commenters pointed out that, while we accepted the RUC recommendation that included filter paper in the list of supplies for this code, this was not reflected in the CPEP database.

Response: This item was omitted inadvertently from the CPEP database and will now be included.

In the November 1999 final rule, we deferred action on the RUC recommendations for a few groups of CPT codes on which we had significant questions. In the July 2000 proposed rule (65 FR 44185), we proposed to accept two groups of CPT codes of the RUC recommendations with the revisions noted below, while the RUC recommendation discussed below for the antigen service has not been previously addressed.

Prostate Procedures

CPT 52647 Non-contact laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)

CPT 53850 Transurethral destruction of prostate tissue; by microwave thermotherapy

CPT 53852 Transurethral destruction of prostate tissue; by radiofrequency thermotherapy

We discussed the inputs for these codes at length with the relevant specialty society, and arrived at a consensus on the staff, supplies, and equipment that were needed for these services.

Comment: The American Urological Association (AUA) applauded us for our proposal to accept the RUC recommendations for the three heat therapy prostate procedures and agreed that all inputs are now included in the CPEP data for these services. One manufacturer recommended that we adopt our proposal for CPT code 53850 in this final rule. Three individual urologists and a manufacturer commented that we should add equipment, such as an autoclave, rigid cystoscope, video system or ultrasound equipment to the equipment inputs for CPT Code 53852. The manufacturer also stated the prices in the CPEP database for the generator system and the hand piece are now outdated, and included the suggested current prices. Two of these commenters also included a list of supplies, most of which are already in the CPEP inputs for this code.

Response: Because our proposal is based on a recommendation from the RUC, and the AUA has stated that it believes the current inputs for this code are correct, we will not add the suggested equipment or supplies at this time, nor change the prices for any of the equipment. However, we have awarded a contract to have all of our direct cost inputs re-priced and any information that is sent to us on current pricing will be forwarded to our contractor.

Chemotherapy Procedures

CPT 96408 Chemotherapy administration, intravenous; push technique

CPT 96410 Chemotherapy administration, intravenous; infusion technique, up to one hour

The RUC had recommended 102 minutes of clinical staff time for CPT code 96408 and 121 minutes for CPT code 96410. After the publication of the November 1999 final rule we met with representatives of the American Society of Clinical Oncology (ASCO) and discussed the society's breakdown by specific tasks of the above staff times. Included in this breakdown were 20 minutes for pre- and post-procedure education and 15 minutes for three phone calls after each visit.

Because we believed that the times for patient education and phone calls should be averaged over the whole course of

chemotherapy treatment, and because there appeared to be some duplication in the pre- and post-procedure education tasks, we reduced both the patient education and phone call times by 5 minutes. Therefore, we proposed 92 minutes of clinical staff time for CPT code 96408 and 111 minutes for CPT code 96410.

Comment: ASCO objected to the 10-minute reduction of the clinical staff time for CPT 96408 and 96410. The commenter argued that the original RUC recommendation was reasonable and appropriate for both services and should be adopted. The comment also objected to our revision of a RUC recommendation unless we have a concrete reason to do so.

Response: Upon reviewing the times the RUC has since recommended for patient education and post-visit phone calls for comparable services, we are adding the 5 minutes we had removed from both patient education and phone calls in the proposed rule. We will now use the RUC-recommended total times of 102 minutes of clinical staff time for CPT code 96408 and 121 minutes for CPT code 96410. We believe that the total time is consistent with subsequent recommendations that we are accepting, though as the PEAC and RUC continue to develop standardized times for clinical staff functions, all previously valued codes are subject to possible review.

CPT 95165, Allergen Immunotherapy

The RUC did not forward any recommendations on the specific inputs required to perform the above service. However, we did receive a recommendation about the interpretation of the meaning of a dose for purposes of calculating the practice expense RVUs for this service. Because we did not believe the recommendation resolved the ambiguity and confusion in the medical community surrounding this issue, we did not accept this recommendation in the July proposed rule. Since that time, we have received clarifying comments from relevant specialties on both the definition of dose and the practice expense inputs to use for this code.

The practice expense inputs have been analyzed and adjusted so that they now correspond to the practice expense of preparing a one cc dose from a ten cc (ten dose) vial. The practice expense inputs for CPT code 95165 are based on an assumption that ten doses are typically included in each vial. Payment will be based on a maximum of ten doses per multidose vial. The practice expense RVUs for preparing a ten dose vial will remain the same, even if twenty doses are obtained from the vial (for example, if the physician administers 0.5cc doses, instead of one cc doses). Therefore, Medicare should be billed for a maximum of ten doses per vial, even if more than ten doses are

obtained from the vial. Furthermore, when a physician dilutes a multidose vial (for example, by taking a one cc aliquot from a multidose vial and mixing it with nine cc's of diluent in a new multidose vial), Medicare should not be billed an additional amount for these diluted doses for CPT 95165. The additional clinical staff and supply costs for preparing such a diluted vial are minimal, because allergens represent over 80% of the direct costs of preparing a multidose vial. In a diluted vial there are no associated allergen costs, since they have already been billed in preparation of the initial vial. Therefore, we expect a maximum of ten doses to be billed for each multidose vial. If fewer doses are prepared from this vial, a dose number less than ten per vial should be billed.

The practice expense inputs per one cc dose are as follows:

Clinical Staff: 2.2 minutes

Supplies: Allergen $6.05

0.5 needles and syringes

0.1 vial and cap

one alcohol pad

1 pair of nonsterile gloves

If multiplied by ten, the inputs correspond to the total practice expense of a ten cc vial from which ten doses of one cc each are administered. Commenters recommended that a typical

ten cc multidose vial contains five antigens and no diluent and that the total number of needles and syringes for the ten cc vial is five. The cost data for allergens was obtained from catalogue information and is based on the typical practice of using standardized extracts when available.

In view of the clarification we have made regarding practice expense inputs, we will revise Section 15050(B)(7) of the Medicare Carriers Manual. In May 1998, we changed the language of that section, in part, to clarify our payment policy for antigen preparation. At that time we stated, "A dose of code 95165 is the total amount of antigen to be administered to a patient during one treatment session, whether mixed or in separate visits." Two examples of antigen preparation and administration follow immediately after this language.

We will revise this section of the carrier manual to define a dose as a one cc aliqout from a single multidose vial. With this clarification physicians will be able to bill Medicare for each dose prepared in each multidose vial. We plan to issue new instructions to the carriers and update the carrier manual to ensure that appropriate payment is made as of January 1, 2001.

2000 RUC recommendations on CPEP inputs

We believe that the recommendations received this year from the PEAC/RUC for the refinement of the CPEP inputs for existing

codes mark a positive step in the CPEP refinement process. We received recommendations for clinical staff, supply and equipment inputs for 49 CPT codes, and for the supply and equipment inputs for four additional services. But the significance of the recommendations goes beyond the number of codes that were refined. First, included in these recommendations were the refinements for the 15 major evaluation and management (E/M) codes. These 15 codes represent over 25% of the payments made under the physician fee schedule. This was a breakthrough not only because the clinical staff times for these codes had previously been a point of major contention, but also because agreement on the inputs for E/M services may make it easier in the future to refine the post-surgical visits for thousands of services. Second, the PEAC/RUC approved supply packages for three specialties: obstetrics-gynecology, ophthalmology and neurosurgery; as a result, the supply inputs for hundreds of codes are now refined. We also understand that the PEAC will be developing further supply packages and is also setting up workgroups to determine approaches to standardizing pre- and post-procedure clinical staff times.

We have reviewed the submitted RUC recommendations and have accepted all of them with only two minor revisions. In order to be consistent with a revision made previously in the November

1999 final rule, we have deleted the skin marking pen when it appears in a recommended supply list because it is not practical to allocate its use to individual procedures. In addition, for the ophthalmology codes that were refined before the supply packages were adopted, we have substituted the ophthalmology visit supply package as appropriate. If future decisions are made on standard clinical staff times, all of these refined codes can be revisited to determine whether any further refinements would be appropriate.

Following is a list of the CPT codes that were included in the PEAC/RUC recommendations: (The complete PEAC/RUC recommendations and the revised CPEP database can be found on our website. See the Supplementary Information section of this rule for directions on accessing our web site.)

CPT 57452 Examination of vagina
CPT 57454 Vagina examination and biopsy
CPT 57500 Biopsy of cervix.
CPT 59000 Amniocentesis
CPT 62270 Spinal fluid tap, diagnostic
CPT 65730 Corneal transplant
CPT 67311 Revise eye muscle
CPT 67800 Remove eyelid lesion
CPT 67961 Revision of eyelid
CPT 90471 Immunization admin*
CPT 90472 Immunization admin, each add*
CPT 90782 Injection, sc/im
CPT 92270 Electro-oculography
CPT 92275 Electroretinography
CPT 92582 Conditioning play audiometry
CPT 94621 Pulm stress test/complex
CPT 95812 Electroencephalogram (EEG)
CPT 95822 Sleep electroencephalogram

CPT 95829 Surgery electrocorticogram
CPT 95830 Insert electrodes for EEG
CPT 95861 Muscle test, two limbs
CPT 95863 Muscle test, 3 limbs
CPT 95864 Muscle test, 4 limbs
CPT 95867 Muscle test, head or neck
CPT 95868 Muscle test, head or neck
CPT 95870 Muscle test nonparaspinal
CPT 95903 Motor nerve conduction test
CPT 95925 Somatosensory testing
CPT 95926 Somatosensory testing
CPT 95930 Visual evoked potential test
CPT 99141 Sedation, iv/im or inhalant
CPT 99142 Sedation, oral/rectal/nasal
CPT 99201 Office/outpatient visit, new
CPT 99202 Office/outpatient visit, new
CPT 99203 Office/outpatient visit, new
CPT 99204 Office/outpatient visit, new
CPT 99205 Office/outpatient visit, new
CPT 99211 Office/outpatient visit, est
CPT 99212 Office/outpatient visit, est
CPT 99213 Office/outpatient visit, est
CPT 99214 Office/outpatient visit, est
CPT 99215 Office/outpatient visit, est
CPT 99241 Office consultation
CPT 99242 Office consultation
CPT 99243 Office consultation
CPT 99244 Office consultation
CPT 99245 Office consultation
CPT 95813 Electroencephalogram (EEG)
CPT 95816 Electroencephalogram (EEG)
CPT 94060 Evaluation of wheezing
CPT 95921 Autonomic nerv function test
CPT 95922 Autonomic nerv function test
CPT 95923 Autonomic nerv function test

*Note: These are noncovered under the Medicare physician fee schedule.

Other Comments on Refinement of CPEP Inputs

Comment: One commenter asked that we clarify whether we plan to implement the RUC CPEP recommendations on a rolling basis, or whether all changes will be made at once.

Response: Unless we announce a change in approach, we plan to deal with the RUC's recommendations on a rolling basis as we receive them.

Comment: A commenter representing three ophthalmology sub-specialty societies expressed disappointment in our belief that it is preferable to have a multi-specialty agreement on changing the CPEP data, rather than accepting the recommendations of a single group. The commenter argued that there is little or no added value from such multi-specialty review when the impact of the changes is limited to a single specialty and when members of other specialties have no additional clinical knowledge.

Response: We strongly disagree with this comment. We have found that the input and recommendations of the RUC play a crucial role in the practice expense refinement. Also, because there are many codes that are shared across a number of specialties, changes in payment for even a specialty-specific service can affect the payment of the shared services that the specialty performs. Therefore, we believe that it is fair and equitable to have a multi-specialty consensus on these changes. In addition, we have found, in our role as observers at RUC

meetings, that RUC members, of whatever specialty, ask pertinent questions and make clinically relevant observations.

Comment: A specialty society representing many medical specialties recommended that we should use panels, corresponding to the refinement panels we use for work, to make recommendations on code-level refinements that are submitted to us.

Response: We certainly do not rule out the use of such refinement panels for code-level practice expense recommendations when and if such panels would be necessary and useful. We have used these panels for work RVU refinement in those cases when we have not accepted the RUC recommendations on a number of codes and subsequently have received comments disagreeing with our actions. Because we have made so few revisions in this current final rule to the PEAC/RUC recommendations for practice expense inputs, there may be no need for practice expense panels next year, although we will consider this issue.

(ii) Clinical Staff Time

In the November 1999 final rule (64 FR 59399), we removed estimates of all clinical staff time allotted to the use of clinical staff in the facility setting from the CPEP data. Commenters have since noted that the clinical staff times

reported by some CPEP panels for pre- and post-service times for 0-day global services performed in the office were recorded in the intra-service field in the CPEP database. These times were, therefore, deleted along with the times for the use of clinical staff in the facility setting.

In the July 2000 proposed rule (65 FR 44186), we stated that these data are not comparable to the data we excluded for clinical staff used in the facility setting. We reviewed the "CPEP Recorders' Notes Files" compiled for each CPEP panel by Abt Associates, Inc., the contractor managing the CPEP panels. When the notes indicated that clinical staff estimates were for activities performed in physicians' offices, we proposed to reinstate the time data for 0-day global services.

Comment: Many medical societies representing specialists such as gastroenterologists, internists, rheumatologists, cardiologists, osteopaths and podiatrists, as well as the AMA, expressed strong support for this proposal to reinstate the pre- and post-procedure clinical staff time in the office for 0-day global services. One reason given in the comments for this support is that this time for staff in the office is not comparable to the data excluded for clinical staff used in the facility setting.

Response: We are pleased that all commenters supported this proposal, and we are implementing this refinement in this rule.

Comment: An organization representing cardiologists stated, in a comment on the November 1999 final rule, that we should enlist the assistance of medical specialties to identify codes for which clinical staff are used in the physician's office during the intra-service period for facility services. In a comment on the current proposed rule, this society agreed with our proposal to add some pre- and post-service clinical staff time to 0-day global services and listed several 0-day cardiology services for which it recommended the addition of clinical staff time.

Response: In this proposal, we added only clinical staff time in the facility setting for those 0-day services when the CPEP recorder notes specified that the time was for pre- and post-service time for staff in the office. We believe that this is appropriate because these CPEP data are as valid as all other non-refined CPEP data. We also believe that changes to the CPEP data for this pre- and post-service clinical staff time should go through the same refinement process as other desired changes and that any group recommending the addition of such time should present this issue to the PEAC/RUC for refinement. We also understand that the issue of "coordination of care" clinical

staff time is one that the PEAC may address across the board at some future meeting. In addition, from the description of the staff duties for the codes listed by the commenter, it is not clear that this staff is in the office, rather than in the facility performing facility nursing functions. Therefore, we will not be making these changes at this time.

Comment: An emergency physician organization recommended that we not limit this proposal to 0-day global period services and submitted the CPEP recorders' notes for emergency room visits, CPT codes 99281 through 99285. The notes indicate that the CPEP panel added 3 minutes of pre-service time and 4 minutes of post-service time for office staff involved in admissions to the emergency room. The commenter recommended that this time be reinstated for these emergency room visit codes.

Response: These emergency room visits have an XXX global period. By the current definition, XXX services do not include pre- and post-service times. Before implementing this specific recommendation, we hope to receive input from the RUC/PEAC on the general issue of appropriate pre- and post- staff times for the different global periods, in order to ensure consistency in our approach to this issue.

In the November 1999 final rule (64 FR 59399) we finalized our decision to remove from the CPEP data all clinical staff

times associated with physician's staff used in the facility setting. We implemented this policy for the following reasons—(1) We should not pay twice for the same service; (2) It is not typical practice for most specialty societies to use their own staff in the facility setting; and (3) Inclusion of these costs is arguably inconsistent with both the statute and Medicare regulations. In response to the November 1999 final rule, we received many comments on this final decision, which, for the most part, reiterated comments that had been made on the original proposal.

Comment: Although several primary care groups expressed support for this decision, most of the commenters objected to the exclusion of this clinical staff CPEP data. Many of these organizations urged us to postpone the implementation of this policy and to collect additional information before making a decision on how to treat these costs. However, taking the opposite approach, a primary care organization stated that the clinical staff time should be removed for services furnished in the facility until the PEAC/RUC can determine that the time for these services is typical and not duplicative of physician work. Several commenters again raised the argument that the BBA prohibits us from excluding these clinical staff costs because the BBA requires us to recognize all costs, not just those that

can be tied to specific procedures. Many organizations reiterated the claim that the practice of taking staff to the hospital is either typical or prevalent in their specialties. However, only the specialty society representing thoracic surgeons submitted any additional information to support this claim. The STS surveyed their members in July 2000,and reported that 74 percent of the respondents said they employ clinical staff who assist in the hospital, though more than half report that they receive Medicare payment for some of these personnel. Commenters made the following recommendations:

Several organizations contended that hospitals no longer supply the staff to furnish adequate care. In relation to this point, two commenters recommended that the issue of cost shifts between hospitals and other providers is one that we should not ignore, and, if there is any double payment, Part A payment to the affected hospitals should be adjusted.

Another specialty society recommended that we establish a modifier to allow for documentation of and payment for non-physician clinical staff who furnish services in a facility setting. This modifier would indicate whether there is a physician practice expense or a hospital practice expense that has been transferred to the physician practice, to ascertain whether payment should come from Medicare Part A or Part B.

One organization recommended that the SMS data be adjusted by the income received for the work of physician assistants.

Response: We have considered all the comments that we have received on this issue, both on the July 22, 1999 proposed rule and the November 1999 final rule. Though many of the commenters raised interesting points, there were neither new arguments nor evidence presented that would cause us to delay or abandon this policy. While we particularly appreciate the effort undertaken by the thoracic surgeons to develop data on the prevalence of their use of clinical staff in the hospital, the survey addresses only the question of typicality. As stated above, there are two other reasons why we eliminated this clinical staff time. First, we believe that we already pay the facility for the clinical staff needed for patient care. Much of what is claimed as physician's clinical staff time in the facility is either separately billable (as illustrated by the survey submitted by the commenter) or is accounted for in the work RVUs. Furthermore, by law, the hospital itself must furnish all services and items to a hospital patient, either directly or under arrangement. (For a more detailed description of our rationale for this policy, see the November 1999 final rule (64 FR 59402).)

As to the recommendations made by the commenters, we agree that it would be desirable to remove costs associated with these mid-level practitioners from the SMS data as well. This would answer the concern raised by another commenter that removing the clinical staff from the CPEP data introduces further inconsistency with the SMS data. It is for that reason that we had recommended to the AMA that several specific questions be added to the SMS survey to capture the needed information on this clinical staff issue, and we anticipate that we will, in the future, be able to obtain such data.

Although we would be interested in receiving data on the cost shifts between hospitals and other providers, we believe that the suggested use of a modifier for this purpose would be extremely difficult to implement and also burdensome for the practitioner. First, however, we must clarify that, even if the practice of bringing physician staff to the hospital pre-dates the advent of the hospital prospective payment system, any costs associated with such a practice were explicitly included in the hospital Diagnosis Related Group (DRG) payments in the September 1, 1983 interim final rule with comment and in the January 4, 1984 final rule. These rules reference section 1862(a)(14) of the Act, and the discussion makes clear that, with certain limited exceptions, all nonphysician services

furnished to hospital inpatients are to be paid under Part A. The exception provided that, for any cost reporting period beginning before October 1, 1986, a hospital that has followed a practice, since before October 1, 1982, of allowing direct billing under Part B to an extent that immediate compliance with the bundling requirements would threaten the stability of patient care, could continue to bill under Part B. There is no indication that the waiver was extended. In response to a comment, we stated the following: "In order for a payment system that is based on a national average rate for a particular diagnosis to succeed, it is vital that the services and supplies included in the payment be essentially the same in every hospital. If the statute had not included the rebundling provision, it would have been possible for hospitals to collect the full prospective payment rate for inpatient services and, at the same time, reduce their costs by having outside providers and suppliers furnish many of the necessary services and bill Part B." Furthermore, these rules state that, to calculate the PPS standardized amounts, base year costs were adjusted "to include the costs of services that were billed under Part B of the program by another provider or supplier during the base period but will be billed under Part A as inpatient hospital services effective October 1, 1983."

We do agree that it would be helpful to determine whether hospitals are still providing the staffing that is assumed in their DRG payments. To this end, we have requested that the Office of Inspector General conduct an independent assessment of staffing arrangements between hospitals and thoracic surgeons.

(iii) Supplies

In the November 1999 final rule, we deleted certain casting supplies from the CPEP data for the casting and strapping CPT codes 29000 through 29750. In the July 2000 proposed rule, we identified additional CPT codes for the treatment of fractures/dislocations and additional casting and splinting supplies that are separately billable under section 1861(s)(5) of the Act. Therefore, we proposed the removal of inputs for fiberglass roll, cast padding, cast shoe, stockingnet/stockinette, plaster bandage, Denver splint, dome paste bandage, cast sole, elastoplast roll, fiberglass splint, Ace wrap, Kerlix, Webril, malleable archbars, and elastics from the following CPT codes: 23500 through 23680; 24500 through 24685; 25500 through 25695; 26600 through 26785; 27500 through 27566; 27750 through 27848; 28400 through 28675, and 29000 through 29750.

Comment: Several specialty societies, representing orthopedic surgeons, podiatrists, and occupational therapists

supported our proposal to delete casting supplies from the CPEP inputs for all applicable fracture management and cast/strapping application procedure codes for which these supplies are separately billable. The orthopedic surgery specialty society comment also included a list of non-fracture/dislocation codes for which it recommended deleting casting supplies and another list of non-fracture codes from which the supplies should be deleted if they are separately billable for these services and left in the CPEP data if they are not. This commenter also stated that the soft goods, such as stockinette, that we propose to delete do not currently have a HCPCS code, and requested that these supplies remain on the CPEP list until a separate code is established.

Response: We appreciate the support expressed for our proposal. Consistent with the statute that limits separate payment for casting supplies only to the treatment of fractures and dislocations, we are not deleting these supplies from either of the two lists of additional codes supplied in the above comment. Also, we will delete soft goods, such as stockinette, from the CPEP data for the appropriate codes, because these are casting supplies that may be separately billed. We will, however, also request that HCPCS codes be developed for these items. Therefore, we will implement the policy as proposed.

Comment: A commenter representing dermatologists sought clarification on whether the unna boot would be separately billable. The commenter stated that the unna boot is not in the list of supplies to be deleted from the CPEP data, but CPT code 29580, *Application of paste boot*, falls within the range of codes listed under this proposal.

Response: We are not deleting the unna boot from CPT code 29580, because this code can be appropriately used for cases other than fractures, and in those cases the supply is not separately billable.

Comment: One supplier of casting supplies agreed with our proposal to delete these casting supplies from the CPEP data, but suggested that we include their product, Procel cast liner, on this list as well, to clarify that it is separately billable.

Response: The purpose of the proposal was not to list all the casting supplies that could be separately billable, but rather to delete from our CPEP input database any casting supplies that are currently listed. Because the Procel cast liner is not currently in our database, it does not need to be deleted.

(iv) Equipment

We currently use the original CPEP definitions for equipment that distinguish between "procedure specific"

equipment and "overhead" equipment. Under the "top-down" methodology, the CPEP inputs are used only as allocators of the specialty-specific practice expense pools, and we believe the distinction between types of equipment has served to hinder the process of refining the CPEP inputs while not leading to a substantive distinction in how we value services. Therefore, we proposed to combine both categories of equipment into a single "equipment" category, assuming an average 50 percent utilization for all equipment.

We also proposed to delete from the CPEP data equipment that is not used typically with any service, but is on "standby" for many services, or that is used for multiple services at the same time. The following is the list of equipment that we proposed to delete from the CPEP inputs of all services: autoclave, wheelchair, refrigerator, film file cabinet, hazard material spill kit, embryo freezer, water system, flammable reagent cabinet, utility freezer, ultra low temperature freezer, acid cabinet, bulk storage refrigerator, abortion clinic security system, abortion clinic security guard, gomco suction machine, doppler, laser printer, lead shielding, defibrillator with cardiac monitor, blood pressure/pulse oximetry monitor, blood pressure monitor, printer, crash cart--no defibrillator, and smoke evacuator.

The following is a list of equipment that we proposed to delete as "standby" equipment for most codes, but that we believed typically may be used with a designated subset of procedures:

X-ray view box--four panels (retain when currently in the CPEP data for codes in the range CPT codes 70010 through 79999).

ECG machine--3 channel (retain when currently in the CPEP data for CPT codes 93000 through 93221).

Pulse oximeter (retain when currently in the CPEP data for CPT codes 94620, 94621, 94680, 94681 and 94690; 94760 through 94770, 95807 through 95811 and 95819).

ECG/blood pressure monitor--3 channel (retain when currently in the CPEP data for CPT codes 43200 through 43202 and 43234 through 43239).

Cardiac monitor (retain when currently in the CPEP data for CPT codes 31615 through 31628).

ECG-Burdick (except for HCPCS code G0166).

Comment: All the specialty societies that commented on these proposals were supportive of what one commenter characterized as “HCFA’s efforts to streamline the treatment of medical equipment” and agreed that the changes will facilitate the refinement process. One of these commenters stated that a

standardized utilization rate overstates the use of some equipment and understates it for others and recommended that we continue to seek reliable data on this issue. Another commenter recommended that we need to provide clear and specific criteria for including medical equipment in the direct practice expense inputs, and gave three possible options—(1) equipment used primarily for a specific procedure or group of procedures; (2) all equipment used for a specific procedure; or (3) all equipment that typically must be available when a specific procedure is performed.

Response: We agree that clear criteria are needed for including equipment in the inputs for a given procedure. The major criterion used for clinical staff time and supplies is that the suggested input must be typically used in the performance of a service to be included as a direct practice expense. We believe that the same criterion should be applied to equipment. This criterion can be applied more clearly than the other options mentioned by the commenters, and, thus, should result in more consistent assignment of equipment across all services. Regarding utilization rates, we did solicit information on specific equipment utilization rates in the 1997 Notice of Intent to Regulate, but very little hard data were submitted. For most specialties, equipment costs are a very

small portion of total practice expense, averaging less than 5 percent of the total practice expense per hour for the “all physicians” category. In addition, for most equipment, a change in the utilization rate would produce a negligible difference in the practice expense RVUs for any service. Therefore, with perhaps a few specific exceptions, and because of the apparent difficulty in obtaining reliable objective data, we expect that this issue will not be a high priority issue during the refinement process.

Comment: One specialty society agreed that it is appropriate to capture as indirect expense the costs of the equipment that we have proposed to delete. The specialty society expressed concern that the SMS survey would not include most of this equipment as indirect expense, disadvantaging certain specialties who have relatively higher costs for indirect or stand-by equipment. Other commenters questioned how the costs of stand-by and multiple-use equipment can be reflected if the equipment is not included in the calculation of practice expense. One society stressed that, because of the high costs of radiology equipment, it is critical that overhead costs are accounted for.

Response: The commenter raised a valid point about the relationship between the deleted “indirect” equipment and the

SMS cost pools. The costs for this deleted equipment are included in the SMS cost pools for each specialty. However, we believe this proposal simplifies the refinement of equipment without introducing new problems. First, it is not clear whether much of this equipment, such as laser printers, lead shielding, refrigerators and freezers, cabinets, water systems, security systems, smoke evacuators and hazard material spill kits, would have been included as medical equipment or as indirect costs in the SMS survey. Second, stand-by equipment, such as crash carts, wheelchairs and ECG machines, would often be available for more than one procedure at a time. Allocating costs of these items for every service for which they are available, rather than for services for which they are typically used, can mean that we are allocating more than their actual costs and thus overstating their value. Third, the inclusion of the costs of equipment that is not typically used in a service means that we have different criteria for equipment than we do for other direct inputs. Fourth, most of this equipment is relatively low cost, which is one reason the impacts of this proposal are not significant. We also want to clarify that combining all equipment into one category does not eliminate from the practice expense calculations any of the overhead

equipment, such as the most expensive radiology equipment, that is typically used for a given service.

Comment: Societies representing various imaging specialties requested clarification on the doppler that was included in the list of potentially deleted items, because, if this is an image-directed spectral doppler, it should not be deleted. One of these commenters supported the elimination of x-ray boxes because they are no longer typically used in current radiology practice.

Response: The doppler we are deleting from all but the relevant procedures is a hand-held doppler, with a cost of $1350, that can be used on obstetric patients, not the ultrasonic doppler at $155,000.

Comment: A society representing obstetricians and gynecologists recommended that the following equipment that we proposed deleting from all services be retained for specific codes:

The doppler should be retained for the prenatal codes CPT 59400, 59425, 59426, 59510, 59610 and 59618.

The blood pressure and pulse oximetry monitors should be retained for procedures requiring anesthesia or sedation, CPT 58555, 58558, 58120, 58800, 59140, 59160, 59812, 59820, 59840 and 59841.

The suction machine should be maintained for procedures that include evacuation of the uterus, CPT 58120, 59140, 59160, 59812, 59820, 59821, 59840, 59841.

Response: We will retain the doppler, monitor and suction machine for the recommended services. Because these were the only code-specific changes recommended in comments on our equipment proposals, we will be implementing our proposals with only the above changes.

Comment: The American Academy of Dermatology (AAD) wanted clarification on whether we are proposing that dermatology-related standby equipment be assigned to the overhead category, because the specialty gains one percent on the overhead proposal and loses one percent on the standby equipment proposal.

Response: We are proposing to delete from the inputs the identified "standby" equipment from those codes for which the equipment is not typically used. It is a coincidence that the impact came out as it did.

Comment: One primary care specialty society recommended that we propose a methodology in the 2001 proposed rule for the use of an alpha-numeric code for billing unusual equipment costs associated with a procedure that are not properly captured in the practice expense data.

Response: We will certainly consider this idea, although we foresee many policy and operational difficulties in implementing this recommendation.

(v) CPEP Anomalies

In the November 1999 final rule, we made corrections to the CPEP data for a number of codes when we learned that the data contained errors and anomalies that we could easily correct. In the July 2000 proposed rule, we listed other egregious errors and anomalies that we are proposing to correct. As we have previously stated, though certain revisions may be made now, all practice expense inputs for these codes are still subject to further comment, refinement, and potential PEAC and RUC review and recommendations. We received the following comments on our proposed corrections.

Comment: A major primary care organization agreed with our decision to correct major errors in the CPEP practice expense data that had been identified by specialty societies. Another association stated appreciation for our correction of the supply list for CPT code 68761 to reflect the cost of a punctal plug.

Response: We are pleased that there was no disagreement on any of the proposed revisions we made in the November 1999 final rule and the July 2000 proposed rule to correct egregious errors and anomalies in CPEP data, with the exception of those

discussed below. Therefore, we will be implementing all other changes at this time.

Comment: Two specialty societies, representing obstetrics and family practice, pointed out that we proposed to crosswalk the CPEP inputs for CPT 59618, which includes antepartum care, delivery and postpartum care, from CPT 59410, which only includes delivery and postpartum care. They recommended that we change the crosswalk to CPT 59510, *Routine obstetric care including antepartum care, cesarean delivery, and postpartum care.*

Response: The above proposed crosswalk was a typographical error. We thank the commenters for pointing this out, and we are now crosswalking the CPEP inputs for CPT 59618 from the inputs for CPT 59510 as requested.

Comment: A specialty society representing interventional radiologists agreed that we had appropriately removed the clinical supplies listed in the facility setting for CPT codes 47510, *Insert catheter, bile duct* and 47511, *Insert bile duct drain.* They recommended that these supplies be listed in the office setting, because these are 90-day global services with two post-procedure visits.

Response: We have added post-procedure supplies to these two codes by crosswalking from the supplies assigned to CPT code 45525, *Change bile duct catheter,* adjusted for two post-visits.

Comment: A radiology specialty society objected to our proposal to crosswalk the inputs of CPT code 78206, *Liver image (3D) with flow* from the inputs of CPT code 78205, *Liver imaging (3D)*. The specialty society suggested that it will work with the PEAC and RUC to determine the appropriate additional expenses.

Response: We view crosswalks of CPEP inputs as a temporary solution, and we would welcome a recommendation from the RUC.

Comment: One specialty society commented that they had previously identified inaccurate inputs, which lead to anomalous RVUs that we have not yet addressed. The commenter requested the status of these suggested changes for 13 procedures. For 11 of these procedures there is a request to increase the number of post-operative office visits. For CPT code 52276, *Cystourethroscopy with direct vision internal urethrotomy,* the commenter questioned why the facility practice expense RVUs are much lower than those for CPT 52340, *Cystourethroscopy with incision, fulguration, or resection of congenial posterior urethral valves, or congenital obstructive hypertrophic mucosal folds*, even though the practice expenses are similar. The

commenter also noted that the supply cost for a double stent (CPEP supply code 93119) should be decreased from $359 to $150.

Response: We do not view a request to increase the number of post-operative visits as a correction of an egregious error, because it is not clear without supporting evidence that the current number of post-operative visits in our database is inappropriate. It would be most beneficial to discuss this issue with the RUC, which could then make recommendations to us. In regard to the second issue, CPT 52340, a code that will be deleted in 2001, is a 90-day global service, while CPT 52276 is a 0-day global service and therefore has lower practice expense RVUs. The double stent is currently priced at $179.50. We appreciate the information that this may be overpriced. However, we have awarded a contract to have the prices of all the CPEP clinical staff, supply and equipment inputs updated in time for next year's proposed rule and will revise the costs at that time. If the society has documentation on the correct price for this item, we will send this information to our contractor.

Comment: An association representing psychiatrists reiterated their concern regarding the physician times assigned to the psychotherapy codes that include evaluation and management services (E/M). The society recommended that the

times assigned to each psychotherapy E/M code be increased so that the total time would be 7 minutes more than the time assigned to the corresponding psychotherapy code without E/M. The commenter argued that this added time would be equal to the time assigned to CPT 99211, the lowest level office visit with an established patient, and that this corresponds to the adjustment made to the work RVUs for the psychotherapy codes with E/M services. In addition, the comment requested that we make the physician time for CPT 90847, *Family psychotherapy (with patient present), equal to CPT 90846, Family psychotherapy (without the patient present)* and the time for CPT 90857, *Interactive group psychotherapy,* equal to CPT 90853, *Group psychotherapy*.

Response: We agree that an increase of seven minutes in the physician times for the psychotherapy codes with E/M is reasonable, and we will make the appropriate changes in our physician time database. In addition, we also agree that the times for CPT 90847 and 90846 should be equal, as should the times for CPT 90857 and 90853, and we will make those increases in physician time as well.

Comment: The association representing psychiatrists also commented that the clinical staff times for psychotherapy with

E/M services are underestimated and questioned why we did not correct this as an egregious error.

Response: We included as egregious errors and anomalies only those instances where there was a clear error or anomaly in the CPEP data and also where the correct input would be obvious, without the benefit of a multi-specialty recommendation. We did not consider the clinical staff times for psychotherapy codes to fall into that category; in fact, we have concerns that the clinical staff time for most of the psychotherapy codes is, in fact, overstated. Therefore, we believe that this issue might better be dealt with initially by the RUC.

Comment: A manufacturer of diathermy equipment commented that the practice expense RVUs for CPT code 97024, *Application of a modality to one or more areas; diathermy,* are undervalued. The commenter stated that this payment rate will threaten the ability of providers to make this service available to the Medicare population.

Response: In checking our direct cost inputs for this service, neither the clinical staff time nor the supplies seem inappropriate. The issue appears to arise from a discrepancy in the cost of the diathermy machine itself. The machine in our database is priced at $2850. The price range quoted by the manufacturer is for $18,000 to $30,000. There is obviously a

wide range of machines available, and we will need to determine the most typical cost to a practice. As mentioned earlier, we have granted a contract to re-price all of our direct cost inputs, including equipment. We would welcome information on this and other equipment used by practitioners and would find recent invoices particularly helpful.

(d) Calculation of Practice Expense Pools -- Other Issues

(i) Technical Refinement to Practice Expense Pools

The Act requires payment of some practitioner services (services of certified registered nurse anesthetists, nurse practitioners, clinical nurse specialists, physician assistants, and certified nurse mid-wives) based on a percentage of the physician fee schedule payment amount. Since the payment under the physician fee schedule for a service performed by a mid-level practitioner is required to be based on a percentage of the amount paid to a physician for a service, we proposed using only physician practice expense data in determining the practice expense RVUs for each practitioner service. Removal of the services performed by mid-level practitioners from the practice expense calculations would assist in simplifying the methodology and would also be consistent with the statutory requirement that we pay for their services based on a percentage of the fee schedule amount.

Comment: A primary care organization expressed concern that removing the services performed by mid-level practitioners from the practice expense calculations might have implications that were not discussed in the proposed rule. The comment encouraged us to withdraw the proposal until there is more information and a thorough discussion of the issue. The AMA stated in its comment that it would be difficult for us to include such mid-level practitioner data since we do not have reliable information concerning the extent to which these practitioners are self-employed or are employed by physicians. The comment further noted that we have recommended that the AMA request in any practice expense survey the amount of revenue and patient care hours generated by mid-level practitioners. Another primary care organization agreed that this proposal will make the methodology more consistent with the statutory requirement.

Response: The statute specifies the payment amounts for practitioners such as nurse practitioners, physician assistants, and certified nurse specialists. Because payment for these practitioners is not based on the calculation of their own practice expense cost pools, w e are removing these services from the practice expense computations and will consider further adjustments as additional information becomes available.

(ii) Medicare Utilization Data

We have received, in response to previous rules, comments from several surgical specialties urging us to evaluate the Medicare claims data to eliminate potential errors in the specialties associated with each service. In the June 2000 proposed rule, we described the analyses we ran to determine whether potential errors in the claims data have an adverse impact on any specialty or merely represent "noise" that creates no significant effect. We tested, for neurosurgery, ophthalmology and otolaryngology, the impact of reassigning to the dominant specialty the small proportion of allowed services associated with specialties not expected to perform these services. The impacts did not even approach a 1-percent increase or decrease in any scenario.

We stated our belief that these simulations demonstrated that the small percentage of potential errors in our very large database have no adverse effect on specialty-specific practice expense RVUs. Therefore, we did not propose any further action at this time.

Comment: One surgical specialty society expressed concern that we had dismissed the impact of less than 1 percent as inconsequential and encouraged us to develop a software program

to reassign obvious errors in the specialty-specific assignment of procedures to the appropriate specialty.

Response: We believe that developing software would not be an easy solution to what we still see as an issue of little significance for the calculation of practice expense RVUs. On what basis do we decide what an obvious error would be? At this time, we do not have policies that limit payment for given services to only certain physician specialties, and we are not convinced that the medical community would actually support our doing this. In addition, because many services are performed appropriately by more than one specialty, on what basis would we decide to which specialty the services should be reassigned? Therefore, though we would certainly want the possible error rate to be zero, at this time we do not plan to propose any changes in our method of handling the utilization data for the purposes of calculating practice expense.

(iii) Allocation of Practice Expense Pools to Codes

In the July 2000 proposed rule, we discussed the work The Lewin Group had recently begun on the third phase of the project, which concentrates specifically on evaluating the indirect cost allocation methodology and considers alternatives to allocating indirect costs by the current method. We expect

their report on this analysis, which will be placed on our website, to be available soon.

Comment: Two specialty societies commented that we should develop and implement ways to reduce or eliminate the pool leakage that can occur in the weight-averaging step of our methodology when procedures are performed by multiple specialties. One commenter argued that the problem is in the allocation formula that sets up the leakage, not the averaging.

Response: These comments refer to methodological issues surrounding the development of the practice expense relative value units under the "top down" methodology. We use a combination of data on practice expense per hour from the SMS survey, the time estimated to perform individual procedures and Medicare utilization data to create aggregate cost pools. These cost pools are allocated to individual codes. Once the costs are allocated, estimates of practice expenses for individual procedures are then weight-averaged by the specialties performing each procedure to produce practice expense RVUs for a procedure. The above commenters are concerned that this process does not result in practice expense payments to each specialty that equal the aggregate cost pools. To the extent that there is "pool leakage," it implies that an individual specialty's practice expense payments are less than its aggregate practice

expense pool. The implication of the comments we have received on this issue is that specialties that receive aggregate cost payments that are less than the aggregate cost pools are underpaid. We disagree. As we indicated in the November 1999 final rule (64 FR 59390), we believe it is more likely that the aggregate practice expense pools are overstated, rather than that aggregate practice expense payments to a specialty are too low.

As we indicated both in that rule and in the June 5, 1998 proposed rule (63 FR 30832), there are two potential sources of bias in the practice expense per hour data that may result in an overstatement of the aggregate practice expense pool. First, mid-level practitioners may have been included in the numerator of the practice expense per hour calculation even though there is generally separate payment for their services. Thus, a mid-level practitioner would be analogous to an employee physician who also generates revenue and whose costs are not included in the practice expense calculation, rather than to a registered nurse or other practitioner who cannot furnish a separately billable service. Second, the mid-level practitioner's hours spent are not included in the denominator of the practice expense per hour calculation even though, like a physician, the mid-level practitioner is generating patient care revenues

during the hours spent in patient care. To the extent that a specialty depends on the use of mid-level practitioners, then the aggregate specialty practice expense pools are likely to be overstated. Based on information in our utilization data and comments made to us by one of the commenters, we believe this is the case with thoracic surgery. Rather than developing a process that ensures that aggregate practice expense payments are equal to overstated aggregate practice expense pools, we believe the better option is to address the issue of mid-level practitioners in the practice expense methodology. In this final rule, we have already addressed one aspect of this issue. Specifically, we have eliminated any utilization data that reflects that the service was performed by a mid-level practitioner. The other aspect of this proposal that we would like to address is the practice expense per hour calculation itself. As we have indicated elsewhere, we are interested in addressing this and other issues related to the practice expense methodology as we develop long-term plans for refining the practice expense RVUs beyond 2002.

(iv) Zero Work Pool

There were no proposals in the July 2000 proposed rule on this issue. However, in the November 1999 final rule, we implemented the proposal to remove requested services from the

zero work pool and return them to the specialty-specific cost pools.

Comment: Many specialty societies and the AMA expressed approval of our decision to remove a list of CPT codes from the "zero work pool" in response to specific requests to do so. Other organizations, representing specialties with technical services, supported our decisions—(1) not to modify the practice expense RVUs for diagnostic imaging "zero work" services in any substantial way at this time; and (2) to keep the zero work pool intact, at least until we can develop a methodology that accurately captures TC costs. Several commenters did express a concern that we erroneously removed from the pool an amount equal to the increased payment the removed services would receive in their own pools, rather than the payment rate the services were assigned in the zero-work pool. Another specialty society representing TC providers argued that the RVUs of the codes remaining in the pool should have been maintained at their previous level.

Response: We are pleased that there is general support of our adjustments to the zero work pool. With respect to the concern expressed, we did deal with the removal of services from the zero work pool in a manner that seems consistent with the views of the commenters. We only subtracted from the pool the

dollars for the utilization associated with the removed services, which would represent the rate the services were assigned in the zero-work pool, not the increased rate in the specialty-specific pool. With regard to the recommendation that the RVUs of the remaining services in the zero-work pool should be maintained in spite of any adjustment we make, we believe that such an approach would be unfair to the other services in the fee schedule whose practice expense RVUs are not similarly protected from the effects of changes we make in the practice expense calculations.

(e) Site of Service

Clarifying the Definition of Facility/Nonfacility

In the July 2000 proposed rule, we clarified the definition of facility and nonfacility sites of service for the purposes of practice expense calculations. This distinction takes into account the higher expenses of the practitioner in the nonfacility setting. The major purpose of this distinction is to ensure that Medicare does not duplicate payment, to the physician and to the facility, for any of the practice expenses incurred in performing a service for a Medicare patient. For purposes of the site-of-service, we have defined hospitals, skilled nursing facilities (SNFs), and ambulatory surgical centers as facilities, because they will receive a facility

payment for their provision of services. In the July 2000 proposed rule, we proposed to revise §414.22(b)(5)(i) (Practice expense RVUs) to define community mental health centers (CMHCs) as facility settings since CMHCs also receive a separate facility payment for their services.

In addition, we clarified that the nonfacility practice expense RVUs should be applied to all outpatient therapy services (physical therapy, occupational therapy, and speech language pathology), even when they are provided in a facility. Only the facility can bill for therapy services furnished to hospital and SNF patients. Because there will be only one bill for this service and because the payment must reflect the practice expenses incurred in furnishing the service, the higher nonfacility RVUs are used to pay for therapy services even in the facility setting.

Comment: Three specialty societies representing gastroenterologists reiterated their disagreement with our site-of-service policy because they believe--

· the policy offers a financial incentive for physicians to perform certain gastroenterological procedures in their offices, rather than in an ASC or hospital outpatient department;

· the policy allows the procedures to be furnished in a physician's office that does not have to meet accreditation standards;

· the wide divergence between the payments in the two settings may be encouraging the performance of gastrointestinal procedures by non-gastroenterologists; and,

· this reduction of payments for endoscopy services in the facility setting is contrary to the intent of the statute.

The commenters had varying recommendations on this issue: one comment urged us to provide the same practice expense RVUs in the facility and nonfacility settings for 18 endoscopic gastroenterological procedures. Another commenter suggested that because we now pay therapy services at the nonfacility rate regardless of setting, we should do the same for the colorectal screening codes. A major specialty society stated that it is in the process of working with gastroenterology societies to develop a proposal to create a single site-of-service payment rate for those services that are furnished less than 10 percent of the time in the office.

Response: We believe that some of the commenters continue to misunderstand the reasons for the distinction between the facility and nonfacility sites of service and the actual implications of this distinction. We have perhaps added to this

confusion by continuing, on occasion, to use the term “site-of-service differential” to describe this policy. Under the charge-based practice expense methodology, there was an actual differential; certain services were automatically reduced by a pre-determined amount when furnished in the facility setting. However, in our current resource-based “top-down” approach, we employ no such reduction. Rather, we carry out the statutory requirement to develop practice expense RVUs that reflect the relative resources involved with furnishing each service. We doubt that any specialty society would argue that the direct costs of performing a service in the office setting are not higher than in the facility setting. In the office setting, the physician must bear the costs for all of the clinical staff, supplies and equipment needed to perform a given service; in the facility setting, these costs are the responsibility of the facility. Our RVUs reflect the relative resources used in furnishing the service in each of the facility and nonfacility settings. Therefore, to the extent that we have correctly identified the relative direct costs, there should be no incentive to perform a service in either setting. It is true that we pay more to the physician if the service is furnished in the office, but that is because greater resources are involved with furnishing the service in that setting. The fact that

there is a significant difference between the facility and nonfacility payment for any given service seems to us both expected and appropriate. We believe that properly reflecting the relative resources involved with furnishing services in the facility and nonfacility settings creates no incentive to perform a service in one setting or another. In contrast, a policy that paid the same amount for a service furnished in a facility and nonfacility setting would create an incentive to furnish the service in the facility setting and, thus, would not be incentive-neutral.

We have serious reservations about adopting a policy to develop a single site-of-service payment for services that are furnished less than 10 percent of the time in the office. First, if there are real concerns regarding patient safety when certain procedures are furnished in the office, sufficient evidence should be presented to the relevant parties so that an appropriate coverage decision can be made. We emphasize that such a decision would be a coverage decision, and would not be a payment policy issue. Second, a 10-percent threshold could eliminate payment in the office setting for some high-volume procedures done thousands of times there. Third, we have some concern that this issue may be a matter of contention between those specialties that generally perform procedures in

physician-owned ASCs and other specialties that would utilize the office setting. We would suggest that this issue, either as a general proposal or on a code-specific level, be discussed in the PEAC/RUC, where a multi-specialty recommendation could then be submitted to us.

The site-of-service policy for therapy services mentioned by a commenter as a precedent is not applicable to other services in the physician fee schedule. As described above, the facility itself must bill for both the technical and professional portion of the therapy service; in these circumstances, the therapist does not bill Medicare at all. Therefore, the nonfacility RVUs are used to ensure that the facility is paid for the direct costs incurred in the service.

Comment: A specialty society representing pediatricians believed that the site-of-service differentials will likely have an adverse impact on pediatric specialty care that is primarily hospital-based. Most pediatric sub-specialists, most of whom are not hospital-employed, incur practice expense (in the form of a lease or rent) when they provide ambulatory services in a hospital-owned facility. This expense most typically includes administrative and clinical staff.

Response: We would need more information on the scenario described before we can formulate a definitive response on this

issue. For example, it is not clear whether these pediatric services as described would always be considered “facility” services. A visit to a physician’s office that is leased from a hospital could, in many circumstances, be considered a “non-facility” service by Medicare, if there is not a Part A bill for the same service. In addition, indirect expenses, such as rent or administrative staff salaries, are treated the same in all sites under our methodology. We would welcome further discussion on this issue.

Comment: A comment from an association representing providers of services in long-term care facilities contended that there should be a site-of-service differential for settings such as SNFs, where patient acuity is higher and where services must be transported to the patients. Use of data from the SMS survey for services performed outside of the physician’s office is not appropriate. An occupational therapy association stated that, though they concur with our clarification that therapy services would always be paid at the nonfacility rate, the resources necessary to provide therapy services in facilities are not adequately reflected in our practice expense calculations. A commenter representing geriatricians commented that pre- and post-care involved in nursing home visits are not reflected in the nursing home visits.

Response: The practice expense RVUs for the office and facility settings differ primarily as a result of the differences in the direct costs in these sites. Because the SNF would bear the costs of the clinical staff, supplies and equipment, the cost to the practitioner is less than it would be in the office setting. It is not clear to us how the acuity of the patients in a SNF would affect the direct practice expense costs of the practitioner, or what resources are not reflected in our calculations, since the practitioner is not responsible for the direct costs in that setting. If there is clinical staff time for staff back in the office associated with nursing home visits, this issue should be brought to the attention of the PEAC/RUC, because they are considering an approach to standardizing "coordination of care" clinical staff times for various services to make recommendations to us on this issue.

Comment: A long-term care association recommended that we clarify our policy on mixed facilities, which are SNFs that also have nursing home beds, to state that the presumption should be made that the therapist is treating a nonfacility patient. A society representing podiatrists requested confirmation of this policy.

Response: We do not agree that the above recommendation would be a clarification of our policy on "mixed" facilities.

We explicitly stated in our July 1999 proposed rule that a service in a mixed facility should be designated as a facility service (that is, the place of service would be a SNF), unless the practitioners can verify that no Part A claim will be made for the service. In the latter case, the place of service would be a nursing home, and the service would be paid at the nonfacility rate. We did not change this policy in our November 1999 final rule, and we believe that this is an appropriate policy.

Comment: Commenters were supportive of the expansion of the definition of facilities to include community mental health centers (CMHCs). However, one commenter, representing a state health department, requested that we clarify the distinction between CMHCs and other types of community mental health entities to which this would not apply.

Response: A CMHC is a distinct type of facility certified for Medicare participation for the purpose of providing "partial hospitalization services". As we had explained in the proposed rule, Medicare payment to a facility typically includes the cost of services furnished. If an entity is not participating in the Medicare program, the nonfacility practice expense RVUs would apply to the services. We believe this may not have been clear in the proposed rule. We are revising §414.22(b)(5)(i)(A) to

specifically provide that, for calculation of practice expense RVUs, a CMHC is considered to be a facility and revising §414.22(b)(5)(i)(B) to parallel the language of §414.22(b)(5)(i)(A). We also specify that the nonfacility practice expense RVUs are applicable to outpatient therapy services regardless of the actual setting.

Comment: One organization commented that the proposed rule did not address coverage or payment for "inpatient" only services performed in the outpatient setting, and referenced the outpatient PPS rule published April 7, 2000.

Response: This issue is addressed in the outpatient prospective payment system rules.

(f) Other Practice Expense Issue

Comment: One specialty society recommended that we keep the practice expense RVUs that will be fully resource-based in 2002 as interim RVUs for a minimum of another three years, during which we would consider comments for further code-level refinement.

Response: As long as there is a good faith effort on the part of all parties to continue the quality work that the PEAC/RUC has already undertaken, we do not plan to close the door on further code-level refinements in 2002. We understand the magnitude of this task and have an interest in ensuring that

there is sufficient time to deal with the CPEP inputs of all services in a thoughtful and equitable manner.

Comment: A specialty society representing neurological surgeons made a number of comments critical of the methodology used to allocate practice expenses. These criticisms pertained to virtually every aspect of the methodology. For instance, there was criticism of the CPEP data, the SMS data, and the idea that indirect practice expenses are a function of the amount of time spent in patient care activities. The commenter further indicated that the "cursory efforts to 'validate' CPEP data by having it reviewed by RUC's Practice Expense Advisory Committee (PEAC) seems more *pro forma* rather than have it based on some independent appraisal of the real costs that may be involved." In addition to the criticism cited above with respect to the methodology for allocating indirect costs, the commenter suggested that we should have summed the three indirect cost categories (administrative labor, office expense, and other expense), and allocated the result to individual codes based on the work RVUs. The commenter suggested that this was a better method than the "unnecessarily tortuous" approach we adopted that "used the total SMS pool and divided it by the pool of direct expenses…to generate a scaling factor that represented the fraction of the total that the CPEP data calculation claimed

as direct." In addition, the commenter objected to a “single adjustment” of 25 percent made to the Harvard physician time data that are being used to generate the practice cost pools. They indicated that this adjustment distorts time values for many codes. The commenter suggested that RUC time data would be more reliable than Harvard time data and that we should consider establishing a rank order reliability in the time data based on dependability of the process that generated the time values. For instance, the commenter suggested that operative logs would provide a measure of skin-to-skin time for intraoperative portion of surgical procedures that should rank above a group of estimates of the same time made by surgeons.

Response: With respect to the criticism of the CPEP data, we acknowledge that there are limitations and anomalies in the data that may distort values for some services. As required by the BBA, we have established a refinement process that will address the inputs for many codes. In this final rule, we are reflecting refinements to the practice expense inputs for office visits and office consultations. As a result, services that account for approximately 22 percent of Medicare allowed charges for physicians’ services will have been reviewed and the inputs been refined. As we describe elsewhere in this rule, we are making other refinements with respect to how equipment costs are

being allocated, and we are continuing to consult with the PEAC on developing supply cost packages that will facilitate refinement of this aspect of the practice expense inputs. Although the commenter believed that surveys of physician practices for resource inputs would be an improvement over the scrutiny being applied by the PEAC, we disagree. A survey process to collect direct cost inputs for the over 7,000 procedures on the Medicare physician fee schedule would be enormously expensive and time consuming and may be unlikely to yield better results than are being recommended by the RUC/PEAC. We believe the RUC/PEAC process allows for a multispecialty review of inputs for particular procedures. These RUC/PEAC recommendations have been helpful to us in simplifying the number of data inputs going into individual codes and in improving the overall quality of the data that are being used to determine practice expense RVUs.

With respect to the indirect methodology, the commenter is essentially suggesting that we abandon the direct inputs and use the work RVUs as the basis for allocating all indirect costs. While this approach may be simpler, we disagree that such a methodology will improve overall equity in Medicare payment for physicians' services. It would, of course, likely increase payments to specialties with relatively high work values and low

direct costs. Furthermore, we do not believe this approach would be consistent with the statutory requirement to recognize “all staff, equipment and supplies and expenses” in determining the practice expense RVUs.

We do agree with the commenter that it may be helpful to validate physician time data using independent information sources such operative logs. In fact, as we described in the July 2000 proposed rule (65 FR 44202), we have several efforts underway to obtain information on times spent performing individual procedures, including using inpatient and outpatient records and operative reports on skin-to-skin surgical times for selected procedures.

Comment: One surgical specialty society reiterated its contention that we have not been providing the impact analysis required by the BBA and requested that we do so. The osteopathic surgeons requested that we publish the impacts rounded to a tenth of a percent and that we display the impact for the entire period of the transition rather than for the individual year. A society representing radiation oncology also requested that we expand the percentage of impact by several decimal places; although the impact table for radiation oncology displays zero percentage impact for each category, there is a total increase of one percent. An ophthalmology society

requested that we publish more detailed impacts, and enumerated five additional impact analyses or tables we should include in the final rule. Three other specialty societies urged us to conduct the sensitivity analyses recommended by the GAO, because, without knowing the effect of a change in methodology or data, it is difficult to know whether the proposed change is acceptable.

Response: We have addressed these comments in previous rules. We provide a discussion of impacts in each proposed and final rule. We also provide detailed information on the HCFA web page, which allows any group to select services of interest and determine the impacts resulting from payment rates.

Comment: A commenter suggested that we should identify a way to incorporate the cost of compliance with regulations into the practice expense payments or into the annual updates to the physician fee schedule.

Response: To the extent that these costs are due to increased clinical or administrative staff time, the SMS or supplementary surveys should reflect these expenses, so they are already reflected in the practice expense calculations.

Comment: A specialty society representing podiatrists requested clarification concerning the reduction in practice

expense RVUs for CPT code 11750, *Removal of nail bed,* as compared to the previous charge-based RVUs.

Response: Because the charge-based practice expense RVUs were not based on the resources used to perform a service, the payment for many services either increased or decreased, some significantly, when we implemented resource-based practice expense. In themselves, such changes are not indicative of an error in our calculations. A comparison to the values assigned to codes in the same or similar families would be more important. It appears that the fully implemented practice expense RVUs for CPT 11750 are in the same range as the values for related services. If the specialty society believes this is not the case, we would need more information as to which codes' values appear anomalous.

Comment: An occupational therapy association noted that the fully-implemented practice expense RVUs for CPT 97110, *Therapeutic exercises* are greater than those for CPT 97530, *Therapeutic activities*, even though the CPEP inputs that we accepted should be the same for both services. The commenter also questioned why, in the November 1999 final rule, the practice expense RVUs for the occupational therapy evaluation and re-evaluation services, CPT 97003 and 97004, were lower than

those for the physical therapy evaluation and re-evaluation services, CPT 97001 and 97002.

Response: We checked the CPEP inputs for CPT codes 97110 and 97530. The time associated with the use of procedure-specific equipment for CPT 97110 was inadvertently overstated, causing a slight increase in the equipment cost for that service. We have corrected this error. In addition, as we explained in the November 1999 final rule, we deleted the tables in the equipment lists from CPT 97530 because we believed the service would typically be performed while the patient was standing. However, even when two services have identical inputs, the final practice expense RVUs can differ, if a different mix of specialties perform the two services. One reason for the difference between the occupational and physical therapy evaluation and re-evaluation services is that the occupational therapy codes were only valued by one CPEP panel. The physical therapy codes were valued by two CPEP panels, one of which estimated higher staff times than the other, giving these codes a higher average time. The refinement of these codes should remove this issue, although, for the reason explained above, the practice expense RVUs may still not be identical.

Comment: Two organizations representing audiologists submitted a joint comment which reiterated their concern regarding our use of data from the other specialties that perform audiology services to calculate the practice expense RVUs for these services. The specialty society intended to perform a survey of audiologists' practice expenses in order to gather more accurate data.

Response: We have published the criteria and process for the submission of specialty-specific supplementary survey data. We would welcome this additional information.

Comment: A specialty society representing geriatricians contended that this specialty requires more office space than other providers and wanted us to increase the space requirements beyond what is allowed for internists. They believe we have set a precedent for this by altering the space allotment for physician and occupational therapists.

Response: Under our current practice expense methodology, we do not have space requirements for any physician specialty. The amount of office space needed would presumably be reflected in the SMS indirect costs for each surveyed specialty, but we have no way of knowing what this is, or of making an adjustment to these costs for a given specialty or sub-specialty. The adjustment for the physical therapists was a different issue.

Because we believed that the crosswalk to the “all physician” rate that we used for physical therapy would overstate the indirect costs, we substituted a lower rate based on a study of physical and occupational therapists that computed costs for therapy services partially on the space used for therapy agencies and later made an adjustment to that rate. This adjustment would have no relevance to any other specialty.

Comment: A commenter objected to the use of salary equivalency guidelines to determine the indirect cost pools for physical therapists. The commenter indicated that the original estimate of 250 square feet was insufficient to reflect expenses for therapists in private practice. While we agreed that these space requirements were insufficient and increased the space to 500 square feet, the commenter continues to believe that the salary equivalency data is not an accurate measure of the expenses associated with operating a physical therapy office since these apply to therapy services furnished by an outside contractor to an outpatient hospital, skilled nursing facility, home health agency, clinic, rehabilitation agency or public health agency.

Response: In general, we believe it is better to use data that reflect a specific physician specialty or nonphysician practitioners’ costs if they are available. For the direct

expense items (clinical staff, equipment and medical supplies), there was no data available for physical therapy so we used a crosswalk to the all physician rate. For the indirect cost items, we used the information that is directly applicable to physical therapy for use in the practice expense methodology. While the use of salary equivalency guidelines data may have been developed for contract physical therapists providing services in facilities, we believe that a potential shortcoming for its use is related to the number of square feet of space that are allotted for each therapist. In response to previous comments we increased the space allocation to 500 square feet in the November 1999 final rule (64 FR 59404). While we are currently using 500 square feet for the space allotment and believe that that amount may recognize some components of indirect costs, the figure still may understate the space requirements for private practice physical therapists because it does not recognize other components of indirect costs that are not incurred by contract physical therapists working in a facility setting. In an earlier comment, the American Physical Therapy Association indicated that 250 feet square feet is inadequate for physical therapists in private practice. The comment indicates that approximately 700 to 850 square feet per therapist are necessary. We are increasing the space

requirements from the salary equivalency guidelines for physical therapy to 750 square feet. This revision will result in use of the following practice expense per hour for physical therapy for calculation of the 2001 practice expense RVUs:

Clinical Staff	Admin Staff	Office Expense	Supplies	Equipment	Other	Total
12.3	5.8	7.5	7.3	3.1	4.4	40.4

Comment: Many individuals and several specialty groups expressed concern about the relatively low rates contained in the July 2000 proposed rule with respect to pain management services. They suggested that this may be due to the practice expense component for these services being undervalued. They also pointed out that a few of the services seemed to have significant reductions.

Response: A few of the pain management codes were affected by a programming error related to work RVUs. We apologize for the error and ensured that this was corrected in this final rule. To the extent that the rates are low due to the practice expense component being undervalued, we would recommend that specialty groups forward the codes in question to the RUC/PEAC for refinement.

B. Geographic Practice Cost Index Changes

The Act requires that payments vary among fee schedule areas to the extent that resource costs vary as measured by the GPCIs. Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. This section of the Act also requires us to phase in the adjustment over 2 years and implement only one-half of any adjustment in the first year if more than 1 year has elapsed since the last GPCI revision.

The GPCIs were first implemented in 1992. (A detailed discussion of the development of the GPCIs and references to obtaining studies on the development of the GPCIs can be found in the July 17, 2000 proposed rule (65 FR 44189). The first review and revision was implemented in 1995, and the second review was implemented in 1998.

The 2001 through 2003 GPCIs represent the third GPCI update. The 2002 GPCIs (Addendum D) are the fully-revised GPCIs. The 2001 GPCIs (Addendum E) represent the one-half transition GPCIs. Addendum F shows the estimated effects on area payments of the fully-revised 2002 GPCIs. The payment effects in 2001 will be about one-half of these amounts.

The same data sources and methodology used for the 1998 through 2000 GPCIs were used for the 2001 through 2003 GPCIs.

The only differences between the 1998 through 2000 GPCIs and the proposed GPCIs are in the cost shares and RVU weighting.

1. Work Geographic Practice Cost Indices

The work GPCIs are based on the decennial census. The 1992 through 1994 work GPCIs were based on 1980 census data because 1990 census data were not yet available. The work GPCIs were revised in 1995 with new data from the 1990 census. New census data will not be available again until after the 2000 census. We searched for other data that would enable us to update the work GPCIs between the decennial censuses, but no acceptable data sources were found.

We therefore made no significant changes to the 2001 through 2003 work GPCIs from the 1998 through 2000 work GPCIs, other than the generally negligible changes resulting from using 1998, rather than 1994, RVUs for this GPCI update, because we were unable to find acceptable data for use between the decennial censuses. We believe that making no changes is preferable to making inaccurate changes based on unacceptable data. We believe that this is a reasonable position given the generally small magnitude of the changes in payments resulting from the changes in the work GPCIs from the 1980 to the 1990 census data.

2. Practice Expense Geographic Practice Cost Indices.

a. *Employee Wage Indices.*

As with the work GPCIs, the employee wage indices are based on decennial census data. For the same reasons discussed above pertaining to the work GPCIs, we are not changing the employee wage indices during this GPCI update.

b. *Rent Indices.*

The office rental indices are again based on HUD residential rent data. No changes have been made in the methodology. The rental indices are based on 2000 rather than 1994 HUD data.

c. *Medical Equipment, Supplies, and Miscellaneous Expenses.*

As with all previous GPCIs, this component will be given a national value of 1.000, indicating no measurable differences among areas in costs.

3. Malpractice Geographic Practice Cost Indices.

As with the previous GPCIs, malpractice premium data were collected for a mature "claims made" policy with $1 million to $3 million limits of coverage, with adjustments made for mandatory patient compensation funds. The only difference is that we proposed to use more recent data. The proposed malpractice indices are based on 1996 through 1998 data, compared to the 1992 through 1994 data used in the previous GPCI update.

We received the following comments and responses on our proposed GPCI changes.

Comment: One commenter stated that Medicare physician reimbursement should not vary by geographic area.

Response: The law requires that payments vary among payment localities as locality cost differences vary as measured by the GPCIs. However, the work GPCI by law reflects only ¼ of the difference in the relative value of physicians' work in the area and the national average.

Comment: One commenter stated that we should not use census data on the earnings of other highly educated professionals as a proxy for physician earnings. The commenter suggested that we instead use IRS income tax data on actual physician income, which also has the advantage of being available on an annual basis rather than every 10 years like the decennial census.

Response: As stated in this year’s proposed rule and in all previous reports on the GPCIs, the actual reported earnings of physicians were not used to adjust geographical differences in fees because the fees are in large part a determinant of the earnings. We believe that the earnings of physicians will vary among areas to the same extent that the earnings of other professionals vary. The GPCI compares average hourly wages of

professionals among geographic areas. IRS data on the earnings of physicians and other professionals were previously examined as a possible work GPCI data source. The IRS data were rejected for numerous reasons, chiefly because--(1) they did not control for hours worked, and thus, average hourly earnings could not be determined; (2) the business tax returns of physicians and other professionals include entrepreneurial return, as well as the opportunity cost of time (what a physician on salary could earn per hour); and, (3) the business returns contain no information on the number and mix of employees (physicians are included with other nonphysician employees). The Medicare physician fee schedule is based on the principle that fees should reflect costs, such as opportunity wages, but not other factors, such as entrepreneurial profit.

Comment: Two commenters stated that the rent GPCI for Puerto Rico is severely understated. They believe the HUD rental data to be inordinately low relative to the national average because of the high level of poverty in Puerto Rico. They believe that physician rents are relatively higher compared to the national average than reflected by the HUD data. The commenters suggested that we fund a special study to examine the rental costs in Puerto Rico to see if the HUD rent proxy is inadequate to reflect physician rental costs, and, if so, to

expand the study to other areas with inordinately high poverty rates.

Response: For the next GPCI update, we will again look for alternative sources to the HUD data.

Comment: One commenter whose malpractice GPCI would have decreased under the proposed rule stated that this would reflect decreasing malpractice premiums, while in reality their malpractice premiums have increased since 1997, and, therefore, their malpractice GPCI must be wrong.

Response: A decreasing malpractice GPCI does not necessarily reflect decreasing malpractice premiums. An area's malpractice GPCI reflects its relative position compared to the national average. An area could have increasing malpractice premiums and still experience a decrease in its malpractice GPCI if its premiums increased less than the national average rate of increase.

Comment: A commenter from Kansas commented that Kansas prohibits territorial rating of malpractice premiums within the State; yet we show two different malpractice GPCIs for Kansas. They state that one of these must be an error.

Response: We agree. Kansas is a single statewide locality under the physician fee schedule. We show two sets of GPCIs because Kansas is served by two carriers. However, the GPCIs

should be the same. The malpractice GPCI shown in the proposed rule for carrier 00740 was erroneous. Both carriers should have the same malpractice GPCI of 0.823.

Result of Evaluation of Comments

The 2002 fully-effective revised GPCIs and the transitional 2001 revised GPCIs can be found at Addendum D and Addendum E, respectively. No changes were made in the 2002 and 2001 GPCIs from those proposed in the July 17, 2000 proposed rule, except to correct the erroneous Kansas malpractice GPCI discussed above. Since the revised GPCIs could result in total payments either greater or less than payments that would have been made if the GPCIs were not revised, it was necessary to adjust the GPCIs for budget neutrality as required by law. Therefore, we adjusted the 2001 through 2002 GPCIs as follows: work by 0.99699; practice expense by 0.99235; and malpractice by 1.00215.

C. Resource-Based Malpractice Relative Value Units

Resource-based malpractice RVUs replaced the prior charge-based malpractice RVUs on January 1, 2000. A detailed description of the methodology used in establishing the 2000 malpractice RVUs can be found in the July 1999 proposed rule (64 FR 39610) and the November 1999 final rule (64 FR 59383). The 2000 malpractice RVUs are based on 1993 through 1995 malpractice

insurance premium data, the latest data available when we began collecting data to establish the resource-based malpractice RVUs. We stated in last year's proposed and final rules that we were collecting more recent premium data, and would update the malpractice RVUs as soon as we had finished collecting and analyzing the more recent data.

In the July 2000 proposed rule we stated that we had obtained, and were currently examining, malpractice premium data for 1996 through 1998. We provided a table that compared the 1993 through 1995 average premiums (used to calculate the 2000 malpractice RVUs) with the 1996 through 1998 average premiums (used to calculate the 2001 malpractice RVUs). The table showed that there was very little change in the national average premiums from 1993 through 1995 to 1996 through 1998. We, therefore, anticipated minimal changes in malpractice RVUs from use of the more recent data.

In addition, in response to comments received on last year's rule, we proposed to accept a comment regarding crosswalking specialties. We proposed to crosswalk surgical oncology to general surgery rather than to all physicians. We also indicated that the malpractice values to be included in the final rule reflecting the updated data would remain interim.

Comment: Numerous commenters commended the use of more recent 1996 through 1998 malpractice premium data to replace the 1993 through 1995 data in calculating the malpractice RVUs.

Response: We plan to use the most recent available data in updating malpractice RVUs.

Comment: Commenters stated that since the proposed 2001 malpractice RVUs were not available for comment in the July proposed rule, and are being seen for the first time in this final rule, they be considered interim and subject to comment and revision.

Response: We agree. The proposed 2001 malpractice RVUs will be considered interim, subject to revision in 2002 based on comments received on this final rule.

Comment: Some commenters stated that they were unable to duplicate the malpractice RVU calculations using the premium data and risk factors shown in our previous proposed and final rules. They requested that we provide them with all necessary information to reproduce the malpractice RVUs.

Response: To address this concern, we had our contractor, KPMG Consulting, prepare a technical addendum. This addendum presents a detailed explanation of all of the information used--a table of specialty premiums, risk factors for each specialty either from the premium data or insurer rating manuals, code

crosswalks for new and revised CPT codes, and the budget-neutrality factor used by KPMG--with examples of the methodology used in calculating the malpractice RVUs. It also discusses special circumstances, such as the use of different risk factors for OB/GYN for surgical, nonsurgical, and delivery services, and the use of the surgical risk factor for cardiology for certain cardiac catheterization services even though the services are not in the surgery section of CPT. When combined with our 1999 specialty utilization data, it should be possible to reproduce KPMG's malpractice RVU calculations. This technical document can be found at Addendum G.

Comment: One commenter stated that we should explore the collection of non-M.D. and non-D.O. premium data (such as for podiatrists, chiropractors, and nurse practitioners) for future malpractice RVU updates.

Response: We will consider searching for such data for specialties such as podiatrists and chiropractors. We would not expect to collect such information for groups such as nurse practitioners since the law establishes their payments at 85 percent of the physician rate.

Comment: One commenter suggested that certain invasive electrophysiology codes, have the same relative risks as cardiac catheterization codes, and should be assigned a surgical risk

factor similar to the risk factor assigned to cardiac catheterization codes.

Response: We agree, and have assigned a surgical risk factor to CPT codes 93600 through 93612, 93618 through 93641, and 93650 through 93652.

Comment: One commenter stated that since most OB/GYNs perform both obstetrics and gynecology, the higher obstetrics premium should be used for all services performed by OB/GYNs.

Response: We disagree. This comment was also addressed in the November 1999 final rule. To reiterate our response, it is true that a physician furnishing a wide range of services—-from low-risk visits to high-risk surgeries or deliveries—-will probably pay a malpractice premium driven by the higher-risk procedures.

The purpose of the resource-based malpractice RVUs is not to guarantee each physician an absolute return of malpractice costs. It is rather to construct malpractice RVUs based on the relative malpractice costs among services. We believe that it is reasonable to use the lower risk factors for the values of the lower risk services and to allocate the higher relative values to the higher risk services that cause them. In the case of OB/GYN services, the higher obstetrical premiums were used for services that were clearly obstetrical and were causing the

higher obstetrical premiums; the gynecological surgical risk factor was used for the surgical services, and the lower nonsurgical GYN risk factor was used for all other services. We would further note that even if we were to adopt the approach suggested by this comment, it would have very little, if any, impact on payment rates since OB/GYN specialties perform such a small proportion of the low risk visits provided to patients in the U.S.

Result of Evaluation of Comments

New malpractice RVUs based on the more recent 1996 through 1998 premium data will become effective on January 1, 2001. These malpractice RVUs will be considered interim for 2001 and subject to comment and possible revision in 2002. These malpractice RVUs can be found in Addendum B.

D. Critical Care Relative Value Units

Based on revisions to the definition of critical care services (CPT codes 99291 and 99292) in the CPT manual for CY 2001, we proposed to value the physician work at 4.0 RVUs for CPT code 99291 and 2.0 RVUs for CPT code 99292.

In addition, consistent with our discussion in the July 2000 proposed rule for electrical bioimpedance (EB), (see section H), we proposed not to allow separate Medicare payment

for EB when it is furnished in conjunction with critical care services (CPT codes 99291 and 99292).

Comment: Commenters supported the revision to the physician work for these two codes. However, in the regulatory impact section of the July 2000 proposed rule (65 FR 44208), we stated that "...any impact of this proposal would be incorporated in the physician fee budget neutrality calculations." Commenters believed it would be inappropriate to make a budget neutrality adjustment, since we made no adjustment last year. They argue that such an adjustment would skew payments.

Response: As indicated in the previous response, we are restoring the work RVUs for critical care to 4.0 for CPT code 99291 and 2.0 for CPT code 99292. The earlier reductions to the work RVUs were made assuming there would be a substitution of critical care for other services that would increase net payments if there were no reductions to the work RVUs. We believe this substitution will not occur because of additional revisions to the definition of critical care for 2001. Thus net payments would decrease if we do not restore critical care RVUs to their former levels.

Comment: One commenter urged that we reconsider including payment for EB services within the critical care codes, because

they believed it would have a negative impact on its use in hospitals.

Response: The physician work required to perform this service involves reading and interpreting a series of numerical measurements. This is generally performed in conjunction with an evaluation and management service because the measurements produced by this procedure are difficult to interpret without a clinical evaluation of the patient. We continue to believe that it is appropriate to include payment for this service within the critical care service since the critical care service includes the review of EB tests. Other services such as the interpretation of cardiac output measurements (CPT 93561 and 93562) are currently included in the payment for critical care services, and we do not believe this has had an adverse impact on their performance in the hospital.

Result of Evaluation of Comments

We will finalize our proposal and value the physician work at 4.0 RVUs for CPT code 99291 and 2.0 RVUs for CPT code 99292. In addition, we will not allow separate Medicare payment for EB when provided in conjunction with critical care services (CPT codes 99291 and 99292).

E. Care Plan Oversight and Physician Certification and Recertification

In anticipation of CPT revisions to the definition of care plan oversight, we proposed establishing two new HCPCS codes for care plan oversight to be consistent with our payment policies. For the 2001 physician fee schedule, we proposed adding a new HCPCS code G0181 (care plan oversight, home health), using the CPT 2000 definition associated with CPT code 99375 and a new HCPCS code G0182 (care plan oversight, hospice) using the CPT 2000 definition associated with CPT code 99378. The definitions proposed for these new codes are:

G0181 Physician supervision of a patient under care of Medicare-covered home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved with the patient's care, integration of new information into the treatment plan and/or adjustment of medical therapy, within a calendar month; 30 minutes or more.

G0182 Physician supervision of a patient under care of Medicare-covered hospice (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of laboratory and other studies, communication (including telephone

calls) with other health care professionals involved with the patient's care, integration of new information into the treatment plan and/or adjustment of medical therapy, within a calendar month; 30 minutes or more.

We also stated that current policy guidance that applied to CPT codes 99375 and 99378 will continue to apply to these G codes, and current payments for CPT codes 99375 and 99378 will be maintained in G0181 and G0182.

In addition, we proposed establishing two new HCPCS codes (G0180 and G0179) to describe the physician's services involved in physician certification (and recertification) of Medicare-covered home health services. These services include creation and review of a plan of care for a patient and verification that the home health agency initially complies with the physician's plan of care. The physician's work in reviewing data collected in the home health agency's patient assessment, including the Outcome and Assessment Information Set (OASIS) data, would be included in these services.

The proposed text for the new codes was as follows:

- G0180 (referred to as Gxxx3 in the proposal but renumbered in this final rule) Physician services for the initial certification of Medicare-covered home health services, for a patient's home health certification period, and

- G0179 (referred to as Gxxx4 in the proposal but renumbered in this final rule) Physician services for the recertification of Medicare-covered home health services, for a patient's home health certification period.

Under the proposed rule, the use of these codes would have been restricted to physicians who are permitted to certify that home health services are required by a patient according to section 1814(a)(2)(C) and section 1835(a)(2)(A) of the Act.

Under the proposed rule, the physician certification for home health code (G0180), could be reported only once every 60 days, except in the rare situation when the patient starts a new episode before 60 days elapses and requires a new plan of care to start a new episode. For services within the episode (generally beyond the first week or two of care plan implementation) that are consistent with the definition of care plan oversight, the care plan oversight code (G0181) would be used.

Because we believed that the physician work associated with HCPCS code G0180 is equivalent to that of a level 3 established patient office visit (CPT code 99213), we proposed a value of 0.67 for the work RVUs. For G0179, we proposed a value of 0.45 work RVUs because we believe the work equates to a level 2 established patient office visit (CPT code 99212). For practice

expense RVUs, we proposed to crosswalk both G0180 and G0179 to the practice expense inputs currently used for care plan oversight (CPT code 99375), since both the certification and recertification and care plan oversight codes do not require a face-to-face encounter between the beneficiary and the physician.

Care Plan Oversight

Comment: Several commenters objected to our proposal for G codes for care plan oversight services because the rationale presented in the July 2000 proposed rule (65 FR 44196) for the change was not clear. They stated that the public was not aware of specific definition changes proposed by the CPT panel, so they could not determine whether the new CPT definitions conflicted with Medicare policy. Thus, the commenters challenged the need for such a complicated change.

Response: We understand the concerns of the commenters but we were at that time unable to provide the full text of the revised CPT codes in the proposed rule. The CPT Committee had not yet released the definitions. The 2001 revised CPT code definitions for CPT codes 99375 and 99378 make a significant change. Specifically, the new definitions include the time the physician spends communicating with non-professional caretakers involved in delivering the home health or hospice services.

While we recognize that non-health professionals contribute to the care of both home health and hospice patients, our long-standing policy has been that payment for these services is included in the payment for evaluation and management services. As we indicated in the December 8, 1994 final rule (59 FR 63421) that originally established Medicare policies for care plan oversight services, we recognize for separate payment only the physician's communications to the health care professionals involved in the patient's care. The goal in care plan management is to be certain that the home health or hospice professional staff communicate with the patient's physician to allow the beneficiary to receive appropriate care. This continues to be the justification for an additional payment.

Comment: One organization requested clarification on whether nurse practitioners are able to bill for care plan oversight and physician certification and recertification services. They stated that the preamble discussion suggested only physicians may bill for these services. The commenter believed that under the provisions of the BBA, nurse practitioners practicing within the scope of State law are also permitted to perform these services.

Response: Under the provisions of the BBA, nurse practitioners, physician assistants and clinical nurse

specialists, practicing within the scope of State law, can bill for care plan oversight services. These non-physician practitioners must have been providing ongoing care for the patient through evaluation and management (E/M) services (but not if they are involved only in the delivery of the Medicare-covered home health or hospice service). Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require that physicians certify and recertify the necessity of home health care in order for a particular beneficiary to receive covered services. Thus, without regard to payment issues, in order to be effective, a certification must be made by a physician. We agree with commenters that, according to section 1861(s)(2)(K) of the Act, nurse practitioners and others can perform and, where appropriate, bill for a service that is a physician service and within the scope of their practice. In adopting codes for certification and recertification of home health services and denominating them as billable physician services, we might be perceived as enabling these practitioners to bill those codes. However, nurse practitioners and others not specified under section 1861(r) of the Act cannot meet the requirements for certifying and recertifying home health services under sections 1814 and 1835 of the Act that

independently require physician certification and recertification to establish the necessity of treatment.

Comment: Many commenters indicated they knew about the CPT panel's plans to change the code definition for 2001. They indicated that the CPT definition revision adding the reference to non-health professionals was merely to clarify that communication with these individuals is sometimes just as integral in providing good care. Some commenters also suggested that this was allowable when the codes were originally developed.

Response: We disagree with the commenters. When we originally established a separate payment for this service, we established a G code to describe the service. The CPT subsequently adopted the code. It was always our intent, as discussed above, to count the time spent with other health care professionals toward the 30-minute threshold. Although we agree that interactions with non-health care professionals are important to the overall care of patients, as explained in the previous response, such communication is included in the pre-visit and post-visit work of evaluation and management codes.

Comment: Many commenters expressed concern that adopting these G codes would complicate billing for care plan oversight services and exacerbate confusion surrounding these services,

particularly since two sets of codes will exist for care plan oversight (CPT and HCPCS).

Response: Although we understand the commenter's concern, we feel the revised definitions for CPT codes 99375 and 99378 necessitate the establishment of temporary HCPCS codes G0181 and G0182. To assure consistency with current Medicare policy, we find it necessary to retain the current definitions of care plan oversight by the use of temporary HCPCS codes G0181 and G0182.

Certification and Recertification

Comment: Commenters generally supported the proposed new codes for certification and recertification, and some commenters emphasized that the codes will have a positive impact on patient care and also enhance the role of the physician in home care. However, some commenters were concerned that the CPT/RUC process was not used for the introduction of these codes, and recommended that these codes be submitted to the CPT panel for establishment of codes.

Response: We wanted the home health certification and recertification codes to become active as soon as possible after the implementation of Medicare's new home health prospective payment system that was effective October 1, 2000. Requesting the CPT panel to adopt these codes was likely to delay their

introduction. However, we will now ask the CPT panel to consider adopting these codes.

Comment: A few commenters expressed concern that the proposed values for the codes were provided with no explanation; thus, it was difficult to evaluate the proposal.

Response: To value these codes, we estimated the value of the work involved. We expect to re-evaluate these services once physicians become more familiar with the new home health payment system and use of this procedure code. In addition, if the CPT panel adopts the codes, we expect that the RUC would also review them.

Comment: A few commenters asked whether surgeons may bill for this service or whether the service is included in the surgeon's global fee. These commenters recommended that surgeons be allowed to bill outside the global surgery rules.

Response: Surgeons who refer patients for Medicare-covered home health care and who are certifying (or recertifying) the plan of care will be able to report codes G0179 and G0180.

Comment: We received comments that objected to our proposal to adjust the conversion factor to assure that physicians expenditures would not increase as a result of separate payment for this service. Some commenters stated that a budget-neutrality adjustment should not be performed because

they believed these were new services that should appropriately increase physician expenditures.

Response: We address this comment in the impact section of this rule.

Comment: One commenter suggested we revise the definition of certification and delete reference to a "patient who has not received Medicare-covered home health services for at least 60 days." There are scenarios when a patient may require a new initial certification but 60 days have not lapsed.

Response: Based on the opinions of our medical experts, we believe that creating a new plan of care is significantly more work than making even major modifications to a home health care plan. We plan to reconsider this issue once we have more experience with these codes.

Comment: Another commenter expressed concern about the ambiguity of codes for care plan oversight, certification, and recertification. The commenter also believed we needed to take a more comprehensive approach to informing physicians about the home health prospective payment system and new codes.

Response: We expect the discussion of these codes in this preamble to clarify their use. If additional questions remain, they can be addressed to our contractors who process Medicare

bills. Our contractors will notify physicians about fee schedule changes for 2001.

Result of Evaluation of Comments

For care plan oversight, we are establishing the following two new codes as proposed:

- G0181 Physician supervision of a patient receiving Medicare-covered services from a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 30 minutes or more, and
- G0182 Physician supervision of a patient receiving Medicare-covered services from a Medicare-participating hospice (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including phone calls) with other health professionals involved

in patient’s care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 30 minutes or more.

As stated in the proposed rule, current policy guidance that applied to CPT codes 99375 and 99378 will continue to apply to these G codes, and current payments for CPT codes 99375 and 99378 will be maintained in G0181 and G0182, respectively.

For the services involved in physician certification (and recertification) and the development of a plan of care for a patient for whom the physician has prescribed Medicare-covered home health services, we are establishing two new codes as proposed:

- G0180 Physician services for initial certification of Medicare-covered home health services, billable once for a patient’s home health certification period. This code will be used when the patient has not received Medicare-covered home health services for at least 60 days.
- G0179 Physician services for recertification of Medicare-covered home health services, billable once for a patient’s home health certification period. This code would be used after a patient has received services for at least 60 days (or one certification period) when the physician signs the certification after the initial certification period.

The G0179 code will be reported only once every 60 days, except in the rare situation when the patient starts a new episode before 60 days elapses and requires a new plan of care to start a new episode. For services within the episode that are consistent with the definition of care plan oversight, the care plan oversight code (G0181) would be used.

Consistent with section 1835(a)(2) of the Act, a physician who has a significant ownership interest in, or a significant financial or contractual relationship with a home health agency (HHA), generally cannot bill this code for patients served by that HHA.

We have retained the proposed relative values, for the reasons stated earlier. The physician work associated with HCPCS code G0180 will be valued at 0.67 and for G0179 the physician work will be valued at 0.45. We will use the practice expense inputs used for care plan oversight (G0181) for both codes.

F. Observation Care Codes

In the July 17, 2000 proposed rule (65 FR 44196) we indicated that allowing payment under the fee schedule for CPT codes 99234 through 99236, Observation or inpatient hospital care services (including the admission and discharge services) for a patient on the same date, conflicts with two policies currently in the Medicare Carrier Manual (MCM). Section 15505.1(c) in the MCM states that we only pay for a hospital admission when a patient is admitted as an inpatient and is discharged on the same day. Section 15504.b of the MCM states that CPT codes 99218 through 99220 (Initial Observation Care) should be used if the patient is discharged on the same day as the admission for observation only. Observation care discharge (CPT code 99217) may be used only on the second or subsequent days for observation care.

These policies also result in different payments for patients whose inpatient stay is less than 24 hours based solely on whether they were in the hospital at midnight. For example, a physician who admits a patient to observation or to inpatient care at 8 a.m. and then discharges the patient at 8 p.m. the same day is paid for only the admission service. On the other hand, a physician who admits a patient to observation or to inpatient care at 8 p.m. and then discharges the patient at

8 a.m. the next day, is allowed payment for both the admission and discharge services.

In response to these concerns, and to clarify our payment policy, we proposed the following:

Inpatient stay of 24 hours or more

We would pay for both inpatient hospital admission services (CPT codes 99221 through 99223) and hospital discharge services (CPT codes 99238 and 99239) when a patient is a hospital inpatient for a period of 24 hours or more. The medical record would have to document that the patient was an inpatient for at least 24 hours for both of these services to be paid.

Inpatient or observation stay of less than 8 hours

If a patient is admitted as a hospital inpatient or an observation care patient for less than 8 hours, we will pay for only the admission service (CPT codes 99221 to 99223 or 99218 to 99220) on that day. The discharge service is not a separately billable service.

Inpatient or observation stay of 8 or more hours, but less than 24 hours

If a patient is admitted as a hospital inpatient or an observation care patient for a period of 8 or more hours, but less than 24 hours, we will pay for both the admission and discharge services under CPT codes 99234 through 99236 with the

following proposed physician work RVUs and documentation requirements:

Physician Work RVUs

To properly value both the admission and discharge work of these services, we proposed to continue valuing the admission portion of the physician work as equivalent to CPT codes 99218 through 99220 (or CPT codes 99221 through 99223) and to reduce the discharge work RVUs from 1.28 to 0.67. Thus, the work RVUs would be as follows: CPT code 99234--1.95 RVUs; CPT code 99235--2.81 RVUs; CPT code 99236--3.66 RVUs. Our policy would allow payment for CPT codes 99234 through 99236 only for stays of equal to or greater than 8 hours, but less than 24 hours.

In addition to the documentation guidelines for history, physical examination, and medical decision making described in CPT 2000 for CPT codes 99234 through 99236, we proposed requiring the following to be documented in the medical record:

- A stay involving 8 hours, but less than 24 hours.
- The billing physician was present and personally performed the services.
- The admission and discharge notes were written by the billing physician.

Comment: A number of commenters disagreed with our proposal. They stated that we recently accepted the work values

for CPT codes 99234 through 99236 and should not make changes now. They also stated that, instead of finalizing our proposal, we should change our payment policy in the MCM regarding payment for hospital admissions and discharges on the same day. Other commenters said that the proposed documentation requirements were onerous. These commenters said that the work value for discharging a patient on the same day as admission to the hospital or observation was the same as the work value for discharging a patient in the hospital for one or more days.

Response: We agree with the commenters that the work value for discharging a patient on the same day as admission is similar to the work value for discharging a patient on subsequent days.

We disagree with the commenters on the subject of documentation. We do not believe it is onerous to require a physician to document the length of time the patient remains in observation status. Minimal documentation, such as noting the hours in observation status, is required in the medical record to do this. There are other reasons to document the time a patient was seen and orders were written. For example, such documentation allows physicians and facilities to improve the quality of care they deliver. We also continue to believe that a recorded time requirement is necessary to assure that patients

are truly being observed and treated for conditions that require ongoing care. Regarding payment for admission and discharge on the same day, we have long established policy that we will pay for only one E/M service per physician per patient per day for the same diagnosis, and we do not wish to revisit that policy.

Admission and discharge of a patient from observation or the hospital on the same calendar date should be billed as CPT code 99234 or 99235 or 99236. The hospital and observation admission/discharge codes should be used when a patient is admitted and discharged on different calendar dates.

In view of the foregoing explanation, our policy is as follows:

- The relative work values of CPT codes 99234 through 99236 will remain unchanged.
- For a physician to appropriately report CPT codes 99234 through 99236 for Medicare payment, the patient must be an inpatient or an observation care patient for a minimum of 8 hours on the same calendar date.
- When the patient is admitted to observation status for less than 8 hours on the same date, then CPT codes 99218 through 99220 should be used by the physician and no discharge code should be reported.

- When patients are admitted for observation care and then discharged on a different calendar date, the physician should use CPT codes 99218 through 99220 and CPT observation discharge code 99217.
- When patients are admitted to inpatient hospital care and then discharged on a different calendar date, the physician should use CPT codes 99221 through 99223 and CPT hospital discharge day management codes 99238 or 99239.
- For an inpatient admission and discharge less than 8 hours later on the same calendar date, CPT codes 99221 through 99223 should be used for the admission service, and the hospital discharge day management service should not be billed.
- The physician must satisfy the documentation requirements for both admission to and discharge from inpatient or observation care to bill CPT codes 99234, 99235, or 99236. The length of time for observation care or treatment status must also be documented.

We believe that this policy meets the concerns of the commenters and allows us to resolve the discrepancies in payment policy regarding same day hospital and observation care admission and discharge.

Result of Evaluation of Comments

The work RVUs for CPT codes 99234 through 99236 used for reporting admission for observation care, or inpatient hospital care and discharge on the same calendar date will not be changed. The policies outlined above must be followed when reporting these codes.

G. Ocular Photodynamic Therapy and Other Ophthalmological Treatments

Ocular photodynamic therapy (OPT) is a treatment recently approved by the Food and Drug Administration for age-related macular degeneration, the most common cause of blindness in the elderly. For CPT 2000, ocular photodynamic therapy was added to CPT code 67220, which was formerly limited to photocoagulation by laser. Because we believe that OPT is significantly different from laser photocoagulation, we proposed to establish new HCPCS codes that specifically identify these procedures as follows:

Gxxx5 "Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photocoagulation (e.g., by laser), one or more sessions." We proposed using this code in place of CPT code 67220 and maintaining the work and malpractice RVUs and the CPEP inputs presently used for CPT code 67220 for payment of this new "G" code.

Gxxx6 “Destruction of localized lesion of choroid (e.g., choroidal neovascularization); ocular photodynamic therapy (includes intravenous infusion).” We proposed a value of 0.55 work RVUs and 0.52 RVUs for the malpractice component with a global period of "XXX.”

We also proposed the following practice expense inputs for non-facility settings:

· *Clinical Staff Time.* Registered nurse/ophthalmology technician -- 40 minutes;

· *Supplies.* Ophthaine, mydriacil, myolfrin, gonisol, post myd spectacles, verteporfin and also infusion supplies including sterile and non-sterile gloves, butterfly needle, syringe, band aid, alcohol swab, staff gown, iv infusion set, and infusion pump cassette;

· *Equipment.* Laser, infusion pump, and exam lane. We noted that, while we proposed establishment of procedure codes for ocular photodynamic therapy, coverage of the procedure is at the discretion of the local carrier.

In instances where both eyes are treated the same day, we proposed the use of the following HCPCS add-on code:

Gxxx7 "Destruction of localized lesion of choroid (e.g., choroidal neovascularization); ocular photodynamic therapy (includes intravenous infusion)-other eye." (List separately in

addition to Gxxx6.) For this add-on code we proposed a "ZZZ" global period, with .28 work RVUs (half of that proposed for Gxxx6) and .52 malpractice RVUs (identical to that proposed for Gxxx6). The proposed practice expense inputs for services in the non-facility setting were as follows:

· *Clinical Staff Time.* Registered nurse/ophthalmology technician - 5 minutes;

· *Supplies.* Ophthaine, mydriacil, myolfrin, and gonisol.

In addition, we identified several other specific ophthalmological treatments that are not distinctly identified in CPT 2000. We proposed to establish specific HCPCS codes for these procedures:

"Destruction of localized lesion of choroid (e.g., choroidal neovascularization); transpupillary thermotherapy, one or more sessions";

"Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photocoagulation, feeder vessel technique, one or more sessions"; and

"Destruction of macular drusen, photocoagulation, one or more sessions".

We did not propose RVUs for HCPCS codes G**xxx**8 through G**xx**10 and indicated that the procedures represented experimental

procedures and that the codes would be used for tracking purposes.

Since publication of the proposed rule, the AMA CPT editorial panel has approved a CPT code for Ocular Photodynamic Therapy, CPT code 67221, effective for CPT 2001, and removed the procedure as an example of a service included in CPT code 67220. In addition, verteporfin has been approved for inclusion in the United States Pharmacopeia and can now be billed separately as a drug under the Medicare program.

Comment: Several commenters requested that we withdraw our proposal to establish a G code for OPT in view of the establishment of a CPT code for this service. These commenters also recommended that we continue to recognize CPT code 67220 with its current RVUs.

Response: We agree with the commenters and are withdrawing our proposed G code for OPT. We will establish RVUs for CPT 67221 as described below. We will also continue to recognize CPT code 67220 and will maintain its current RVUs. We are removing verteporfin from the supplies included in practice expenses because the drug is now separately billable under Medicare.

Comment: We received comments in agreement with our proposal to establish an add-on G code for OPT performed on a second eye at the same sitting.

Response: We agree with the commenters and are finalizing this proposal. We will establish RVUs for this G code as described in a response found later in this section.

Comment: We received comments from physician groups agreeing with our proposal to establish three G codes for transpupillary thermotherapy (TTT), feeder vessel technique, and destruction of macular drusen. It was also pointed out that these services are not necessarily experimental, as we had stated in the proposed rule. All of these commenters said that coding these procedures as CPT 67220 was inappropriate because the work involved in performing these three procedures was substantially less than the work required for 67220. These commenters also agreed with our goal of tracking the utilization of these services and offered to assist us in developing national payment policy when appropriate. One commenter, representing a laser manufacturer, recommended continuing to allow TTT to be coded as 67220. Although this commenter stated that the work of TTT was similar to the work of 67220, no rationale was submitted for this comparison.

Response: We agree with the commenters who supported our proposal and are finalizing it. However, coverage and payment for these G codes will be at the discretion of each carrier. We want to thank the commenters offering to assist us in developing national payment policy at the appropriate time. We will review the frequency with which these procedures are performed on Medicare beneficiaries, and, when there is sufficient Medicare experience with this procedure, we will consider development of national payment policies for these services.

Comment: Several national ophthalmologic organizations submitted detailed information and recommendations regarding work RVUs, practice expense inputs, and malpractice RVUs for OPT.

Comment: Regarding work RVUs, the physician organizations submitted a joint recommendation of 5.08 work RVUs for this service based on a RUC survey and comparison of OPT to similar retinal procedures such as CPT codes 67141 and 67210 and the similar photodynamic procedure 43228 and 96570.

Response: Based on comments received from specialty societies and a comparison of the work values for this procedure with the work values for CPT code 67210 (Destruction of localized lesion of retina), we have assigned 4.01 work RVUs to this service. The intraservice times and work intensities for

CPT codes 67210 and 67221 are comparable. Therefore, adjusting for the work value of the postoperative visits (because CPT code 67210 has a 90-day global period) and the 20 percent retreatment rate included in CPT code 67210 and then applying the intraservice work intensity of CPT codes 67210 and 67221 yields an appropriate work value for CPT 67221. In addition, we are assigning a 0-day global period to this code, since this most accurately reflects the pre-, intra-, and post-service work and practice expense RVUs for this procedure.

Comment: Commenters agreed that the work value for performing OPT on a second eye at the same session as the first eye was 10 percent of the work value for the first eye. This was felt to be uniform for pre-, intra-, and post-service work.

Response: We agree with the commenters and are establishing a work RVU of 0.47 for G0184, the add-on code for the second eye. The global period for this code will be ZZZ as proposed.

Comment: Commenters agreed with our crosswalk of malpractice RVUs from CPT code 67220.

Response: We are finalizing our malpractice RVUs as proposed.

Comment: Commenters submitted a list of practice expense inputs for ocular photodynamic therapy.

Response: We agree with the practice expense inputs submitted by the commenters; however, we are adjusting the registered nurse time to eliminate a duplication in the counting of tasks reflected in their comments (reduction of two minutes) and have omitted the lens, which is reusable. A list of the direct inputs for practice expense is provided below under "Result of Evaluation of Comments".

Result of Evaluation of Comments

We will continue to recognize CPT code 67220 "Destruction of localized lesion of choroids (e.g., choroidal neovascularization); photocoagulation, one or more sessions, (e.g., by laser)" with its current RVUs. We are recognizing new CPT 67221 "Destruction of localized lesion of choroids (e.g., choroidal neovascularization); photodynamic therapy (includes intravenous infusion)" for ocular photodynamic therapy and establishing a work RVU of 4.01, a malpractice RVU of 0.52 and using the following direct inputs for determining practice expense:

· *Clinical Staff Time.* Registered nurse - 65 minutes; Certified ophthalmology technician - 14 minutes;

· *Equipment.* Laser, infusion pump, exam chair and slit lamp; and,

· *Supplies.* Opthaine, mydriacyl, myolfrin, gonisol, infusion kit (includes all infusion supplies), gloves, drape, gown, band aid.

For G0184 “Destruction of localized lesion of choroid (e.g., choroidal neovascularization); ocular photodynamic therapy (includes intravenous infusion)-other eye” which is the add-on code for ocular photodynamic therapy of the second eye, we are establishing a work RVU 0.47 and a malpractice RVU of 0.52. The following direct inputs will be used for calculating practice expense:

· *Supplies.* Opthaine, mydriacyl, myolfrin, and gonisol.

In addition, we are establishing the following HCPCS codes for other ophthalmologic procedures:

G0185 for “Destruction of localized lesion of choroid (e.g., choroidal neovascularization); transpupillary thermotherapy, one or more sessions”; G0186 for “Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photocoagulation, feeder vessel technique, one or more sessions”; and G0187 for “Destruction of macular drusen, photocoagulation, one or more sessions”. Coverage and payment for these G codes will be at the discretion of each carrier.

H. Electrical Bioimpedance

Electrical bioimpedance (EB), a noninvasive method of measuring cardiac input, is a covered procedure under Medicare, if medically necessary. Performance of this procedure is reported by the Level 2 HCPCS code M0302, and the procedure is currently carrier-priced. In the July 17, 2000 rule, we proposed the following RVUs for this procedure:

1. Practice Expense

We proposed the following direct inputs for determining practice expense RVUs.

· *Clinical staff time.* Registered nurse -- 15 minutes.

· *Supplies.* Four disposable sensors, patient gown, exam table paper, and pillowcase.

· *Equipment.* Cardiac output monitor and exam table.

2. Malpractice

We proposed 0.02 RVUs for this procedure.

3. Physician Work

We stated that with respect to RVUs for physician work, we had insufficient information to propose a work value and invited comments on this subject.

We also proposed that the payment for this procedure be included in reporting critical care. Therefore, separate payment would not be made for this procedure when provided in

conjunction with critical care services (CPT codes 99291 and 99292).

Comment: There was general agreement with the proposed direct practice expense inputs. Commenters agreed that, although the amount of time for the procedure can vary, the typical time is 15 minutes. They noted that the price for the sensors per treatment was higher than the type of sensors used in an EKG. Commenters also indicated that the average cost of the bioimpedance monitor was $27,000 (we had priced the equipment at $22,790). A specialty group provided direct practice data obtained from a survey they had conducted. The data reflected similar supplies as proposed, with the addition of alcohol swabs and also stated the price of the equipment was $26,225. These data also reflected a clinical staff (registered nurse) time of 29 minutes.

Response: For the practice expense inputs, we are adjusting the cost used for the bioimpedance monitor (increasing the proposed amount $22,790 to $25,700). In addition, the alcohol swabs will be added to the supplies. The specific price allocated to the disposable sensors was $9.95 which was comparable to the $9 to $10 range reflected in the comments received; therefore, no change is being made to the price of the sensors. We are making no adjustment to the clinical staff time

because, based on further discussions and observation of the service being performed, we believe 15 minutes of registered nurse time is reasonable.

Comment: While some commenters agreed with the proposed value of .02 for malpractice, a few commenters indicated that the proposed value of .02 for malpractice was slightly low. They recommended a value of .06 that is the malpractice RVU for CPT code 93720 (plethysmography).

Response: We will finalize our proposal of .02 RVUs for the malpractice component of this service because we continue to believe it is most similar to the malpractice component for an EKG.

Comment: Commenters recommended work values ranging from 0 work RVUs to work RVUs similar to EKG Interpretation (CPT code 93010), Total Body Plethysmography (CPT code 93720), Exercise Tolerance Test (CPT code 93018), Cardiac Output Measurement by thermodilution (CPT code 93561) and Echocardiography (CPT code 93320).

Response: The physician work required for performance of this service involves reading and interpreting a series of numerical measurements. This is generally done in conjunction with an evaluation and management service because the

measurements produced by this procedure are difficult to interpret without a clinical evaluation of the patient. To determine what, if any, work RVUs to establish for this procedure, we identified physician work that would be attributed to this procedure and would not be billed as part of an evaluation and management service.

The fact that the information gained from a test is used in making treatment decisions is irrelevant to the issue of determining physician work (for example, results of urinalyses, complete blood counts (CBCs) are used to make clinical decisions, but these tests do not contain a physician work component). For example, it is possible to make an electrocardigraphic diagnosis (for example, left ventricular hypertrophy, acute Myocardial Infarction, Heart Block) through analysis of the waveforms on an EKG without a clinical evaluation of the patient. This separately identifiable work is what justifies establishment of work RVUs for interpretation of EKGs. It is not as easy to identify separately identifiable work in the case of cardiac bioimpedance. The measurements produced by cardiac bioimpedance include blood pressure, pulse, cardiac output, vascular resistance and thoracic fluid content. Generally, abnormalities in any of these do not allow a diagnosis to be made (for example, hypertension or heart

failure). These measurements are used to provide additional information to a physician who is clinically evaluating a patient, in much the same way that results of a CBC and urinalysis are used. However, after reviewing the comments, we currently believe there is a small amount of physician work in interpreting the measurements produced by cardiac bioimpedance that is not billable as part of an E/M service. For example, if a physician reviews, interprets, and issues a report, then separate work can be identified.

We believe that this physician work is most similar to the work of interpreting an EKG and have assigned a work RVU of .17 for the professional component of cardiac bioimpedance. We wish to emphasize that in order for the PC to be billed, all the requirements for billing a diagnostic test must be satisfied. We will also bundle the PC into critical care when critical care services are furnished, since the critical care service includes the review of such tests. Furthermore, we will allow this service to be billed once per physician, per patient, per day.

Result of Evaluation of Comments

For HCPCS code M0302, we are establishing a work RVU of .17, a malpractice value of .02 and are using the following inputs for PE

- *Clinical Staff Time.* Registered nurse -- 15 minutes.
- *Supplies.* Four disposable sensors, patient gown, exam table paper, pillowcase, and four alcohol swabs.
- *Equipment.* Cardiac output monitor and exam table (using a price of $25,700 for the monitor).

We note that there is a TC and a PC for this service. The direct practice expense inputs listed above will be part of the TC.

I. Global Period for Insertion, Removal, and Replacement of Pacemakers and Cardioverter Defibrillators

We proposed to change the global period for the insertion, removal, and replacement of pacemakers and cardioverter defibrillators (CPT codes 33206, 33207, 33208, 33212, 33213, 33214, 33216, 33217, 33218, 33220, 33233, 33234, 33235, 33240, 33241, 33244, 33249, 33282, and 33284) to 0 days. This would permit separate payment for any care furnished during the post-operative period by the physician who performed the pacemaker or cardioverter defibrillator procedure. We also proposed an adjustment to the physician work RVUs and practice

expense inputs to reflect the change in global period for these codes.

Comment: Several physician organizations recommended withdrawal of this proposal. They commented that the proposed reduction in work and payment for these codes was too drastic and was inappropriate since most of the work in these procedures was intraservice work. They also stated that physicians who insert pacemakers and cardioverter defibrillators generally do not see their patients postoperatively and do not render any postoperative care for related conditions.

Response: We are deferring this proposal because of the concerns raised about the adjustment to the work RVU under our proposed policy. Nonetheless, we believe that some commenters have raised points that, if accurate, suggest that a 0-day global period and adjustment to the work RVU is appropriate. We proposed this policy because of our concern that cardiologists are providing post-operative services during the 90-day global period, as well as evaluation and management services to treat underlying heart conditions that are unrelated to the insertion, removal and replacement of a pacemaker or cardioverter defibrillator.

Our proposed policy was intended to facilitate separate payment for the evaluation and management services unrelated to

the surgical service. Our concern was that the 90-day global period was precluding separate payment for the evaluation and management services. However, we received comments that indicated that cardiologists do not typically provide the post-operative services related to surgical service. If this is the case, we believe that a 0-day global period is appropriate for these procedures. Moreover, if the comment is accurate, the current (not the proposed) work and practice expense RVUs are likely overstated because these values are based on one physician providing both the surgical and post-operative services. In general, we believe that the refinement process is useful for revaluing services when the nature of the service has changed from its previous valuation. If the commenters are correct, the issue of the global period and appropriate relative value units for these services will need further review. We look forward to working with the physician community to better understand the typical practice with regard to the provision of services related to insertion, removal and replacement of pacemakers and cardioverter defibrillators. We welcome any review of this issue that may be undertaken by the RUC as part of their recommendation related to the 5-year review of work and the PEAC on issues related to practice expense.

Nevertheless, we are not finalizing our proposal with respect to this issue because we believe that physicians have raised valid concerns that the adjustment to the work RVU in the proposal may result in an underpayment for the service. Until there is further review of this issue, we are continuing with current pricing for these services and the use of a 90-day global period.

Result of Evaluation of Comments

No change will be made to the global period for CPT codes 33206, 33207, 33208, 33212, 33213, 33214, 33216, 33217, 33218, 33220, 33233, 33234, 33235, 33240, 33241, 33244, 33249, 33282, and 33284 in this rule.

J. Antigen Supply

In the July 2000 rule we proposed amending §410.68(b), Antigens: Scope and conditions, to change the limitation of antigen supply from 12-weeks to 12-months to be more reflective of current industry standards and guidelines.

Comments: The majority of commenters, including national and State specialty associations, supported this change and indicated that it was not only reflective of current industry standards but would improve patient care and benefit patients and practitioners alike. However, a few commenters did not agree with this revision, and felt that stability of the

extracts over time is still questionable. They recommended that the 12-weeks limitation be maintained, or that it be changed to no more than 6 months.

Response: We continue to believe that revising the regulation is appropriate, so that it is reflective of current industry standards. To the extent that the 12-month time period is inappropriate for specific antigens, it is a physician's responsibility to assure that the clinical potency of the antigen is preserved by furnishing a supply of antigens for a shorter time frame. The revision to the regulation simply allows a physician to furnish a 12-month supply of antigens when the physician believes it is appropriate, based on the specific antigens involved.

Result of Evaluation of Comments

We are revising the regulation at §410.68(b) as proposed.

K. Low Intensity Ultrasound

We proposed to remove the RVUs that were assigned to CPT code 20979, low intensity ultrasound stimulation to aid bone healing. We made this proposal because of concerns raised by commenters, and because the service was a noncovered service under Medicare.

Comment: One specialty organization pointed out that on July 31, 2000, subsequent to publication of the proposed rule, a

HCFA National Coverage Decision Memorandum was issued stating that ultrasound stimulation for the treatment of established nonunions is now covered under Medicare.

Response: As pointed out by the commenter, since publication of our proposed rule on July 17, 2000, a National Coverage Decision has been made that states that low intensity ultrasound will be covered by Medicare as a treatment modality for nonunion of extremity fractures. This restricted coverage takes effect on April 1, 2001. Therefore, this service will be noncovered until that time. Although low intensity ultrasound was approved under the durable medical equipment benefit, a single training session for the patient in the use of the device is required. This session is generally provided by a physician, or under the direction of a physician, and is appropriately reported as CPT code 20979, “Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)”. This service is comparable to the service provided under CPT code 20974 “Electrical bone stimulation to aid bone healing; noninvasive (nonoperative)”. Both are training sessions provided to a patient once per course of treatment by a physician or under a physician’s direction. Based on this, and in light of concerns raised on the interim RVUs contained in last year’s final rule, we will crosswalk the work RVUs and the

malpractice RVUs for CPT code 20974 to CPT code 20979. We will use the following direct inputs for determining practice expense:

- *Clinical Staff Time.* Technician – 45 minutes.
- *Equipment.* Exam table
- *Supplies.* Minimum visit package.

In addition, we are assigning a global period of "XXX". However, we expect that CPT code 20979 will be billed only once per treatment period, and we will require the use of the -25 modifier with any E/M service billed by a physician for the same patient on the same day as CPT code 20979. Therefore, any E/M service billed in addition to CPT code 20979 must be distinct and separately identifiable.

Comment: One commenter agreed with our proposed elimination of RVUs for this code, and requested that we eliminate all RVUs for status N codes (that is, codes that are non-covered by Medicare). The commenter felt that the RVUs associated with status N codes may contain overvalued misrepresentations and that since non-governmental insurers use the Medicare Fee Schedule as a basis for payment, use of RVUs for status N codes grossly misrepresents equitable payment for these types of services.

Response: As noted in the response above, based on the National Coverage Decision Memorandum, we are retaining the RVUs for CPT code 20979 in the Medicare fee schedule. We will further review issues related to publishing RVUs for non-covered services and may address it in future rulemaking.

Result of Evaluation of Comments

We are assigning .62 work RVUs and .04 malpractice RVUs to CPT code 20979 (which are the values also used for CPT code 20974) and the direct inputs of: technician time of 45 min., an exam table, and minimum supply package will be used to determine practice expense. We note that the inputs for practice expense are subject to refinement.

L. Implantation of Ventricular Assist Devices

In the July 2000 rule, we proposed to revise the practice expense RVUs associated with the CPT codes 33975 and 33976 (implantation of ventricular assist devices) to reflect an "XXX" global period. The purpose of this revision was to ensure that the practice expense RVUs reflect the global period change published in the April 11, 2000 correction notice (65 FR 19332) to the November 1999 final rule. No comments were received on this proposal and we are finalizing it as proposed.

III. Other Issues

A. Incomplete Medical Direction

We currently do not have a national policy that instructs carriers on the method of payment for a service when the anesthesiologist does not fulfill all the medical direction requirements. One option carriers may use is instructing the anesthesiologist to report this service as a reduced or unusual service to determine appropriate payment. We did not make a specific proposal, but indicated that we would like to clarify this policy. We outlined possible options in the July 2000 proposed rule that could be alternatives for future rulemaking consideration. We requested comments, particularly from physicians and practitioners most affected by this policy.

We received comments from both of the major anesthesia groups, the American Society of Anesthesiologists and the American Association of Nurse Anesthetists, as well as a few state anesthesiology groups and practicing anesthesiologists. We will review these suggestions as we determine whether to make a future proposal.

B. Payment for Pulse Oximetry Services

In the July 2000 proposed rule, we clarified that we will continue to pay separately for certain diagnostic codes, including pulse oximetry (CPT codes 94760 and 94761), when they are medically necessary and there are no other services payable under the physician fee schedule billed on the same date by the same supplier.

Comment: Commenters were appreciative of the policy clarification; however, they continue to believe that we should allow separate payment for this service when provided in conjunction with other services, particularly after years of paying separately for this service. Under current policy, physicians are unable to receive payment for the practice expense associated with the service if it is provided on the same day as another service (for example, E/M). Commenters continue to believe that there is additional identifiable work involved that should be paid by Medicare. One commenter stated that this activity is not included in an E/M vignette, and thus, it should not be bundled into an E/M service.

Response: As explained in last year's final rule, we believe pulse oximetry is no more resource intensive, and arguably less so, than recording the patient's temperature, another example of a diagnostic service for which we do not make

separate payment. Because this technology has progressed and been simplified and reduced in cost, pulse oximetry is a routine, minor part of a procedure or visit. We will continue to bundle payment for CPT codes 94760 and 94761 when they are provided the same day as other services. The interpretation of pulse oximetry is part of the medical decision making included in the E/M service. The medical decision making process involves the physician's assessment and treatment plan unique to the individual patient. CPT vignettes are examples and do not necessarily include every potential activity which may occur in the medical decision making process.

Comment: One commenter pointed out that we require an arterial blood gas (ABG) or pulse oximetry for patients requiring oxygen, and that an ABG is a more expensive service than pulse oximetry, and also can be more burdensome to the patient. Therefore, we should continue to reimburse for this service.

Response: As previously explained, we will make separate payment for pulse oximetry services (CPT codes 94760 and 94761) when it is medically necessary and there are no other services payable under the physician fee schedule billed on the same day by the same supplier.

Result of Evaluation of Comments

We will continue with the policy of bundling payment for pulse oximetry (CPT codes 94760 and 94761) when it is provided on the same day as another service. Separate payment for these codes may be made only when the services are medically necessary and there are no other services payable under the physician fee schedule billed on the same date by the same supplier.

C. Outpatient Therapy Supervision

In the July 2000 proposed rule, we clarified that therapy assistants must be personally supervised by the therapist in private practice and employed directly by the therapist, by the partnership or group to which the therapist belongs. We did not make a proposal, and the discussion was provided for informational purposes only. We felt that this explanation was necessary, since revisions in the November 1998 final rule (63 FR 58814) had prompted confusion in the therapy industry. They believed that we had misinterpreted the supervision requirement or had established a new requirement for therapy assistants in the private practice setting. We wanted to clarify that the requirements for therapy assistants in a private practice setting had not changed from the longstanding requirements established in Medicare Carriers Manual (MCM) instructions (see section 2215F, HCFA Pub. 6) revised in 1981.

Comment: Two therapy associations asserted that we have established a new supervision requirement for therapy assistants in the private setting. They base their assertion upon an analysis of the legislative and regulatory history pertaining to supervision of therapy assistants in a private practice setting. According to the associations, we should state in this rule that direct supervision, rather than personal supervision, is required for therapy assistants in the private practice setting. In addition, they requested this statement because Medicare carriers are now examining claims prior to 1999, and seeking money from therapists for services furnished without the therapist being “in the room” with the therapy assistant.

Response: In light of the comments received, we are carefully examining this issue. We did not propose any change in the supervision requirement for therapy assistants in the private setting in the final rule published November 2, 1998 (63 FR 58860). Any change in the level of supervision would need to be addressed in a future proposed rule.

Comment: Two medical associations requested clarification as to whether a physical therapist could bill for services without ever providing or supervising the performance of that service. In addition, clarifications were requested about the application of the physical therapy supervision policy and the

"incident to" rules applicable to the physician services benefit.

Response: First, we note that the physical therapy supervision policy only relates to the therapist in the private practice setting. A therapist cannot bill for services that he or she has not either personally performed or supervised the performance of the service. Moreover, there is no "incident to" provision in the physical therapy benefit, unlike the physician services benefit. However, a physician may employ a therapist, and the services of the therapist may be billed as "incident to" the physician's services if all the requirements of section 2050 through 2050.1 of the MCM are met.

Comment: A revision in section 2050.2 of the MCM is urged by a psychiatric association to allow physicians who own a practice to be off the premises when other legally authorized practitioners, for example, psychologists and clinical social workers are present. An analogy to physical therapists in private practice was provided.

Response: The regulatory change that allowed physical therapists in private practice to be off the premises when other qualified therapists are present resulted from Congressional statements in both the House and Senate committee reports associated with our fiscal year 1997 appropriations process. To

address the concerns expressed in these reports, we revised the regulations at §§ 410.59(c)(2) and 410.60(c)(2). With respect to the commenters reference to section 2050 of the MCM, this section discusses services and supplies furnished "incident to" a physician's professional services. As stated in section 2050.2 of the MCM, in order for the services of a nonphysician practitioner to be covered as incident to the services of the physician, the services must meet all the requirements for coverage specified in sections 2050 through 2050.1. There is no analogy between physicians and therapists in this circumstance, because there is no similar benefit covering services and supplies provided incident to a therapist's professional services. We have, therefore, no plans to revise section 2050.2 of the MCM. We would also note that some practitioners, such as clinical psychologists and clinical social workers, have a statutory benefit under Medicare, and may provide and bill for services without supervision of a psychiatrist.

D. Outpatient Therapy Caps

Section 221 of the BBRA placed a 2-year moratorium on Medicare Part B outpatient therapy caps (the $1500 cap on outpatient physical therapy services including speech language-pathology services and the $1500 cap on outpatient occupational therapy services in all nonhospital settings). The two $1500 caps were implemented in 1999 as required by the BBA.

The BBRA also requires us to submit to the Congress a report by January 1, 2001 that includes recommendations on--(1) the establishment of a mechanism for assuring appropriate utilization of outpatient therapy services; (2) the establishment of an alternative payment policy for outpatient therapy services based on classifications of individuals by diagnostic category, functional status, prior use of services (in both inpatient and outpatient settings), and other criteria, in place of uniform dollar limitations, and (3) how to do this in a budget-neutral manner.

In the July 17, 2000 rule, we provided examples of informal recommendations we have received on this issue, and asked for comments from the public on other alternatives that we might consider in developing a payment policy for outpatient therapy services. We indicated that this information would be

considered in preparing our report to Congress on outpatient therapy services.

Result of Evaluation of Comments

Several organizations commented on the issue of outpatient therapy caps. Some groups responded to the examples provided in the proposed rule, while others offered other alternatives. We appreciate the information provided and will consider it as we develop the report to Congress.

E. HCPCS G Codes

Several commenters recommended that, instead of creating G codes, we work more closely with the AMA CPT Editorial Panel to establish or revise CPT codes to meet our requirements.

We have a long-established working relationship with the AMA CPT Editorial Panel. We prefer the use of CPT codes to the use of G codes for reporting physicians' services. In fact, this year, we initiated the establishment of a new CPT code that describes ocular photodynamic therapy (67221) for CPT 2001, and the revision of an old CPT code (67220) to remove ocular photodynamic therapy. We did this proactively to avoid the need to establish a G code. We, along with the ophthalmology societies, brought these recommendations to the CPT Editorial Panel. Thus we were able to withdraw our proposal for a G code for ocular photodynamic therapy. We also worked with the panel

to establish CPT codes for artificial skin placement and wound care management that will enable to us to retire our G codes for these services.

We believe that sometimes HCPCS level 2 codes are useful to the CPT Editorial Panel process. For example, use of a new service can be tracked with the G codes to determine if a future CPT code is appropriate.

Frequently, we create G codes to reflect our own coverage and payment requirements. These requirements are usually very specific, and may make it inappropriate to create a CPT code for general use.

Moreover, in response to requests from physicians and others, we make coverage decisions on a rolling basis. Because the CPT process requires at least 1 year between approval and implementation of a CPT code, we must create a G code during the interim. We occasionally have specific coverage and payment requirements according to which Medicare payment is not made for a specific CPT code. This was the case with the revision of the care plan oversight codes. We specifically informed the CPT Editorial Panel before the codes were revised that the proposed revisions would be inconsistent with our established payment policy, and, therefore, we would need to create G codes for care plan oversight and not use the revised CPT codes. Similarly, we

are finalizing our proposal to create G codes for several ophthalmologic procedures to track the use of these services and permit coverage and payment on a carrier-by-carrier basis. We had comments from the appropriate medical specialty societies, and determined that it was not appropriate to create CPT codes for these services at present. The specialty societies supported our creation of the G codes; this mechanism permits payment for these services while establishing a way to track their use. In the case of physician certification and recertification of a plan of care for home health services, we created two new G codes because of our interest in providing explicit payment for these services as a result of development of the home health prospective payment system (PPS). As we indicated in the home health PPS rule (65 FR 41163), we have decided to "focus our attention on physician certification efforts and education in order to better involve the physician in the delivery of home health services." While we are imposing no new regulatory requirements on physicians related to these services, we felt that it was important to establish these two new codes quickly to allow separate payment for these services as soon as possible after implementation of the home health PPS on October 1, 2000.

Use of G codes is also consistent with section 1848(c)(5) of the Act, which specifically provides us with the authority to establish a uniform procedure coding system for the coding of all physicians' services.

In summary, we support the use of CPT codes. We establish G codes only when absolutely necessary. We would like to assure the medical community that we will continue work with the AMA CPT Editorial Panel to minimize the need for G codes. However, we have the responsibility for developing and implementing payment policy for the Medicare program. On occasion, we need to establish G codes to appropriately administer the Medicare program.

F. Work RVUs in Proposed Rule

Comment: A few commenters stated that work RVUs for some services were incorrect due to the incorrect placement of the decimal in Addendum B of the July 2000 proposed rule (65 FR 44210). They requested that we correct them in the final rule.

Response: Due to a programming error, some services were assigned incorrect work RVUs in Addendum B of the proposed rule. We have taken steps to ensure that this programming error is corrected.

G. Five-Year Refinement of Relative Value Units

In the July 17, 2000 proposed rule (65 FR 44201), we included a discussion on the activities underway with respect to the second five-year refinement of work RVUs. We indicated that we had received comments on potentially misvalued services from approximately 30 specialty groups, organizations and individuals, involving over 900 codes. We shared these comments with the RUC, which makes recommendations to us on the assignment of RVUs to new and revised CPT codes. We also discussed current initiatives involving the validation of physician time data.

Comment: Commenters expressed concern about the discussion on five-year review activities. They were unsure as to how the contractor activities outlined in the proposed rule would be coordinated with the RUC recommendations on work RVUs that will be forwarded to us for consideration. Commenters also expressed concern that contractor activities are primarily focused on physician time. They cautioned that other factors need to be considered in conjunction with time (for example, stress, physician effort, and technical effort) when valuing physician work.

Response: We discussed the data obtained by our contractors with the RUC. We also discussed with the RUC and the physician community the best use of the data obtained by our contractors.

Comment: One organization stated that, during the initial five-year review, budget neutrality was achieved by applying an 8.3 percent reduction to all physician work RVUs. They strongly encouraged us to distribute any impact across all specialties and all CPT codes for the current 5-year review.

Response: Based on our prior experience, we acknowledge that there has been significant interest in how we make adjustments to achieve budget neutrality as a result of work refinement. We will discuss potential options and propose an adjustment to ensure budget neutrality resulting from the work RVU refinement in next year's proposed rule.

Comment: One commenter asked when the Health Economics Research (HER) study data discussed in the proposed rule would be available.

Response: We anticipate that the study data will be available by December 1, 2000. We will be posting this information on our homepage. (Access to the homepage is discussed in the introductory section of this rule under "Supplementary Information".)

IV. Refinement of Relative Value Units for Calendar Year 2001 and Responses to Public Comments on Interim Relative Value Units for 2000 (Including the Interim Relative Value Units Contained in the July 17, 2000 Proposed Rule)

A. Summary of Issues Discussed Related to the Adjustment of Relative Value Units

Section IV.B. of this final rule describes the methodology used to review the comments received on the RVUs for physician work and the process used to establish RVUs for new and revised CPT codes. Changes to codes on the physician fee schedule reflected in Addendum B are effective for services furnished beginning January 1, 2001.

B. Process for Establishing Work Relative Value Units for the 2001 Fee Schedule and Clarification of CPT Definitions

Our November 2, 1999 final rule on the 2000 physician fee schedule (64 FR 59380) announced the final work RVUs for Medicare payment for existing procedure codes under the physician fee schedule and interim RVUs for new and revised codes. The RVUs contained in the rule apply to physician services furnished beginning January 1, 2000. We announced that we considered the RVUs for the interim codes to be subject to public comment under the annual refinement process. In this section, we summarize the refinements to the interim work RVUs

that have occurred since publication of the November 1999 final rule and our establishment of the work RVUs for new and revised codes for the 2001 fee schedule.

Work Relative Value Unit Refinements of Interim and Related Relative Value Units

1. Methodology (Includes Table titled Work Relative Value Unit Refinements of the 2000 Interim and Related Relative Value Units)

Although the RVUs in the November 1999 final rule were used to calculate 2000 payment amounts, we considered the RVUs for the new or revised codes to be interim. We accepted comments for a period of 60 days. We received substantive comments from approximately 11 specialty societies on approximately 29 CPT codes with interim work RVUs. Only comments on codes listed in Addendum C of the November 1999 final rule were considered.

We used a process similar to the process used in 1997. (See the October 31, 1997 final rule on the physician fee schedule (62 FR 59084) for the discussion of refinement of CPT codes with interim work RVUs.) We convened a multispecialty panel of physicians to assist us in the review of the comments. The comments that we did not submit to panel review are discussed at the end of this section, as well as those that were reviewed by the panel. We invited one representative from each

of those specialty societies from which substantive comments were received to attend a panel for discussion of the codes on which they had commented. The panel was moderated by our medical staff, and consisted of the following representatives. Voting Members:

- One or two clinicians representing the commenting specialty(s), based upon our determination of those specialties which are most identified with the service(s) in question. Although commenting specialties were welcomed to observe the entire refinement process, they were only involved in the discussion of those services for which they were invited to participate.
- Two Primary care clinicians nominated by the American Academy of Family Physicians and the American Society of Internal Medicine.
- Five Carrier medical directors.
- Four clinicians with practices in related specialties, who were expected to have knowledge of the services under review.

The panel discussed the work involved in each procedure under review in comparison to the work associated with other services on the fee schedule. We had assembled a set of reference services, and asked the panel members to compare the

clinical aspects of the work of services they believed were incorrectly valued to one or more of the reference services. In compiling the set, we attempted to include—(1) services that are commonly performed whose work RVUs are not controversial; (2) services that span the entire spectrum from the easiest to the most difficult; and (3) at least three services performed by each of the major specialties so that each specialty would be represented. The set listed approximately 300 services. Group members were encouraged to make comparisons to reference services. The intent of the panel process was to capture each participant's independent judgement based on the discussion and his or her clinical experience. Following each discussion, each participant rated the work for the procedure. Ratings were individual and confidential, and there was no attempt to achieve consensus among the panel members.

We then analyzed the ratings based on a presumption that the interim RVUs were correct. To overcome this presumption, the inaccuracy of the interim RVUs had to be apparent to the broad range of physicians participating in each panel.

Ratings of work were analyzed for consistency among the groups represented on each panel. In general terms, we used statistical tests to determine whether there was enough agreement among the groups of the panel, and whether the agreed-

upon RVUs were significantly different from the interim RVUs published in Addendum C of the November 1999 final rule. We did not modify the RVUs unless there was a clear indication for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group, and looked for agreement among the remaining groups as the basis for new RVUs. We used the same methodology in analyzing the ratings that we first used in the refinement process for the 1993 fee schedule. The statistical tests were described in detail in the November 25, 1992 final rule (57 FR 55938).

Our decision to convene multispecialty panels of physicians and to apply the statistical tests described above was based on our need to balance the interests of those who commented on the work RVUs against the redistributive effects that would occur in other specialties. Of the 11 codes reviewed by the multispecialty panel, all were the subject of requests for increased values. Of the 11 interim work RVUs that were reviewed, 9 were increased and 2 were unchanged.

We also received comments on RVUs that were interim for 2000, but which we did not submit to the panel for review for a variety of reasons. These comments and our decisions on those comments are discussed in further detail below.

The table below lists the interim and related codes reviewed during the refinement process described in this section. This table includes the following information:

· CPT Code. This is the CPT code for a service.

· Description. This is an abbreviated version of the narrative description of the code.

· *2000* Work RVU. The work RVUs that appeared in the November 1999 rule are shown for each reviewed code.

· Requested Work RVU. This column identifies the work RVUs requested by commenters.

· *2001* Work RVU. This column contains the final RVUs for physician work.

[GPO--Insert XL File Table-Titled "Refinement of 2000 Interim Work Relative Value Units]

2. Interim 2000 Codes.

CPT code 11980 Subcutaneous hormone pellet implantation

We did not receive a work RVU recommendation from the RUC for this code, and therefore crosswalked it to CPT 11980 for the 2000 fee schedule. One commenter indicated that a recommendation for work RVUs would be included in the RUC recommendations for 2001, and urged that we accept this RVU recommendation.

Final decision: *The 2001 RUC recommendation for CPT Code 11980 has been reviewed and accepted.*

CPT code 27096 Injection procedure for sacroiliac joint arthrography and/or anesthetic steroid

We reduced the work RVU for 27096 from the RUC proposed value of 1.40 to 1.10 based on a weighted average with CPT code 20610 (Large joint injection—work RVU of 0.79) Commenters pointed out that while this was one of the codes used prior to approval of CPT code 27096, it (20610) was cited as being inadequate, because the sacroiliac joint injection requires more precision and skill than does a large joint (for example, hip) injection. They also indicated that the reduction made by HCFA to account for the fact that this procedure may be performed without contrast was not justified. In light of these comments we referred the code to a refinement panel for review.

Final decision: As a result of the statistical analysis of the refinement panel ratings, the final work RVUs are established as 1.40 for CPT code 27096.

CPT code 61862 Subcortical neurostimulator array implantation

The RUC evaluated this code using a building block approach that included the work of sterotactic localization, the device implantation and 140 minutes of intra-operative testing.

A few commenters expressed concern about our rejection of the RUC recommendation of 27.34 work RVUs and our proposed 19.34 work RVUs. We subtracted 8.00 RVUs attributed to 140 minutes of intra-operative testing, since this time was variable and it could be reported under other CPT codes. The commenters explained that the assignment of surgeon work during this 140 minutes of electrode maneuvering was done by comparing the work, including intensity, to CPT code 99291 at an equivalent rate of 4.00 RVUs for each of the approximately 2 hours in this average. Information was provided during the discussion at the RUC that the time of 140 minutes was truly an average, with some testing requiring as long as 3 to 4 hours to achieve satisfactory electrode placement. The commenters recommended that we restore the missing 8.00 RVUs and accept the RUC recommendation of 27.34 for this code. Due to the questions concerning our reduction of

8.00 RVUs, we referred this code to a refinement panel for review.

Final decision: As a result of the statistical analysis of the refinement panel ratings we are retaining the work RVU of 19.34 for CPT code 61862.

CPT code 61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

CPT code 61885 was revised to add a delimiter to the code that specified connection of the neurostimulator to a single electrode array, and a new code (CPT code 61886) was introduced for situations involving two or more electrode arrays. We had received recommendations for work RVUs for the revised CPT code 61885, as well as the new CPT code 61886. Commenters disagreed with our statement that there was no evidence to justify an increase in the work RVU for CPT code 61885. We also noted that the work RVU for this code had been increased in the last 5-year review. Commenters felt that the RUC analyses presented supported an increase in the work RVU. In light of these comments, we referred this code to the refinement panel for review.

Final decision: As a result of the statistical analysis of the refinement panel ratings, the final work RVUs are 5.85 for CPT code 61885.

CPT code 62263 Percutaneous lysis of epidural adhesions using solution injection (for example, hypertonic saline, enzyme) or mechanical means (for example, spring-wound catheter) including radiologic localization (includes contrast when administered)

This was a new CPT code for which the RUC had recommended work RVUs of 7.20. We reduced the value to 6.02 based on two determinations—(1) that the RUC had erroneously counted the insertion of a catheter twice in compiling the component services; and (2) the appropriate building block for the fluoroscopic guidance was code 76003, not 76005. Commenters requested that we reconsider these decisions. They indicated that they had intentionally doubled the value for catheter insertion, as insertion of a catheter into a tight scarred epidural space involved more work than the typical epidural injection. They also felt that the fluoroscopic code the RUC had used was appropriate, and more accurately reflected the work involved. In response to these comments, we referred this code to the refinement panel for review.

Final decision: As a result of our statistical analysis of the refinement panel ratings the final work RVU for CPT 62263 will be 6.14.

CPT codes 62310, 62311, 62318, 62319 Epidural or subarachnoid spine injection procedures

We had agreed with the relativity of these new codes established by the RUC, but in order to retain budget neutrality within this family of codes, we had to uniformly reduce the RUC recommended values. Commenters indicated that our calculations of the amount of reduction in the work RVUs needed slight adjustments. The specialties involved in developing the work RVUs submitted the following re-scaled work RVUs that they felt were a better reflection of the budget neutrality adjustment while preserving the intra-family relativity of the new codes (62310-1.95; 62311-1.57; 62318-2.26; and 62319-1.88).

Final decision: We reviewed the work RVUs submitted by the specialty, and found the proposed work RVUs not to be budget neutral. We apply a standard technique, using the most recent available data, to arrive at budget neutral values. The work RVUs, as published in the November 1999 final rule will be retained.

CPT code 72275 Epidurography

We reduced the work RVUs for this new code by approximately one third, from the 0.83 recommended by RUC to 0.54. Commenters disagreed with this reduction, noting that the comparison codes selected by HCFA medical staff to support this reduction did not accurately reflect the work involved. They indicated that the RUC survey reflected that there was a greater amount of time involved. This code was referred to the refinement panel for review.

Final decision: As a result of our statistical analysis of the refinement panel ratings, we are assigning a work RVU of 0.76 to CPT code 72275.

CPT code 73542 Sacroiliac joint arthrography

The RUC recommended value of 0.64 work RVUs was reduced to 0.54 work RVUs based on our belief that there was no difference in work from the primary survey reference code (CPT code 73525 which has a work RVU of 0.54). Commenters disagreed with this reduction. Although the time estimates between CPT code 73542 and the reference code are similar, the mean intensity/complexity measures are consistently higher for CPT code 73542, and therefore warranted the RUC recommended work RVU of .64. The RUC valued this code not only according to the time required, but also according to the intensity of the service.

Commenters recommended adoption of the RUC work RVUs of 0.64 for CPT code 73542. This code was referred to the refinement panel for review.

Final decision: As a result of our statistical analysis of the refinement panel ratings, we are assigning a work RVU of 0.59 to CPT code 73542.

CPT code 76005 Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint, paravertebral facet joint nerve or sacroiliac joint) including neurolytic agent destruction

The RUC recommended value of 0.60 work RVUs for this new code was reduced to 0.54, because we did not believe there was enough difference in work from the primary survey reference code 76003 (0.54 work RVUs). Commenters disagreed with this determination, and indicated that the survey data results were evidence that comparison between CPT codes 76005 and 76003 was not appropriate, since the survey showed more time for CPT code 76005, as well as a consistently higher estimation of intensity and complexity. Commenters also pointed out that another established code in the same family (CPT code 76001 with a work RVU of .67) was also previously used to report this service.

Final decision: The RUC recommended .60 work RVUs for CPT code 76005. We reduced this recommendation to .54 work RVUs based upon reference procedure CPT code 76003. We inadvertently failed to also examine the other reference procedures identified on the RUC survey. Based upon the other reference procedures which were listed, CPT code 76001 (work RVU = .67), we are changing the work RVU to the RUC recommended value of .60.

CPT code 76873 Prostate volume study

We reduced the RUC recommendation of 1.92 work RVUs to .99, since we did not believe that general anesthesia is used in this procedure. Commenters disagreed with this point and indicated that, because the patient must remain motionless during the procedure, significant sedation, either general or spinal anesthesia, is used. Thus, this is usually performed in a hospital operating room (outpatient) or ambulatory surgical center. Commenters also objected to the comparison we made between this code (76873) and CPT code 76805 *Echography, pregnant uterus, B-scan and/or real time with image documentation; complete.* An obstetric ultrasound does not require anesthesia and is done in a physician's office. Commenters also questioned our statement that we would not allow payment for a prostate volume study when performed on the same day as seed implantation or other services that are part of seed

implantation. During the RUC deliberations, it was specifically discussed that the prostate volume study was not included in the work for seed implantation (CPT code 55859). This code was referred to the refinement panel for review.

Final decision: As a result of our statistical analysis of the refinement panel ratings, we are assigning a work RVU of 1.55 to CPT code 76873.

CPT codes 90471 and 90472 Immunization administration

In the final rule published November 2, 1999, we included a discussion of practice expense inputs and omitted a discussion of the RUC recommended work RVUs for these codes. Commenters encouraged us to publish the values for these codes, noting that while these are not reimbursed under the Medicare program, fee schedule values provide guidance to other payers who use the fee schedule.

Final decision: While we realize that other payers may use the RVUs under the physician fee schedule, since these are noncovered services under Medicare, we are not including values for these services in the fee schedule. The discussion on practice expense was erroneously included. As we indicated in an earlier discussion, we will be examining the issue of including values for noncovered services in the fee schedule.

CPT codes 93741, 93742, 93743, 93744 Electronic analysis of pacing cardioverter-defibrillator

We reduced the RUC recommendations for work RVUs for these codes (93741-0.64; 93742-0.73; 93743-0.83, and 93744-0.95) because we felt there were inconsistencies between the recommendations and the survey data. Commenters stated that the differences in time reflected between the earlier surveys and three 1998 and 1999 surveys were a result of the large increase in the complexity of the technologies associated with these procedures over the last few years. With older devices, there was less information to analyze. The new technology provides more information, thus, the work involved is significantly greater than it was when the reference procedure was initially evaluated. These codes were referred to the refinement panel for review.

Final decision: As a result of our statistical analysis of the refinement panel ratings, we are assigning the following work RVUs: 93741-0.80, 93742-0.91, 93743-1.03, 93744-1.18.

Practice Expense Refinements of 2000 Interim and Related Relative Value Units

We received the following comments on the interim practice expense RVUs assigned to the new and revised CPT codes for 2000:

CPT code 33410, Replacement, aortic valve, with cardiopulmonary bypass; with stentless tissue valve

A specialty group commented that the practice expense RVUs for this code should be slightly higher than for CPT code 33406, *Replacement, aortic valve, with cardiopulmonary bypass; with homograft valve (freehand)*, due to the difference in the grafts. However, the practice expense RVUs for CPT code 33410 are 0.09 less than the practice expense RVUs for CPT code 33406. The commenter adds that, due to this error, physicians have received unfairly low reimbursement for this procedure in CY 2000, and should receive fair compensation after this error is corrected.

Response: The RUC made no recommendation on the practice expense inputs for this code, but the Society of Thoracic Surgeons recommended that we crosswalk the direct inputs from those assigned to CPT code 33406, which we did. The identified payment anomaly did not exist in the practice expense RVUs published in our November 1999 final rule. There was a calculation error reflected in the published RVU values in the July 2000 proposed rule (65 FR 44210) that has been corrected in this final rule. We hope that the code will be refined soon, so that it will no longer be necessary to use a crosswalk for the practice expense inputs.

CPT code 33249 Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter defibrillator and insertion of pulse generator

We received comments from two organizations representing cardiology and pacing electrophysiology on the interim PE RVUs for this procedure. Both commenters indicated that the practice expense RVUs should be increased to account for the fact that under the revised definition, this procedure now includes the implantation of dual chamber ICDs.

Response: We did not receive a practice expense recommendation on this revised code from either the RUC or the specialty societies, and we kept the practice expense inputs at their original level. Because this is a procedure that would only be performed in the facility setting, an increase in the physician work involved to perform the service would not lead to an increase in the practice expense, unless there would be more post-surgical visits associated with the revised service. No claim has been made that this is the case. Therefore, we believe that there is no justification for increasing the practice expense RVUs.

CPT code 92961, Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure)

One organization indicated that, for the PE inputs, we crosswalked this code to CPT code 93610, intra-atrial pacing, which does not include costs associated with a cardioversion, which is part of the procedure. They recommended that we use a building block approach, using inputs from CPT code 93610-26 (a similar intra-atrial pacing code) and CPT code 92960 (a similar cardioversion code) for establishing the PE RVUs.

Response: We did not originally receive a practice expense recommendation on this code from either the RUC or the specialty society. Because this is a 0-day procedure that would only be performed in the facility setting, there would be few or no direct inputs associated with the service. Thus, an increase in the physician work involved to perform the service would not lead to an increase in the practice expense. CPT code 92960 also has no inputs in the facility setting, so including that code as an added crosswalk, as recommended in the comment, would have no effect on the practice expense RVUs for CPT code 92961. Therefore, we are making no change in our recommended crosswalk.

CPT code 93727, Electronic analysis of implantable loop recorder (ILR) system (includes retrieval of recorded and stored ECG data, physician review and interpretation of retrieved ECG data and reprogramming)

Two organizations objected to our crosswalk of the practice expense inputs for this code from CPT code 93272, *Patient demand single or multiple event recording with presymptom memory loop, per 30 day period of time; physician review and interpretation only.* The commenters stated that this crosswalk does not accurately reflect all the practice expense inputs associated with the service, and recommended we crosswalk the inputs from CPT code 93271, *Patient demand single or multiple event recording with presymptom memory loop, per 30 day period of time; monitoring, receipt of transmissions, and analysis.*

Response: We did not originally receive a practice expense recommendation on this revised code from either the RUC or the specialty societies. We have reviewed this comment, and have changed the crosswalk as recommended by the commenters.

CPT 90471/72 Immunization Administration and CPT 99173 Visual Screening Test

Two organizations requested that we publish the RUC recommended values for these immunization codes, as well as the visual screening test and other services with RUC recommendations not reimbursed under Medicare, because other payors use the RVUs under the physician fee schedule.

Response: While we realize that other payers may use the RBRVS fee schedule, since these are non-covered services under

Medicare, as indicated above, we are not including values for these services in the fee schedule.

We received the following comments on HCPCS codes established in the November 2, 1999 final rule:

G0166 External Counterpulsation

One commenter indicated this service was undervalued and recommended inputs for this code. We continue to believe that the values assigned in last year's rule are appropriate, and we are retaining these values.

G0167 Hyperbaric oxygen treatment

We received comments expressing concerns about the new code, G0167, *Hyperbaric Oxygen Treatment Not Requiring Physician Attendance, per Treatment*. The commenter requested that we clarify the intended use of this code. Our contractors have discretion to cover hyperbaric oxygen with or without physician supervision. Our coverage staff is currently reviewing hyperbaric oxygen therapy services policies generally, including the appropriate levels of physician supervision. The progress of this review can be tracked on our web site, http:\\www.hcfa.gov, by selecting Coverage Policies.

G0168 Wound closure utilizing tissue adhesives only

One specialty was concerned that the services described by this code were not coded as a simple repair as recommended by

the CPT panel. The commenter suggested that the cost of the supply, Dermabond, could be reimbursed separately. Another commenter was concerned about the 10-day global period assigned to this code.

The work and practice expense values for this code were based upon an evaluation and management visit, CPT code 99212, except that the price of Dermabond was added as a practice expense. We assigned these values because many of these wounds could have been closed with Steri-strips, a service that is also coded with evaluation and management, rather than a simple repair. We will be analyzing the use of HCPCS code G0168 to learn more about the use of this product, and will consider revaluing it after that analysis is completed.

Although we believe that the typical service involving the use of Dermabond as the only closure will typically not involve a visit for suture removal, we concede that, if another visit were needed for a complication, we should allow another evaluation and management visit. For this reason, we will change the global period to 0 days.

G0169 Removal of devitalized tissue, without use of anesthesia

For 2000, we created G0169 to describe a service that involved removal of devitalized tissue. For 2001, CPT adopted a code 97601 that is sufficiently similar to the services

described by G0169 that we will ask providers to utilize that code for selective removal of devitalized tissue, and we will eliminate G0169. We crosswalked the values for G0169 to CPT Code 97601. This code will continue to have no global period.

Establishment of Interim Work Relative Value Units for New and Revised Physician's Current Procedural Terminology Codes and New HCFA Common Procedure Coding System Codes for 2001 (Includes Table titled American Medical Association Specialty Relative Value Update Committee and Health Care Professionals Advisory Committee Recommendations and HCFA's Decisions for New and Revised 2001 CPT Codes)

One aspect of establishing RVUs for 2001 was related to the assignment of interim work RVUs for all new and revised CPT codes. As described in our November 25, 1992 notice in the 1993 fee schedule (57 FR 55983) and in section III.B. of our November 22, 1996 final rule (61 FR 59505 through 59506) we established a process, based on recommendations received from the AMA's RUC, for establishing interim work RVUs for new and revised codes.

This year we received work RVU recommendations for approximately 131 new and revised CPT codes from the RUC. Our staff and medical officers reviewed the RUC recommendations by comparing them to our reference set or to other comparable services for which work RVUs had been previously established, or

to both of these criteria. We also considered the relationships among the new and revised codes for which we received RUC recommendations. We agreed with the majority of these relationships reflected in the RUC values. In some instances, when we agreed with the relationships, we revised the work RVUs to achieve work neutrality within families of codes, that is, the work RVUs have been adjusted so that the sum of the new or revised work RVUs (weighted by projected frequency of use) for a family will be the same as the sum of the current work RVUs (weighted by projected frequency of use). For approximately 91 percent of the RUC recommendations, proposed work RVUs were accepted, and for approximately 9 percent, we disagreed with the RUC recommendation. In a majority of instances, we agreed with the relativity proposed by the RUC, but needed to decrease work RVUs to retain budget neutrality.

There were also 38 CPT codes for which we did not receive a RUC recommendation. After a review of these CPT codes by our staff and medical officers, we established interim work RVUs for the majority of these services. For those services for which we could not arrive at interim work RVUs, we have assigned a carrier priced status until such time as the RUC provides work RVU recommendations.

We received 5 recommendations from the Health Care Professionals Advisory Committee (HCPAC). Two of the HCPAC recommendations were reduced while 3 of the recommendations were for services that we do not cover. Additionally, there were 2 services for which we did not receive recommendations from the HCPAC.

The table titled AMA RUC and HCPAC Recommendations and HCFA Decisions for New and Revised 2001 CPT Codes lists the new or revised CPT codes, and their associated work RVUs, that will be interim in 2001. This table includes the following information:

- A "#" identifies a new code for 2001.
- CPT code. This is the CPT code for a service.

· Modifier. A "26" in this column indicates that the work RVUs are for the professional component of the code.

· Description. This is an abbreviated version of the narrative description of the code.

· RUC recommendations. This column identifies the work RVUs recommended by the RUC.

· HCPAC recommendations. This column identifies the work RVUs recommended by the HCPAC.

· HCFA decision. This column indicates whether we agreed with the RUC recommendation ("agree") or we disagreed with the RUC recommendation ("disagree"). Codes for which we did not

accept the RUC recommendation are discussed in greater detail following this table. An "(a)" indicates that no RUC recommendation was provided. A discussion follows the table.

· HCFA Work RVUs. This column contains the RVUs for physician work based on our reviews of the RUC recommendations.

- 2001 Work RVUs. This column establishes the 2001 work RVUs for physician work

[GPO - Insert TABLE AMA RUC AND HCPAC RECOMMENDATIONS AND HCFA DECISIONS FOR NEW AND REVISED 2001 CPT CODES]

Discussion of Codes for Which There Were No RUC Recommendations or for Which the RUC Recommendations Were Not Accepted

The following is a summary of our rationale for not accepting particular RUC work RVU recommendations. It is arranged by type of service in CPT order. Additionally, we also discuss those CPT codes for which we received no RUC recommendations for physician work RVUs. This summary refers only to work RVUs.

Bioengineered tissue grafts (CPT codes 15342 and 15343)

Temporary HCPCS Codes G0170 and G0171, established in the November 1999 final rule, will be deleted. The two aforementioned deleted codes have been replaced by CPT codes 15342 and 15343. The RUC recommended that the work RVUs for CPT codes 15342 and 15343 be crosswalked from deleted HCPCS codes

G0170 and G0171, which are currently being used to report bioengineered tissue grafts. The work RVUs for CPT codes 15342 and 15343 are crosswalked from G0170 and G0171, with the following modification. Currently, HCPCS code G0170 includes the work of CPT codes 15000 and 15350. The CPT instructions for CPT code 15342 state that it can be billed with CPT code 15000. For this reason the crosswalk for CPT code 15342 would be to 25 percent of the work RVU of CPT code 15350, or 1.00 work RVUs. This percentage was chosen because CPT code 15342 is for graft sizes of up to 25 square centimeters, and CPT code 15350 is for graft sizes up to 100 square centimeters. Similarly, the RUC recommended work RVUs for CPT code 15343 are adjusted to 25 percent of 15351, or 0.25 work RVUs. Additionally, we note that some commenters requested the global period for HCPCS code G0170 be lowered from ten to seven days. This was not done, because we use only three global period lengths zero, ten, and ninety days. Clearly the ten-day global period is the most appropriate and consistent with the recommendation of the commenters. This decision will be applied to CPT code 15342. CPT code 15343 is an add-on service that does not have a global period.

Percutaneous Vertebroplasty (CPT code 22522)

The RUC recommended a work RVU of 4.31 for CPT code 22522. The RUC arrived at this value based upon the fact that the work

involved with CPT code 22522 was 50 percent of the total work of CPT codes 22520 and 22521. The RUC failed to remove the pre-service 99213 and the post-service 99238 associated with CPT codes 22520 and 22521 before performing their calculations. CPT code 22522 is an add-on procedure, and there should be no pre- and post-service work associated with this service. We have removed the work RVUs of 99213 (pre-service) and 99238 (post-service) from the weighted average of CPT codes 22520 and 22521. For this reason, we have assigned a work RVU of 3.00 to CPT code 22522.

Naso- or Oro-gastric tube placement (CPT code 43752)

The RUC did not supply us with a recommendation for CPT code 43752. We believe that this service is bundled into evaluation and management services. For this reason, there is no work RVU associated with this service.

Small bowel implantation (CPT codes 44132, 44133, 44135, and 44136)

The RUC recommended carrier pricing for these services. These services are not covered transplant services under Medicare. For this reason, there are no work RVUs associated with these services.

Endoscopic enteral stenting (CPT codes 43256, 44370, 44379, 44383, 44397, 45327, 45345, 45387)

The RUC determined a work increment, from the applicable endoscopic base code, for transendoscopic stent placement including predilation of 1.96 RVUs. We agree with this increment. For the endoscopic stent placement CPT codes for which we did not receive a work recommendation from the RUC, we applied this increment to the applicable endoscopic basecode. Because endoscopic stent placement is being currently billed under existing endoscopic CPT codes, we needed to make a work neutrality adjustment to each family of codes in which a stent placement code had been created.

Incision and drainage of vaginal hematoma (CPT code 57023)

The RUC did not supply a work RVU recommendation for CPT code 57023. We did receive a work RVU recommendation for similar CPT code 57022. Until such time as we receive more information allowing us to appropriately value CPT code 57023, we will adopt the RUC recommended work RVU for CPT code 57022. For these reasons, we have assigned a work RVU of 2.56 to CPT code 57023.

Laminotomy re-exploration (CPT codes 63040, 63042, 63043, and 63044)

The RUC did not supply work RVU recommendations for CPT codes 63040 through 63044. CPT codes 63040 and 63042 were revised to account for single interspace cervical and lumbar

laminotomy, respectively. CPT codes 63043 and 63044 were added to account for each additional cervical and lumbar interspace laminotomy(s). We will bundle CPT code 63043 into CPT code 63040 and CPT code 63044 into CPT code 63042, and retain the existing work RVUs for CPT codes 63040 and 63042. We will re-evaluate these services when the RUC supplies work RVU recommendations.

Ocular photodynamic therapy (CPT code 67221)

The RUC did not supply work RVU recommendations for CPT code 67221. Subsequent to the publication of the July 2000 proposed rule in which we proposed establishing a new HCPCS code for this service, the CPT editorial panel approved CPT code 67221 for ocular photodynamic therapy. We have deleted our proposed temporary code and established values for CPT code 67221. Based on comments received from specialty societies and a comparison of the work values for this procedure with CPT code 67210, Destruction of localized lesion of retina, we have assigned 4.01 work RVUs to this service. The intraservice times and work intensities for CPT codes 67210 and 67221 are comparable. Therefore, adjusting for the work value of the postoperative visits (because 67210 has a 90-day global period) and the 20 percent retreatment rate included in CPT code 67210, and then applying the intraservice work intensity of 67210 to

67221, yields an appropriate work value for 67221. For a further discussion of this issue, see section II.G.

Computed tomographic angiography (CPT codes 71275, 72191, 73206, 73706, 74175, and 75635)

CPT created a series of new codes for 2001 describing computed tomographic (CT) angiography for different parts of the body. The RUC submitted work recommendations of 1.75 RVUs for CPT codes 70496 and 70498, with which we agree. The RUC did not submit work recommendations for the other CT angiography codes. The RUC compared the head and neck CPT angiography codes to MRI angiography and CT scans without contrast followed by contrast of the same region in determining the values for these services. However, upon our review, we determined that the work RVUs recommended by the RUC were more comparable to the work RVUs associated with CPT code 75671, Angiography, carotid, cerebral, bilateral, radiological interpretation and supervision*, and CPT code 75680,* Angiography, carotid, cervical, bilateral, radiological interpretation and supervision. Both CPT code 75671 and CPT code 75680 have work RVUs of 1.66. The proportional work RVU increase from the angiography supervision and interpretation code to the CT angiography code was 1.05. Therefore, in determining the work RVUs of the other CT angiography codes, we--(1) compared each code to its most

comparable angiographic radiological supervision and interpretation code, and (2) applied a proportionate work increase of 1.05 to the CT angiography code. The CPT codes to which we compared the CT angiography codes were 75605, 75736, 75710, 75625, and 75630. Note that CT angiography of the extremities has been valued as a unilateral service. However, CPT code 75635 is valued for bilateral lower extremity run.

Magnetic resonance imaging procedures (CPT codes 70540, 70542, 70543, 71550, 71551, 71552, 72195, 72196, 72197, 73218, 73219, 73220, 73221, 73222, 73223, 73718, 73719, 73720, 73721, 73722, 73723, 74181, 74182, and 74183)

CPT 2000 has a single code to describe MRI of each region of the body except for MRI of the brain, where three separate codes exist that describe MRI of the brain without contrast, with contrast, and without contrast followed by contrast. For CPT 2001 the single MRI code for each area of the body will be broken out into three separate CPT codes describing MRI for that body area without contrast, with contrast, and without contrast followed by contrast.

The only codes for which we received work RVU recommendations from the RUC were CPT 70540 (*MRI orbit/face/neck, w/o contrast*), 70542 (*MRI orbit/face/neck, w/ contrast*), and 70543 (*MRI orbit/face/neck, w/out then w/*

contrast). The recommended work RVUs were 1.48, 1.78, and 2.36 respectively. The services that will be described under these three CPT codes are currently being coded under a single CPT code, 70540 (current descriptor is *Magnetic Resonance (e.g. proton) imaging, orbit, face, and neck* with a current work RVU of 1.48). For this reason we must make the new CPT codes work neutral to the current CPT code; that is, the total work RVUs associated with the three new codes must result in the same total work RVUs of the current CPT code. The RUC recommendations were not work neutral. Since neither the RUC nor the specialty society supplied us with relative utilization rates for these CPT codes, we applied the current relative utilization pattern for MRI of the brain. MRI of the brain currently has three separate CPT codes for MRI without contrast, with contrast, and without contrast followed by contrast. This resulted in work RVUs of 0.98, 1.17, and 1.56 for MRI of the orbit, face, and neck without contrast, with contrast, and without contrast followed by contrast, respectively.

We did not receive work recommendations or utilization data for any of the other new MRI codes. In each case, a single MRI code describing MRI of a body area was broken out into three codes describing MRI of that body area without contrast, with contrast, and without contrast followed by contrast. In order

to assign appropriate work values for these codes, we followed the following procedure for MRI of each body area--(1) we assigned a work RVU to MRI without contrast, MRI with contrast, and MRI without contrast followed by contrast that maintained the same relationship as the work RVUs the RUC assigned to the three codes for MRI of the orbit, face, and neck, (2) we determined the total work RVUs for the body area by utilization of the current MRI code for that body area, (3) we applied the relative utilization of the brain MRI codes to the new MRI codes for each body area, and (4) we adjusted the work RVUs assigned in step 1 for MRI of each body area to make them work neutral to the work RVUs determined from step 2.

Fetal biophysical profile (CPT code 76818 and CPT code 76819)

The RUC recommended a work RVU of 1.05 for CPT code 76818 and 0.77 for CPT code 76819. Although we agree with the relativity established by the RUC, the codes needed to be adjusted for budget neutrality. For this reason, we have assigned 0.86 work RVUs to CPT code 76818 and 0.63 work RVUs to CPT code 76819.

Sensory Integrative Techniques (CPT code 97532 and CPT code 97533)

The RUC recommended a work RVU of 0.51 for CPT code 97532 and 0.48 for CPT code 97533. These two new services were

created to replace the deleted CPT code 97770. We believe the work associated with these two new services is analogous to deleted CPT code 97770. For this reason, we have assigned the same work RVU (0.44) that was assigned to deleted CPT code 97770 to both CPT code 97532 and CPT code 97533.

Active wound care management (CPT code 97601 and CPT code 97602)

The HCPAC did not supply a work RVU recommendation for either CPT code 97601 or CPT code 97602. We had established temporary HCPCS code G0169 for the work described in new CPT code 97601. For this reason, we have assigned the same work RVU (0.50) to CPT code 97601 that was assigned to now-deleted HCPCS code G0169. We consider CPT code 97602 to be bundled into CPT code 97601 and therefore will not establish work RVUs for this service.

Medical nutrition therapy (CPT codes 97802 through 97804)

The HCPAC supplied work RVU recommendations of; 0.45 for CPT code 97802, 0.37 for CPT code 97803, and 0.25 for CPT code 97804. These services do not fall under any enumerated category of Medicare services, and thus these services are not covered by Medicare. Additionally, these services are not physician services and, therefore, would not be assigned physician work RVUs. Finally, the American Diabetic Association is unhappy with the descriptors CPT has assigned to CPT codes 97802 through

97804, and is in the process of submitting a request to CPT for a revision to the descriptors for these services. For these reasons, we have decided not to assign work RVUs to these services.

Establishment of Interim Practice Expense Relative Value Units for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New HCFA Common Procedure Coding System Codes for 2001.

We have developed a process for establishing interim practice expense RVUs (PERVUs) for new and revised codes that is similar to that used for work RVUs. Under this process, the RUC recommends the practice expense direct inputs, that is, the staff time, supplies and equipment associated with each new code. We then review the recommendations in a manner similar to our evaluation of the recommended work RVUs.

The RUC recommendations on the practice expense inputs for the new and revised 2001 codes were submitted to us as interim recommendations. We, therefore, consider that these recommendations are still subject to further refinement by the PEAC, or by us, if it is determined that such future review is needed. We do have concerns regarding some of the recommended inputs, particularly clinical staff times, for certain services, and we may revisit these inputs in light of future decisions of

the PEAC regarding supply and equipment packages and standardized approaches to pre- and post-service clinical staff times.

We have accepted, at least in the interim, almost all of the practice expense recommendations submitted by the RUC for the codes listed in the following table titled "AMA RUC and HCPAC Recommendations and HCFA Decisions for New and Revised 2001 CPT Codes." We made the following minor changes to the inputs where relevant:

- We rounded all clinical staff time to the nearest minute.

C For consistency with the CPEP revisions contained in the November 1999 final rule, we deleted separately billable fluid and contrast material, and the skin marking pen, disinfectant and biohazard bag, because these items cannot easily be allocated to individual services.

C The RUC assigned the E/M visit supply package, which includes a tongue depressor, drape sheet, and disposable otoscope speculum, as well as the E/M equipment package, which includes an otoscope-ophthalmoscope, to several vascular, spine and other post-surgical visits. We deleted the otoscope-ophthalmoscope, because it is not typically used for such post-surgical visits and, instead of the E/M visit supply package, substituted the multi-specialty

minimum visit supply package that includes: exam table paper, patient gown, pillow case, nonsterile gloves, and thermometer probe cover. We also added a patient education book.

C For those codes refined before the multi-specialty minimum visit supply package was adopted, we substituted this package for the list of individual items when they matched exactly. In the same manner, we substituted the ophthalmology visit supply package as appropriate.

C For CPT 11980, *Subcutaneous hormone pellet implantation,* we deleted the disinfectant solution because it is already included in the OB-GYN visit supply package assigned to this code.

C The RUC only priced CPT 36870, *Thrombectomy, percutaneous, arteriovenous fistula,* in the office setting. We added inputs for the facility setting, using the clinical staff time for coordinating pre-surgery services and providing pre-service education, as well as the clinical staff time for the one post-surgical visit. We also added the supply and equipment inputs for the post-surgical visit. For the non-facility setting, we added a multi-specialty minimum visit supply package for the post-surgical visit. However, we deleted the oxygen tank from the equipment inputs,

because it appeared that it is only used on a stand-by basis, and would thus be considered an indirect cost.

- The RUC Health Care Professional Advisory Committee submitted a recommendation on the inputs for CPT 97533, *Sensory integrative techniques*. The inputs included a long list of specific equipment that we have combined into one package called "sensory integration equipment."
- The RUC deferred making a recommendation on the practice expense inputs for CPT 43752, *Naso- or oro-gastric tube placement*. We have assumed that this service is performed only in the facility setting, and, as a 0-day global, has no direct inputs.

For the following CPT codes we did not receive practice expense recommendations. Therefore, we are providing practice expense inputs through crosswalking to an existing code as indicated below:

NEW CPT CODE	*EXISTING CPT CODE*
43256 Upper GI Endoscopy	43241 Upper GI endoscopy with tube
44370 Small bowel endoscopy/stent	44363 Endocholaniopancreatograph
44379 S bowel endoscope w/stent	44377 Small bowel endoscopy/biopsy
44383 Ileoscopy w/stent	44382 Small bowel endoscopy
57023 I&D vag hematoma, trauma	57022 I&D vag hematoma,ob
71275 CT angiography, chest	71270-TC Contrast CAT scans of chest
71551 CT angiography, chest	70552-TC Magnetic image, brain (MRI)
71552 MRI chest w/o&w dye	70553-TC Magnetic image, brain (MRI)
72191 CT angiograph pelv w/o&w dye	72194-TC Contrast CAT scans of pelvis
72195 MRI pelvis w/o dye	70551-TC Magnetic image , brain (MRI)
72197 MRI pelvis w/o&w dye	70553-TC Magnetic image, brain (MRI)

73206 CT angio upr extrm w&w/o dye	73202-TC Contrast CAT scans of arm
73218 MRI uppr extremity w/o dye	70551-TC Magnetic image , brain (MRI)
73219 MRI uppr extremity w/ dye	70552-TC Magnetic image, brain (MRI)
73222 MRI joint upr extrem w/dye	70552-TC Magnetic image, brain (MRI)
73223 MRI joint upr extr w/o&w dye	70553-TC Magnetic image, brain (MRI)
73706 CT angio lwr extr w/o&w dye	73702-TC Contrast CAT scans of leg
73718 MRI lower extremity w/o dye	70551-TC Magnetic image , brain (MRI)
73719 MRI lower extremity w/ dye	70552-TC Magnetic image, brain (MRI)
73722 MRI joint of lwr extr w/dye	70552-TC Magnetic image, brain (MRI)
73723 MRI joint lwr extr w/o&w dye	70553-TC Magnetic image, brain (MRI)
74175 CT angio abdom w/o&w dye	74170-TC Contrast CAT scans, abdomen
74182 MRI abdomen w/dye	70552-TC Magnetic image, brain (MRI)
74183 MRI abdomen w/o& w dye	70553-TC Magnetic image, brain (MRI)
75635 CT angio abdominal arteries	74170-TC Contrast CAT scans, abdomen

C. Other Changes to the 2001 Physician Fee Schedule and Clarification of CPT Definitions

For the 2001 physician fee schedule, we are establishing or revising several alpha-numeric HCPCS codes for reporting certain services that are not clearly described by existing CPT codes. This is in addition to the HCPCS codes for ocular photodynamic therapy, certification/recertification for home health services and care plan oversight previously discussed. We view these codes as temporary since we will be referring them to the CPT Editorial Panel for possible inclusion in future editions of CPT. Additionally, included in this section are some clarifications of proper use of some new or revised codes.

Evaluation of swallowing function

We are proposing the following new codes to describe the evaluation of swallowing function. These codes will replace the

more general CPT 92525, *Evaluation of swallowing and oral function for feeding,* which represents a combination of these separate examinations. Our contractors requested the more precise coding to improve claims review for evaluation of dysphagia. The new codes are described as follows:

G0193 Endoscopy study of swallowing function, often referred to as fiberoptic endoscopic evaluation of swallowing (FEES).

G0194 *Sensory testing during endoscoping study of swallowing.* This service, often referred to as fiberoptic endoscopic evaluation of swallowing with testing, will be coded as an add-on code to G0193.

The creation of these two codes does not imply coverage. Coverage of G0193 and G0194 remains at the discretion of the contractor processing the Medicare claim. These codes will be priced by contractors.

Two additional codes are also used to describe swallowing evaluations:

G0195 *Clinical evaluation of swallowing function.* This service describes the clinical examination and evaluation of the patient, typically by a speech and language pathologist.

G0196 *Evaluation of swallowing involving swallowing of radio-opaque materials*. This code involves the participation and interpretation of results from the dynamic observation of the

patient swallowing materials of various consistencies. It is observed fluoroscopically and typically recorded on video. This evaluation involves using the information to assess the patient's swallowing function and developing a treatment plan for the patient.

Both codes G0195 and G0196 will be assigned the same work and malpractice RVUs as CPT 92525. For practice expense, we have crosswalked the inputs from 92525 for these codes. CPT 92525 will no longer be an active code for Medicare.

Note that CPT 31575 (laryngoscopy, flexible fiberoptic, diagnostic) and CPT 31579 (laryngoscopy, flexible or rigid fiberoptic, with stroboscopy) should not be used for evaluations of swallowing.

Speech-Generating Devices

Because of the change in coverage policy on speech-generating devices, effective January 1, 2001, we needed codes that more specifically describe the services needed to evaluate and train patients to use these devices. As a result, we will be replacing CPT 92597, *Evaluation for use and/or fitting of voice prosthetic or augmentative/alternative communication device to supplement oral speech*) and 92598, *Modification of voice prosthetic or augmentative/alternative communication*

device or supplemental oral speech, with the following new codes:

G0197 Evaluation of patient for prescription of speech-generating devices. This code describes the services to evaluate a patient to specify the speech-generating device recommended to meet the patient's needs and capacity for use. This code involves face-to-face involvement of the practitioner (typically a speech and language pathologist experienced in the use of these devices) with the patient. The work and malpractice RVUs for this new code will be cross-walked to the ones used for CPT code 92597, the code it replaces. For practice expense, we have crosswalked the inputs to CPT code 92527 for these codes.

G0198 Patient adaptation and training for use of speech-generating devices. This code describes the services delivered to the patient to adapt the device to the patient, and train him or her in its use. This code involves face-to-face involvement of the practitioner (typically a speech and language pathologist experienced in the use of these devices) with the patient. The work and malpractice RVUs, as well as the practice expense inputs for this new code, will be crosswalked to the ones used for CPT code 92598, the code it replaces.

G0199 Re-evaluation of patient using speech-generating devices. This code describes the services to re-evaluate a patient who

has previously been evaluated for a speech-generating device, and either is currently using a device or did not have a device recommended. This code involves face-to-face involvement of the practitioner (typically a speech and language pathologist experienced in the use of these devices) with the patient. The work RVUs for this new code will be 75 percent of the value for CPT code 92597, reflecting that it is likely to be less intensive than the initial evaluation. The malpractice and practice expense inputs are also crosswalked to CPT code 92957.

G0200 Evaluation of patient for prescription of voice prosthetic. This code describes the services to evaluate a patient for the use of a voice prosthetic device. This code involves face-to-face involvement of the practitioner (typically a speech and language pathologist experienced in the use of these devices) with the patient. The work and malpractice RVUs for this new code will be crosswalked to the ones used for CPT code 92597, the code it replaces. We will also crosswalk practice expense inputs to CPT code 92957.

G0201 Modification or training in use of voice prosthetic. This code involves the modification or training of a patient in the use of a voice prosthetic. This code involves face-to-face involvement of the practitioner (typically a speech and language pathologist experienced in the use of these devices) with the

patient. The work and malpractice RVUs, as well as the practice expense inputs for this new code, will be crosswalked to the ones used for CPT code 92598, the code it replaces. The RUC recommendations, as well as the revised CPEP data for all codes, can be found on our homepage. See the Supplementary Information section of this rule for instructions on accessing our website.

V. Physician Fee Schedule Update and Conversion Factor for Calendar Year 2001

The 2001 physician fee schedule conversion factor is $38.2581. The separate 2001 national average anesthesia conversion factor is $17.26.

The 2001 physician fee schedule update is 5.1 percent. However, miscellaneous adjustments will result in an increase in the conversion factor from 2000 to 2001 of 4.5 percent. The specific calculations to determine the physician fee schedule update and conversion factor for physicians' services for calendar year 2001 are explained below.

Detail on Calculation of the Calendar Year 2001 Physician Fee Schedule Update and the 2001 Conversion Factor

Physician Fee Schedule Update and Conversion Factor

The conversion factor is affected by section 1848(c)(2)(B)(ii)(II) of the Act, which requires that changes to the relative value units of the Medicare physician fee schedule not cause expenditures to increase or decrease by more than $20 million from the amount of expenditures that would have been

made if such adjustments had not been made. We implement this requirement through a uniform budget-neutrality adjustment to the conversion factor. There are two changes that will require us to make an adjustment to the conversion factor to meet the budget neutrality requirements in section 1848(c)(2)(B)(ii)(II). We are making a 0.3 percent reduction (0.997) in the conversion factor to account for separate payment for certification and recertification of a plan of care for home health services. We are also making a 0.14 percent (0.9986) reduction in the conversion factor to account for an anticipated increase in the volume and intensity of services.

After considering this factor, as well as the percent change in the MEI, the update adjustment factor, and statutory adjustment described below, the 2001 conversion factor is calculated as follows:

2000 Conversion Factor	$36.6137
2001 Update	1.05163
2001 Legislative Adjustment	0.998
Volume and Intensity Adjustment	0.9986
Other Factors	0.997
2001 Conversion Factor	$38.2581

Under section 1848(d)(3) of the Act, the update is equal to the product of the MEI and the update adjustment factor. For 2001, the MEI is equal to 2.1 percent (1.021). A more detailed description of the MEI and its calculation follows. The update adjustment factor is equal to 3.0 percent (1.030). Thus, the product of the MEI (1.021) and the update adjustment factor (1.030) equal the 2001 update (1.05163). Section 1848(d)(4)(F) of the Act provides for an additional adjustment to the update for 2001 of -0.2 percent (0.998). Thus, taking into account the 2001 update, the 2001 legislative adjustment, the 2001 volume and intensity adjustment, and the adjustment for certification and recertification of a plan of care for home health services, the conversion factor for 2001 is determined as follows:

$36.6137 x 1.05163 x 0.998 x 0.9986 x 0.997 = $38.2581

The MEI and the update adjustment factor are described below.

The Percentage Change in the Medicare Economic Index

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide labor productivity. This index, which has 1996 base weights, is comprised of two broad categories: Physician's own time and physician's practice expense.

The physician's own time component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents--wages and salaries, and fringe benefits. These components are adjusted by the 10-year moving average annual percent change in output per man-hour for the nonfarm business sector to account for productivity growth in the general economy.

The physician's practice expense category represents the rate of price growth in nonphysician inputs to the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. Like physician's own time, the nonphysician staff categories are adjusted for productivity using the 10-year moving average annual percent change in output per man-hour for the nonfarm business sector. The physician's practice expense component also includes the following categories of

nonlabor inputs--office expense, medical materials and supplies, professional liability insurance, medical equipment, professional car, and other expense. The table below presents a listing of the MEI cost categories with associated weights and percent changes for price proxies for the 2001 update. The calendar year 2001 MEI is 2.1 percent.

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2001[1]		
Cost Categories and Price Measures	1996 Weights[2]	CY Pe Ch
Medicare Economic Index Total.....	100.0	
1. Physician's Own Time[3] [4].....	54.5	
a. Wages and Salaries: Average hourly earnings private nonfarm, net of productivity.....	44.2	
b. Fringe Benefits: Employment Cost Index, Benefits, private nonfarm, net of productivity.....	10.3	
2. Physician's Practice Expense[3].....	45.5	
a. Nonphysician Employee Compensation.....	16.8	
1. Wages and Salaries: Employment Cost Index, wages and salaries, weighted By occupation, net of productivity....	12.4	
2. Fringe Benefits: Employment Cost Index, fringe benefits, white collar, net of productivity.....	4.4	
b. Office Expense: Consumer Price Index for Urban Consumers (CPI-U), housing.....	11.6	
c. Medical Materials and Supplies: Producer Price Index (PPI), ethical drugs/PPI, surgical appliances and supplies/CPI-U, medical equipment and supplies (equally weighted).....	4.5	
d. Professional Liability Insurance: HCFA professional liability insurance survey[5].....	3.2	
e. Medical Equipment: PPI, medical instruments and equipment.....	1.9	
f. Other Professional Expense.....	7.6	
1. Professional Car: CPI-U, private transportation.....	1.3	
2. Other: CPI-U, all items less food and energy.....	6.3	
Addendum:		

Productivity: 10-year moving average of Output per man-hour, nonfarm business sector...	n/a
Physician's Own Time, not productivity Adjusted.....	54.5
Wages and salaries, not productivity Adjusted.....	44.2
Fringe benefits, not productivity Adjusted.....	10.3
Nonphysician Employee Compensation, not productivity adjusted.....	16.8
Wages and salaries, not productivity adjusted.....	12.4
Fringe benefits, not productivity adjusted.....	4.4

1	The rates of historical change are for the 12-month period endi June 30, 2000, which is the period used for computing the calen year 2001 update. The price proxy values are based upon the la available Bureau of Labor Statistics data as of September 15, 2		
2	The weights shown for the MEI components are the 1996 base-year weights, which may not sum to subtotals or totals because of ro The MEI is a fixed-weight, Laspeyres-type input price index who category weights indicate the distribution of expenditures amon inputs to physicians' services for calendar year 1996. To dete the MEI level for a given year, the price proxy level for each component is multiplied by its 1996 weight. The sum of these p (weights multiplied by the price index levels) over all cost categories yields the composite MEI level for a given year. Th annual percent change in the MEI levels is an estimate of price over time for a fixed market basket of inputs to physicians' se		
3	The Physician's Own Time and Nonphysician Employee Compensation category price measures include an adjustment for productivity. price measure for each category is divided by the 10-year movin average of output per man-hour in the nonfarm business sector. example, the fringe benefits component of the Nonphysician Compensation category is calculated by dividing the rate of gro the employment cost index-benefits for private, white collar wo by the 10-year moving average rate of growth of output per man- for the nonfarm business sector. Dividing one plus the decimal of the percent change in the employment cost index-benefits (1+.046=1.046) by one plus the decimal form of the percent chan the 10-year moving average of labor productivity (1+.019=1.019) one plus the change in the employment cost index-benefits for w collar workers net of the change in output per manhour (1.046/1.019=1.026). All Physician=s Own Time and Nonphysician Employee Compensation categories are adjusted in this way. Due higher level of precision the computer calculated quotient may from the quotient calculated from rounded individual percent ch		
4	The average hourly earnings proxy, the Employment Cost Index p as well as the CPI-U, housing and CPI-U, private transportat published in the Current Labor Statistics Section of the Bu Labor Statistics' *Monthly Labor Review*. The remaining CPIs a in the revised index can be obtained from the Bureau o Statistics' *CPI Detailed Report* or *Producer Price Indexes*.		
5	Derived from a HCFA survey of several major insurers (the available historical percent change data are for the period second quarter of 2000).		
N/A	Productivity is factored into the MEI compensation categorie adjustment to the price variables; therefore, no explicit exists for productivity in the MEI.		

The Update Adjustment Factor

Under sections 1848(d)(3) and (d)(4) of the Act, the physician fee schedule update is equal to the product of the Medicare Economic Index ar an "update adjustment factor." The update adjustment factor represents an amount that is applied to the inflation update to reflect success or failure in meeting the expenditure target that the law refers to as "allowed expenditures." Allowed expenditures are equal to actual expenditures in a base period updated each year by the sustainable growth rate. The sustainable growth rate is a percentage increase that is determined by a formula specified in section 1848(f) of the Act. The nex section describes the SGR and its calculation in detail. The update adjustment factor is determined based on a comparison of actual and allowed expenditures. For years beginning with 1999, the BBA required that the update adjustment factor be determined under section 1848(d)(3) of the Act to equal--

(i) the difference between--(I) the sum of the allowed expenditures for physicians' services (as determined under subparagraph (C)) for the period beginning April 1, 1997, and ending on March 31 of the year involved, and (II) the amount of actual expenditures for physicians' services furnished during the period beginning April 1, 1997, and ending on March 31 of the preceding year; divided by-

(ii) the actual expenditures for physicians' services for the 12-month period ending on March 31 of the preceding year, increased by the sustainable growth rate under subsection (f) for the fiscal year which begins during such 12-month period.

Pub. L. No. 106-113, the Medicare, Medicaid and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA) made changes to the methodology for determining the physician fee schedule update beginning in 2001. In particular, it established that the methodology in section 1848(d)(3) of the Act would only be used for determining the physician fee schedule update for 1999 and 2000. The BBRA established that the physician fee schedule update for 2001 and subsequent years would be determined under section 1848(d)(4) of the Act. While the general principle of adjusting the inflation update (the MEI) by the update adjustment factor continues, the BBRA made fundamental changes to the calculation of the update adjustment factor. In general, these changes do two things. First, the measurement of actual expenditures will occur on the basis of a calendar year rather than an April 1 to March 31 year. This essentially conforms the measurement of actual expenditures with other aspects of the SGR system that are also occurring on the basis of a calendar year as a result of BBRA amendments. As we explained in our April 10, 2000 SGR final

notice (65 FR 19000), the BBRA essentially changed the SGR system from one that spanned 3 different time periods, ((1) measurement of actual expenditures on the basis of an April 1 to March 31 period; (2) calculation of the SGR rate of increase on a federal fiscal year basis; and (3) application of the update on a calendar year basis) to one that spans only one time period. (All three are on the basis of a calendar year). Second, it ensures that any deviation between cumulative actual expenditures and cumulative allowed expenditures will be corrected over several years rather than in a single year. This will result in less year-to-year volatility in the physician fee schedule update than would occur if adjustments to the update are made to bring expenditures in line with the target in one year.

Under section 1848(d)(4)(A) of the Act, the physician fee schedule update for a year is equal to the product of--1) 1 plus the Secretary's estimate of the percentage increase in the MEI for the year, and 2) 1 plus the Secretary's estimate of the update adjustment factor for the year. Under section 1848(d)(4)(B) of the Act, the update adjustment factor for a year beginning with 2001 is equal to the sum of the following: (i) Prior Year Adjustment Component. An amount determined by:(I) computing the difference (which may be positive

or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for such services for that year;

(II) dividing that difference by the amount of the actual expenditures for such services for that year; and

(III) Multiplying that quotient by 0.75.

(ii) Cumulative Adjustment Component. An amount determined by:

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996 through the end of the prior year and the amount of the actual expenditures for such services during that period;

(II) dividing that difference by actual expenditures for such services for the prior year as increased by the sustainable growth rate for the year for which the update adjustment factor is to be determined; and

(III) multiplying that quotient by 0.33.

Thus, the CY 2001 update adjustment factor will be determined as the sum of the following:

(i) Prior Year Adjustment Component. This equals the difference between allowed expenditures in 2000 and our current estimate of actual expenditures for 2000. This difference is divided by our current estimate of actual expenditures for 2000 and the quotient is multiplied by 0.75. Our current estimate of allowed expenditures for CY 2000 is $56.6 billion. Our current estimate of actual expenditures for all of 2000 based on claims received through June 30 is $55.1 billion. Thus, the prior year adjustment component is equal to:

($56.6 - $55.1) / $55.1)) X 0.75 = .020

(ii) Cumulative Adjustment Component. This amount equals the difference between allowed expenditures for the period April 1, 1996 through December 31, 2000 ($244.4 billion) and actual expenditures for the same period ($240.6 billion) divided by the product of actual expenditures for the year 2000 ($55.1) increased by the SGR for 2001 (5.6 percent). This quotient is multiplied by 0.33. Thus, the cumulative adjustment component is equal to:

($244.4 - $240.6) / ($55.1x1.056))) X 0.33 = 0.022.

The prior year adjustment component and the cumulative adjustment component are added. Adding these figures together would make the update adjustment factor equal 0.042. However, section 1848(d)(4)(D) of the Act indicates that the update adjustment factor determined under section 1848(d)(4)(B) of the Act for a year may not be less than –0.07 or greater than 0.03. Since 0.042 exceeds 0.03, we are limiting the update adjustment factor consistent with section 1848(d)(4)(D) of the Act to 0.03. Section 1848(d)(4)(A)(ii) of the Act indicates that 1 should be added to the update adjustment factor determined under section 1848(d)(4)(B) of the Act. Thus, adding 1 to 0.03 makes the update adjustment factor equal 1.030.

(As indicated in the SGR discussion below, allowed expenditures through the end of CY 2000 will be revised one more time, no later than November 1, 2001. We will also be revising the measurement of actual expenditures for CY 2000 based on claims received through June 30, 2001. These revised figures will be determined no later than November 1, 2001. The SGR for 2001 will also be revised two more times. Any differences that result in the update adjustment factor for 2001 from revision of estimates will be reflected in update adjustment factor determined for 2002.)

VI. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

A. Medicare Sustainable Growth Rate

Section 1848(f) of the Social Security Act (the Act), as amended by section 4503 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, replaced the Medicare Volume Performance Standard (MVPS) with a Sustainable Growth Rate (SGR). Section 1848(f)(2) of the Act specifies the formula for establishing yearly SGR targets for physicians' services under Medicare. The use of SGR targets is intended to control the actual growth in aggregate Medicare expenditures for physicians' services.

The SGR targets are not limits on expenditures. Payments for services are not withheld if the SGR target is exceeded by actual expenditures. Rather, the appropriate fee schedule update, as specified in section 1848(d)(3) of the Act, is adjusted to reflect the success or failure in meeting the SGR target. If expenditures exceed the target, the update is reduced. If expenditures are less than the target, the update is increased.

As with the MVPS, the statute specifies a formula to calculate the SGR based on our estimate of the change in each of

four factors. The four factors for calculating the SGR are as follows:

(1) The estimated change in fees for physicians' services.

(2) The estimated change in the average number of Medicare fee-for-service beneficiaries.

(3) The estimated projected growth in real gross domestic product (GDP) per capita.

(4) The estimated change in expenditures due to changes in law or regulations.

Section 211 of the BBRA amended sections 1848(d) and 1848(f) of the Act with respect to the physician fee schedule update and the SGR. Section 211(b) of the BBRA maintains the formula for calculating the SGR, but amends section 1848(f)(2) of the Act to apply the SGR on a calendar year (CY) basis beginning with 2000 while maintaining the SGR on a fiscal year (FY) basis for FY 1998 through FY 2000. Specifically, section 1848(f)(2) of the Act, as amended by section 211(b) of the BBRA, states that—"...[t]he sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal 1998 and ending with fiscal year 2000) and a year beginning with 2000 shall be equal to the product of:

(1) 1 plus the Secretary's estimate of the weighted average percentage increase (divided by 100) in the fees for all physicians' services in the applicable period involved,

(2) 1 plus the Secretary's estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous applicable period to the applicable period involved,

(3) 1 plus the Secretary's estimate of the projected percentage growth in real gross domestic product per capita (divided by 100) from the previous applicable period to the applicable period involved; and

(4) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the applicable period (compared with the previous applicable period) which will result from changes in law and regulations, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under section 1834 (d)(3)(B) or (d)(4)(B) of the Act, as the case may be, minus 1 and multiplied by 100."

Under section 1848(f)(4)(C) of the Act, as added by section 211(b)(3) of the BBRA, the term "applicable period" means--(1) a

FY, in the case of FY 1998, FY 1999 and FY 2000, and (2) a CY with respect to a year beginning with 2000.

To make the transition from a FY SGR to a CY SGR in 1999 using the FY 2000 SGR, sections 211(b)(2) and (b)(3) of the BBRA require us to calculate SGRs for both FY and CY 2000. Section 1848(d)(4)(C) of the Act, as modified by section 211(a)(1)(B) of the BBRA, required us to determine the allowed expenditures for both the 9-month period beginning April 1, 1999 and for CY 1999. The SGR for CY 2000 is then applied to allowed expenditures for CY 1999.

As stated in the April 10 final notice (65 FR 19002), the BBRA requires the estimate of the FY 2000 and CY 2000 SGR to be revised based on more recent data, but, as explained below, the BBRA does not provide for revision of either the FY 1998 or the FY 1999 SGR. This means that, for the transition to a calendar year SGR system, allowed expenditures for the period April 1, 1999 through December 31, 1999 (determined by applying the FY 2000 SGR to allowed expenditures for the 12-month period ending March 31, 1999) are subject to change based on revision of the FY 2000 SGR; allowed expenditures for the period January 1, 1999 through March 31, 1999 (determined using the FY 1999 SGR) are not subject to revision.

In general, the BBRA requires us to publish SGRs for three different time periods, no later than November 1 of each year, using the best data available as of September 1 of each year. Under section 1848(f)(3)(C)(i) of the Act, as added by section 211(b)(5) of the BBRA, the SGR is estimated and subsequently revised twice (beginning with the FY and CY 2000 SGRs) based on later data. Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the initial estimate.

The requirement of revisions to the SGR based on later data means that we will estimate and publish an SGR for the upcoming year, the contemporaneous year, and the preceding year by not later than November 1 of each year. For example, by not later than November 1, 2002, we will publish an estimate of the SGR for CY 2003, a revision of the CY 2002 SGR estimated in the previous year, and a revision of the CY 2001 SGR first estimated two years earlier and first revised in the previous year. Under section 1848(f)(3)(C)(ii) of the Act, this would be the final revision to the CY 2001 SGR.

Sections 1848(f)(3)(A) and (f)(3)(B) of the Act, as added by section 211(b)(5) of the BBRA, specify special rules with respect to the SGR and the CY 2001 and CY 2002 updates. Section

1848(f)(3)(A) of the Act requires us, not later than November 1, 2000, to revise the SGRs for FY 2000 and CY 2000 and to establish the SGR for CY 2001, based on the best data available, as of September 1, 2000. Section 1848(f)(3)(B) of the Act requires us, by not later than November 1, 2001, to revise the SGRs for FY 2000 and CYs 2000 and 2001 and to establish the SGR for CY 2002, based on the best data available as of September 1, 2001. In accordance with section 1848(f)(3)(C)(ii) of the Act, there will be no further revisions to the FY 2000 and CY 2000 SGRs after their revision in the 2001 notice.

Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The BBRA made no changes to this definition that was also used for the MVPS. For this reason, we are continuing to use the same definition of physicians' services for the SGR in this notice as we did in prior SGR notices and for the MVPS published in the **Federal Register** (61 FR 59717) on November 22, 1996.

C. Provisions Related to the SGR

We are implementing section 211(b)(1)(A) of the BBRA that requires us to publish in the **Federal Register,** not later than November 1, 2000, a notice containing--(1) a preliminary estimate of the SGR for 2001; and (2) a revised estimate of the CY 2000 SGR. In addition, consistent with section 1848(f)(3)(A) of the Act, we are revising the SGR for FY 2000 for purposes of determining the physician fee schedule update for 2001 under section 1848(d)(4)(B) of the Act.

In general, the update for a year is based on the Medicare Economic Index (MEI) as adjusted, within bounds, by the amount of actual expenditures for physicians' services compared to allowed (that is, growth target) expenditures. A key difference between the MVPS and the SGR is that the comparison of actual and allowed expenditures is made on a cumulative basis under the SGR, while it was made on an annual basis under the MVPS. The "update adjustment factor" in section 1848(d)(4)(B) of the Act is an adjustment to the MEI that reflects the difference between actual expenditures and target expenditures.

Section 1848(d)(3)(C) of the Act, as modified by the BBA, defines allowed expenditures for the 12-month period ending March 31, 1997 as equal to actual expenditures for physicians' services during that period (that is, April 1, 1996 through

March 31, 1997), as we have estimated. Section 1848(d)(3)(C) of the Act defines allowed expenditures for subsequent 12-month periods to be equal to allowed expenditures for physicians' services for the previous year increased by the SGR for the FY which begins during the 12-month period. For example, allowed expenditures for the 12-month period April 1, 1997 through March 31, 1998 are equal to allowed expenditures for the 12-months ending March 31, 1997, increased by the SGR for FY 1998. As explained above, BBRA subsequently provided for a transition to a calendar year SGR system in 1999 with allowed expenditures in 2000 equal to 1999 allowed expenditures increased by the 2000 SGR. Allowed expenditures for each subsequent year will equal expenditures from the prior year updated by the SGR.

The following table shows annual and cumulative allowed expenditures for physicians' services from April 1, 1996 through December 31, 2001.

Period	Annual Allowed Expenditures	Cumulative Allowed Expenditures	FY or CY SGR
4/1/96-3/31/97	$48.9 billion	$48.9 billion	N/A
4/1/97-3/31/98	$49.6 billion	$98.5 billion	FY 1998=1.5%
4/1/98-3/31/99	$49.4 billion	$147.9 billion	FY 1999=-0.3%
1/1/99-3/31/99	$12.5 billion		
4/1/99-12/31/00	$39.5 billion	$187.9 billion	FY 2000=7.9%
1/1/99-12/31/99	$52.4 billion	Included in $187.9 billion above	See Note
1/1/00-12/31/00	$56.6 billion	$244.4 billion	CY 2000=8.1%
1/1/01-12/31/01	$59.8 billion	$304.2 billion	CY 2001=5.6%

*Note: Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR and allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

In the above table, for the period April 1996 through March 1997, annual allowed expenditures are equal to actual expenditures for the period. Annual allowed expenditures for each subsequent year are equal to the figure from the prior April 1 through March 31 12-month period (shown in the annual allowed expenditure column) multiplied by the SGR figure one row down in the right hand column. For example, allowed expenditures from April 1997 through March 1998 are equal to $48.9 multiplied by 1.015. Cumulative allowed expenditures in a year are equal to the sum of the annual allowed expenditures figure in the same row and annual allowed expenditures for all prior years. The transition to the calendar SGR occurs in 1999. Our current estimates of the FY 2000 SGR of 7.9 percent (2.1

percent for factor 1, 0.8 percent for factor 2, 4.5 percent for factor 3 and 0.3 percent for factor 4), the CY 2000 SGR of 8.1 percent (2.1 percent for factor 1, 1.0 percent for factor 2, 4.3 percent for factor 3, and 0.5 percent for factor 4) and the CY 2001 SGR (1.9 percent for factor 1, 0.9 percent for factor 2, 2.7 percent for factor 3 and 0.0 percent for factor 4) are described in more detail below. All estimates are based on the best data available to the Secretary as of September 1.

Allowed expenditures for the April 1, 1999 through the December 31, 1999 period are based on the FY 2000 SGR. As previously discussed, section 1848(f)(3) of the Act requires two revisions to the FY 2000 SGR. The first revision must be made not later than November 1, 2000 based on the best data available as of September 1, 2000; the second revision must be made not later than November 1, 2001, based on the best data available as of September 1, 2001. The allowed expenditures figure in the above table for the April 1, 1999 through the December 31, 1999 period reflects the revisions of the FY 2000 SGR contained in this notice. Similarly, the allowed expenditure figure for 2000 reflects our current estimate of the SGR for 2000. Both figures will be revised for the final time not later than November 1, 2001.

As we explained in our April 10, 2000 SGR notice (65 FR 19002), section 1848(d)(4)(C)(ii)(II) of the Act, as added by section 211(a)(1)(B) of the BBRA, specifies that allowed expenditures for the year of 1999 must be our estimate of the amount of the allowed expenditures that would be permitted under section 1848(d)(3)(C) of the Act for that year. We are, therefore, calculating allowed expenditures for CY 1999 as the sum of allowed expenditures for--(1) The January 1, 1999 through March 31, 1999 period; and (2) allowed expenditures for the April 1, 1999 through December 31, 1999 period.

Annual allowed expenditures for the period April 1, 1998 through March 31, 1999 are $49.4 billion. Our actuarial estimate of allowed expenditures for the 3-month period January 1, 1999 through March 31, 1999 is $12.5 billion that was determined by updating quarterly allowed expenditures included in the January 1, 1997 through March 31, 1997 period by the SGRs for FY 1998, FY 1999 and FY 2000. Adding this figure to the $39.9 billion figure for April 1, 1999 through December 31, 1999 equals allowed expenditures for 1999 of $52.4 billion. (Due to rounding, the figures may not add precisely to the total for 2000.)

Allowed expenditures for the period April 1, 1998 through March 30, 1999 are equal to allowed expenditures for the

previous 12-month period increased by the FY 1999 SGR. As discussed in the April 10, 2000 SGR final notice (65 FR 19001), because there is no provision in the Act for revising the FY 1999 SGR or, consequently, the allowed expenditures for the April 1, 1998 through March 31, 1999 period, we are not revising the January 1, 1999 through March 31, 1999 portion of allowed expenditures included in the 1999 allowed expenditures. Thus, allowed expenditures for the January 1, 1999 to March 31, 1999 period are the same as those included in our April 10, 2000 final notice (65 FR 19002). However, as indicated above, revisions to the FY 2000 SGR contained in this notice result in an increase in our earlier estimates of allowed expenditures for April 1, 1999 through December 31, 1999 and, hence, allowed expenditures for 1999.

D. Preliminary Estimate of the SGR for CY 2001

According to sections 1848(f)(2)(A) through (f)(2)(D) of the Act, as amended by section 211(b) of the BBRA, we have determined the preliminary estimate of the CY 2001 SGR to be 5.6 percent. Our determination is based on estimates of the following four statutory factors as indicated in the table below:

Statutory Factors	April 10 Estimate	Current Estimate
Fees	1.5	1.9
Enrollment	-0.6	0.9
Real Per Capita GDP	1.9	2.7
Law and Regulation	0.0	-0.0
Total	2.8	5.6

(Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, 1.019 X 0.991 X 1.027 X 1.000 = 1.056.) A more detailed explanation of each figure is provided below.

E. Sustainable Growth Rate for CY 2000

According to sections 1848(f)(2)(A) through (f)(2)(D) of the Act, as amended by section 211(b) of the BBRA, our current estimate of the CY 2000 SGR is 8.1 percent. This compares to an estimate of 5.8 percent included in our April 10, 2000 notice (65 FR 19003). The table below shows our April 10 and current estimates of the four statutory factors that determine the CY 2000 SGR:

Statutory Factors	April 10 Estimate	Current Estimate
Fees	2.1	2.1
Enrollment	-0.6	1.0
Real Per Capita GDP	2.5	4.3
Law and Regulation	1.7	0.5
Total	5.8	8.1

A more detailed explanation of each figure is provided below.

F. Sustainable Growth Rate for FY 2000

According to sections 1848(f)(2)(A) through (f)(2)(D) of the Act, as amended by section 211(b) of the BBRA, our current estimate of the FY 2000 SGR is 7.9 percent. This is in comparison to an estimate of 2.1 percent included in our October 1, 1999 notice (64 FR 53394). At the time of the April 10, 2000 final (SGR) notice, we estimated the SGR for FY 2000 would be 5.7 percent. The table below shows our October 1, 1999 and current estimates of the four statutory factors that determine the FY 2000 SGR:

Statutory Factors	April 10 Estimate	Current Estimate
Fees	2.1	2.1
Enrollment	-0.4	0.8
Real Per Capita GDP	2.7	4.5
Law and Regulation	1.2	0.3
Total	5.7	7.9

A more detailed explanation of each figure is provided below.

G. Calculation of the FY 2000 CY 2000 and CY 2001 Sustainable Growth Rate

1. Detail on the CY 2001 SGR

A more detailed discussion of our preliminary estimates of the four elements of the 2001 SGR follows.

Factor 1--Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2001

This factor was calculated as a weighted average of the CY 2001 fee increases that apply for the different types of services included in the definition of physicians' services for the SGR.

Physicians' services represent approximately 89 percent of allowed charges for physicians' services under the SGR and are updated by the Medicare Economic Index (MEI). Our current estimate of the MEI for 2001 is 2.1 percent. Diagnostic

laboratory tests represent approximately 11 percent of the Medicare allowed charges for physicians' services under the SGR. The BBA provided for a 0.0 percent update for CY 2001 for laboratory services. The table below shows both the physicians' and laboratory service updates that were used to determine the percentage increase in physicians' fees for CY 2001.

	Weight	Update
Physician	.89	2.1
Laboratory	.11	0.0
Weighted Average	1.0	1.9

After taking into account the elements described in the table, we estimate that the weighted-average increase in fees for CY 2001 for physicians' services under the SGR (before applying any legislative adjustments) will be 1.9 percent.

Factor 2--The Percentage Change in the Average Number of Part B Enrollees from CY 2000 to CY 2001

This factor is our estimate of the percent change in the average number of fee-for-service enrollees for CY 2001 as compared to CY 2000. Medicare+Choice (M+C) plan enrollees, whose Medicare-covered medical care is outside the scope of the SGR, are excluded from this estimate. Our actuaries estimate that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in M+C plans) will

increase by 0.9 percent in calendar year 2001. This estimate was derived by subtracting estimated M+C enrollment from estimated overall Medicare enrollment as illustrated in the table below.

	2000	2001
Overall	37.476 million	37.824 million
Medicare+Choice	6.303 million	6.382 million
Net	31.174 million	31.442 million
Percent Increase		0.9 percent

In our April 10 final notice (65 FR 19005), we indicated that the enrollment factor is one of two elements of the SGR upon which there has been the largest difference between our actuaries' estimates and the actual percentage change in the factor. At this time, our actuary has no information on actual enrollment in M+C organizations for 2001. While we do receive information on whether a M+C Plan will continue to participate or withdraw from the program in 2001, it remains difficult to estimate the number of beneficiaries that will select a M+C plan or fee-for-service before the start of the calendar year. While some managed care organizations will no longer offer a M+C plan, other plans are available as an option to most beneficiaries in areas where there have been plan withdrawals. We have considered this issue in developing our 2001 M+C enrollment

estimate. While there have been plan withdrawals the past three years, we have continued to observe increased enrollments. For 2001, we considered the issue of plan withdrawals and are forecasting a smaller increase than in prior years. Since beneficiaries have the option of moving between the fee-for-service and M+C sectors on a monthly basis, there may be movement during the year between the fee-for-service and M+C programs. This is another factor that contributes to the difficulty of estimating the size of the M+C enrollee population prior to the start of a calendar year. Since the fee-for-service enrollment figure is determined net of the change in M+C enrollment, it makes early estimates of this factor difficult. We would further point out that our estimate of this factor will have little bearing on the estimate of the update adjustment factor for 2001; it has no impact since the update adjustment is already at its limit. Since the law requires revisions of the estimates used in setting the SGR, we will have information on actual enrollment in M+C plans for the first eight months of 2001, and will be better able to predict the change in fee-for-service enrollment for the year by the time we determine the 2002 physician fee schedule. Thus, our estimate of the increase in fee-for-service enrollment contained in this final rule has no affect on the 2001 physician fee schedule update and will

reflect later estimates based largely on actual information for the period by the time we set the 2002 physician fee schedule update.

Factor 3--Estimated Real Gross Domestic Product Per Capita Growth in CY 2001

Section 1848(f)(2)(C) of the Act, as amended by section 211 of the BBRA, requires us to estimate growth in real GDP per capita. This factor is applied on a CY basis beginning with the CY 2000 SGR. We estimate that the growth in real GDP will be 2.7 percent in CY 2001. Our past experience indicates that there have also been large changes in estimates of real per capita GDP growth and the actual change in this factor. Again, we note that we will use revised estimates of real per capita GDP growth in setting future year updates.

Factor 4--Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in CY 2001 Compared With CY 2000

There are no statutory or regulatory provisions that will affect expenditures in CY 2001 relative to CY 2000. The percentage change in expenditures for physicians' services resulting from changes in law or regulations is estimated to be 0.0 percent for 2001.

2. Detail on Calculation of the FY 2000 and CY 2000 SGRs

A more detailed discussion of our revised estimates of the four elements of the FY 2000 and CY 2000 SGR follows.

Factor 1--Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for FY 2000 SGR and CY 2000 SGR.

We are continuing to use 2.1 percent for this element of the SGR for the FY 2000 SGR and the CY 2000 SGR. This factor is unchanged from earlier estimates previously described respectively for FY 2000 and CY 2000 in the October 1, 1999 Federal Register (65 FR 53395) and the April 10, 2000 Federal Register (65 FR 19003).

Factor 2--The Percentage Change in the Average Number of Part B Enrollees for the FY 2000 SGR and CY 2000 SGR.

This factor is our estimate of the percent change in the average number of fee-for-service enrollees for FY 2000 as compared to FY 1999 and CY 2000 as compared to CY 1999. As we indicated above, this factor is difficult to estimate prior to the beginning of the period for which the estimates are being made because of the interaction of the fee-for-service and M+C program and the lack of availability of actual data on beneficiary selection of M+C enrollment. We currently have such information on actual enrollment in the M+C program for FY 2000 and CY 2000 that permits estimates of the change in fee-for-

service enrollment for these years that will be more reflective of the final actual change. The estimates for FY 2000 and CY 2000 were derived by subtracting estimated M+C enrollment from estimated overall Medicare enrollment as illustrated in the tables below.

	1999	2000
Overall	37.055 million	37.746 million
Medicare+Choice	6.191 million	6.303 million
Net	30.864 million	31.174 million
Percent Increase		1.0 percent

Our actuaries' estimate of the percent change in the average number of fee-for-service enrollees, net of M+C enrollment for 2000 compared to 1999 (0.8 percent for fiscal year 2000, and 1.0 percent for calendar year 2000) is greater than earlier estimates of this factor (-4.3 percent for FY 2000 and -0.6 percent for CY 2000). This is because the historical base from which our actuarial estimate is made has changed (that is, we have more information on actual enrollment in M+C plans from CY 1999 and CY 2000 that affects our estimates for these and future years).

Factor 3--Estimated Real Gross Domestic Product Per Capita Growth in FY 2000 and CY 2000

In the FY 2000 SGR notice published on October 1, 1999 (64 FR 53396), we estimated that real GDP growth per capita for FY 2000 would be 1.8 percent. In our April 10, 2000 SGR notice, we estimated that real per capita GDP growth for CY 2000 would be 2.5 percent. We are now estimating real GDP growth per capita to be 4.5 percent for FY 2000 and 4.3 percent for CY 2000. As we explained in our April 10, 2000 SGR notice (65 FR 19004), the higher estimate of the FY 2000 SGR is due in part to Bureau of Economic Analysis (BEA) revisions to the historical National Income and Product Accounts (NIPA) and in part due to a change in the outlook for growth in 2000. The historical revisions, released by BEA on October 29, 1999, raised historical real GDP per capita growth by 0.2 percentage points on average between 1959 and 1998, with larger differences in recent years. (For detailed description of changes to NIPA, see Brent R. Moulton, Robert P. Parker, and Eugene P. Seskin, "A Preview of the 1999 Comprehensive Revision of the National Income and Product Accounts," Survey of Current Business (August, 1999): 7-20.) Subsequently, the projections of growth in real GDP per capita for FY 2000 have been revised upwards to reflect these revisions. Also, projections of real GDP per capita in 2000 (both FY and CY) have been revised upward to reflect stronger than expected stock market performance and less

than expected buildup of inventories in preparation for Y2K in 1999.

Factor 4--Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in FY 2000 Compared with FY 1999 and CY 2000 Compared With CY 1999

As we explained in our October 1, 1999 and April 10, 2000 SGR notices, legislative changes contained in the BBA and the BBRA will have an impact on expenditures for physicians' services under the SGR in FY 2000 and CY 2000. Section 4103 of the BBA mandates a new prostate screening benefit effective January 1, 2000. We originally did not include any costs associated with the prostate screening benefit in our FY 2000 SGR notice published on August 1, 1999 (64 FR 53394). In the CY 2000 SGR notice published on April 10, 2000 (65 FR 19004), we indicated that inclusion of the prostate screening benefit would increase the FY 2000 SGR by 1.4 percentage points. We inadvertently included both the estimated physician and hospital expenditures associated with the prostate screening benefit in this figure while only Part B physician expenditures should be included in the SGR. In the April 10, 2000 SGR notice, we estimated that factor 4 would be 1.2 percentage points for the FY 2000 SGR and 1.7 percentage points for the CY 2000 SGR. The corresponding figures are now 0.3 percent for FY 2000 and 0.5

percent for CY 2000. The correction of the prostate screening benefit largely explains the reduction in this factor from our April 10, 2000 notice. We also incorporated a higher price for the prostate screening test itself that has the effect of slightly increasing this component of the FY and CY 2000 SGR. Other factors that affect the FY 2000 and CY 2000 SGR are the elimination of the requirement that subluxation of the spine be demonstrated by an x-ray before a beneficiary can receive Medicare coverage for chiropractic services. This provision is resulting in a small increase in expenditures in FY 2000 and CY 2000. The impact of BBA Medicare Secondary Payer provisions will have marginal impact on reducing expenditures in FY 2000 and CY 2000.

Certain BBRA provisions also have a small impact on expenditures in FY 2000 and CY 2000. Section 224 of the BBRA increases payments for pap smears and is slightly increasing expenditures. Section 221 of the BBRA postponed the implementation of payment caps on physical and occupational therapy and speech-language pathology services. The effect of this provision on physicians and independent practitioners is resulting in a small increase in expenditures for these years. There is no effect on the SGR of provisions related to the technical component of a physician pathology service or the use

of modifier 25. We are not implementing the proposed policy related to modifier 25, and the savings associated with the technical component of a physician pathology service are not large enough to affect calculation of the FY 2001 SGR.

After taking into account these provisions, the percentage change in expenditures for physicians' services resulting from changes in law or regulations is estimated to be 0.3 percent for FY 2000 and 0.5 percent for CY 2000.

VII. Provisions of the Final Rule

The provisions of this final rule restate the provisions of the July 2000 proposed rule, except as noted elsewhere in the preamble. Following is a highlight of the changes made from the proposed rule:

For changes related to the Geographic Practice Cost Index (GPCI), we made no changes in the 2002 and 2001 GPCIs from those proposed in the July 2000 proposed rule except to correct the Kansas malpractice GPCI. Since the revised GPCIs could not result in total payments either greater or lesser than payments that would have been made if GPCIs were not revised, it was necessary to adjust the GPCIs for budget neutrality as required by law. Therefore, we adjusted the 2001 through 2002 GPCIs as follows--work by 0.99699; practice expense by 0.99235; and malpractice by 1.00215.

For malpractice RVUs, new malpractice RVUs, based on the more recent 1996 through 1998 premium data, will become effective January 1, 2001. These malpractice RVUs will be considered interim for 2001 and subject to comment and possible revision in 2002.

We are not finalizing our proposal relating to global period for insertion, removal, and replacement of pacemakers and cardioverter defibrillators, because we believe that physicians have raised valid concerns that the adjustment to the work RVUs in the proposed rule may result in an underpayment for the service. Until we review this issue further, we are continuing with current pricing for these services and the use of the 90-day global period.

For our proposal relating to low intensity ultrasound, we are assigning .62 work RVUs and .04 malpractice RVUs to CPT code 20979 (which are the values also used for CPT code 20974). To determine the practice expense RVUs, we are applying direct inputs of technician time of 45 minutes and an exam table and minimum supply package. Since the publication of the July 2000 proposed rule, a national coverage decision has been made stating that low intensity ultrasound will be covered by Medicare as a treatment modality for nonunion of extremity fractures beginning April 1, 2001.

For our proposal concerning observation care codes CPT 99234 through 99236, we are not adjusting the work RVUs as proposed. We are maintaining the current work RVUs and clarifying the policies to be followed for the use of these codes.

VIII. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IX. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

X. Regulatory Impact Analysis

We have examined the impacts of this final rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4), the Regulatory Flexibility Act of 1980 (RFA) (Pub. L. 96-354), and Executive Order 13132 of August 4, 1999 (Federalism).

EO 12866 directs agencies to assess costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). In the proposed rule impact analysis, we indicated that the rule would not be a major rule because it would not increase or decrease expenditures to a physician specialty or geographic area by more than $100 million. While the changes in the Medicare physician fee schedule are for the most part, budget neutral, they do involve redistribution of Medicare spending among procedures and physician specialties and geographic areas. The redistributive effect of this rule on any particular specialty or geographic area is, in our estimate, likely to exceed $100 million for at least one physician specialty. For this reason, we are considering this to be a major rule. The GPCI changes are expected to increase payments by less than $10 million in one locality and decrease payments by about $20 million in another locality. The effect on all other payment localities is likely to be less than these amounts.

The UMRA also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more. We have determined that this rule has no consequential effect on State, local, or tribal governments. We believe the private sector cost of this rule falls below the above-stated threshold as well.

The RFA requires that we analyze regulatory options for small businesses and other small entities. We prepare a Regulatory Flexibility Analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives and lessen significant adverse economic impact on the small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the

provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

For purposes of the RFA, all physicians are considered to be small entities. There are about 700,000 physicians and other practitioners who receive Medicare payment under the physician fee schedule.

For the purpose of EO 12866 and the RFA we have prepared the following analysis, which, together with the rest of this preamble, meets all four assessment requirements. It explains the rationale for and purpose of the rule, details the costs and benefits of the rule, analyzes alternatives, and presents the measures we considered to minimize the burden on small entities.

A. Resource-Based Practice Expense Relative Value Units

Revisions in resource-based practice expense RVUs for physicians' services are calculated to be budget neutral, that is, the total practice expense RVUs for calendar year 2001 are calculated to be the same as the total practice expense RVUs that we estimate would have occurred without the changes in this regulation. This also means that increases in practice expense RVUs for some services will necessarily be offset by corresponding decreases in values for other services.

The following table shows the impact on total allowed charges by specialty of this rule's practice expense changes. In addition to the provisions of the rule, this table incorporates any impacts that result from using 1999 utilization data and other changes that we have made to practice expense inputs. The column labeled “Year 2001-2002 Impact” shows the impact on the fully implemented practice expense RVUs of changes resulting from this final rule. The column labeled “Year 2001” impact reflects only the 2001 portion of the changes from “Year 2001-2002 Impact” column. The difference between the two columns reflects the effect of the transition to fully implemented practice expense RVUs. That is, the impact in the 2001 column will reflect 75 percent of the impact on the fully implemented RVUs. These impacts are in addition to the impacts announced in previous rules related to the adoption of resource-based practice relative value units.

Impact of Practice Expense Changes, Transition, and 2001 - 2002

Specialty	Allowed Charges (Billions $)	Impact Year 2001 %	Impact 2001-2002 %
Anesthesiology	1.5	-1	-1
Cardiac Surgery	0.3	-1	-2
Cardiology	4.1	-1	-1
Chiropractor	0.4	1	1
Clinics	1.5	0	0
Dermatology	1.4	-1	-2
Emergency Medicine	1.0	0	0
Family Practice	3.3	-2	-2
Gastroenterology	1.2	1	2
General Practice	1.0	-1	-2
General Surgery	1.9	0	0
Hematology Oncology	0.6	-2	-2
Internal Medicine	6.8	-1	-1
Nephrology	0.9	2	3
Neurology	0.8	0	0
Neurosurgery	0.3	-1	-1
Nonphysician Practitioner	1.1	1	2
Obstetrics/Gynecology	0.4	0	-1
Ophthalmology	3.7	0	0
Optometrist	0.5	-1	-2
Orthopedic Surgery	2.2	-1	-1
Other Physician	1.5	0	0
Otolaryngology	0.6	-2	-2
Pathology	0.6	-2	-3
Plastic Surgery	0.2	0	1
Podiatry	1.1	0	0
Psychiatry	1.0	1	1
Pulmonary	1.0	0	1
Radiation Oncology	0.7	0	0
Radiology	3.0	4	5
Rheumatology	0.3	-1	-1
Suppliers	0.5	-5	-6
Thoracic Surgery	0.5	-1	-1
Urology	1.3	0	0
Vascular Surgery	0.3	-1	-1

The following table shows the impact of this final rule compared to the proposed rule that was published on July 17. There are 3 major changes that occurred between the proposed and final rule that may have an impact on specialty level payments. First, we corrected an error in the practice expense methodology that affected physical and occupational therapy. We inadvertently used the incorrect practice expense per hour for physical and occupational therapy in the proposed rule. This caused the nonphysician practitioner category to reflect a 4 percent increase in payments. The correct figure should have been 1 percent. Second, we are using 1999 utilization data. Use of the 1999 utilization data generally appears to have little impact on any particular specialty. It does result in a small reduction in payments for pathology and a somewhat larger reduction in payments for the supplier category. Third, we adopted the recommendations of the RUC and PEAC to make refinements to the practice expense inputs for office visits and office consultation services. This change will have the effect of reducing payments for specialties whose incomes are derived in large part from these services. We note that the table shows the impact of this rule only and does not incorporate practice expense changes from two final rules, November 2, 1998 (63 FR 58895) and November 2, 1999 (64 FR 59433), that resulted in

large increases in payments for visit and consultation services provided in physicians' offices. Since the statute requires a transition to payments based on resource-based practice expense RVUs, the increase in payments for these services is occurring over a 4-year period. Payment for these services is continuing to increase under the transition to resource-based practice expense RVUs. However, it is increasing by a lesser amount than earlier anticipated.

Impact of Practice Expense Changes of the Final Rule Compared to the Proposed Rule

Specialty	Allowed Charges (Billions $)	Proposed Rule Impact %	Final 2001-2002 Impact %
Anesthesiology	1.5	-1	-1
Cardiac Surgery	0.3	-3	-2
Cardiology	3.9	0	-1
Chiropractor	0.4	1	1
Clinics	1.5	0	0
Dermatology	1.3	0	-2
Emergency Medicine	0.9	0	0
Family Practice	3.2	0	-2
Gastroenterology	1.1	2	2
General Practice	1.0	0	-2
General Surgery	1.9	-1	0
Hematology Oncology	0.6	-1	-2
Internal Medicine	6.7	0	-1
Nephrology	0.9	2	3
Neurology	0.8	0	0
Neurosurgery	0.3	-1	-1
Nonphysician Practitioner	0.9	4	2
Obstetrics/Gynecology	0.4	-1	-1
Ophthalmology	3.7	-1	0
Optometrist	0.5	-2	-
Orthopedic Surgery	2.2	-1	-1

Other Physician	1.3	1	0
Otolaryngology	0.6	-1	-2
Pathology	0.6	-1	-3
Pastic Surgery	0.2	0	1
Podiatry	1.1	0	0
Psychiatry	1.1	-1	1
Pulmonary	1.0	0	1
Radiation Oncology	0.6	1	0
Radiology	2.9	3	5
Rheumatology	0.3	0	-1
Suppliers	0.5	-1	-6
Thoracic Surgery	0.5	-2	-1
Urology	1.3	0	0
Vascular Surgery	0.3	-1	-1

The following table titled Impact of this Final Rule on Payments for Selected Codes shows the percentage change in total payment (in 2001 physician fee schedule dollars) for selected high-volume procedures that result from practice expense and malpractice changes announced in this final rule. These tables reflect the impact of this final rule only on the fully implemented fee schedule amount. The payments in these columns are determined using a conversion factor $38.2581. The RVUs used for calculating payment in the “old” columns are from the November 2, 1999 final rule. The RVUs used in calculating payments in the “new” columns are from this final rule. By using the conversion factor of $38.2581 and the 2001 malpractice RVUs to calculate payments in both the “old” and “new” columns, the impact of changes in practice expense are illustrated. These tables do not show the actual impact on payment from 2000 to 2001 because they do not incorporate the effect of the transition or physician fee schedule update (that is, “old” and “new” payments both reflect use of the 2001 conversion factor).

B. Geographic Practice Cost Index Changes

Section 1848(e)(1)(A) of the Act requires that payments under the Medicare physician fee schedule vary among payment areas only to the extent that area costs vary as reflected by the area GPCIs. The GPCIs measure area cost differences in the three components of the physician fee schedule: physician work, practice expenses (employee wages, rent, medical supplies, and equipment), and malpractice insurance. Section 1848(e)(1)(C) of the Act requires that the GPCIs be reviewed and, if necessary, revised at least every 3 years. The first GPCI revision was implemented in 1995. The second revision was implemented in 1998, and the next revision will be implemented in 2001. Section 1848(e)(1)(C) of the Act also requires that the GPCI revisions be phased in equally over a 2-year period if more than one year has elapsed since the last adjustment.

An estimate of the overall effects of proposed GPCI changes on fee schedule area payments can be demonstrated by a comparison of area geographic adjustment factors (GAFs). The GAFs are a weighted composite of each area's work, practice expense, and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall area costs and payments. The

actual effect on payment for any actual service will deviate from the GAF to the extent that the service's proportions of work, practice expense, and malpractice expense RVUs differ from those of the GAF. Addendum H shows the estimated effects of the revised GPCIs on area GAFs in descending order.

Only 14 of the 89 fee schedule areas will change by at least 2 percent. Only 16 areas will change by from 1 to 1.9 percent. The remaining 59 areas are estimated to experience payment changes of less than 1 percent under the revised GPCIs. These are very minor changes that would be expected in that we are revising only the rent indices, comprising 11.6 percent of the total GPCI, and the malpractice expense indices, comprising 3.2 percent of the GPCI. Thus, only about 15 percent of the GPCIs will be subject to change. The effects in the transition year 2001 will only be one-half of these amounts as the revised GPCIs will be phased in over a 2-year period as required by law.

C. Resource-Based Malpractice Relative Value Units

The malpractice RVUs in this final rule reflect the newer data and refinements made as a result of comments made on last year’s rule. As we anticipated in the proposed rule, use of the updated data results in little impact on the specialty level payments. Tables showing the impacts can be found in the technical addendum at Addendum G. Of the 62 specialties shown,

the overall median effect on specialty payments is 0.0 percent. The median impact on specialties whose payments are estimated to increase is +0.2 percent. The median impact on specialties whose payments are expected to decrease is –0.1 percent.

D. Critical Care Relative Value Units

As we explained in the preamble in the November 1999 final rule, we established interim work RVUs for 2000 for CPT codes 99291 and 99292 (critical care services). These RVUs were decreased in 2000 due to concerns about changes in the CPT definition for these services. In the proposed rule we indicated our intent to increase the work RVUs for critical care services and value the physician work at 4.0 RVUs for CPT code 99291 and 2.0 RVUs for CPT code 99292 because of changes that were made to the definition of critical care for 2001. The earlier reductions to the work RVUs were made assuming there would be a substitution of use of the critical care codes for other codes that would increase net payments if there were no reductions to the work RVUs. We do not believe this substitution will occur because of additional revisions to the definition of critical care for 2001. Thus net payments would decrease if we do not restore critical care RVUs to their former levels. For this reason we are finalizing our proposal and

increasing the work RVUs to 4.0 RVUs for CPT code 99291 and 2.0 RVUs for CPT code 99292.

E. Care Plan Oversight and Physician Certification/Recertification

We are establishing two new HCPCS codes for care plan oversight that are consistent with our coverage criteria. We are establishing two new HCPCS codes to describe the services involved in physician certification or recertification and development of a plan of care for a patient for whom the physician has prescribed Medicare-covered home health services. We are assuming there would be no additional cost or savings as a result of the two new HCPCS codes for care plan oversight. We are merely instituting these codes for consistency with our coverage criteria, and they would be used in place of the CPT codes when these services are provided.

In our proposed rule we indicated that new HCPCS codes are being established for physician certification or recertification and development of a plan of care. We stated that payment for these services is currently included in the payment for a variety of services such as E/M services that are provided independently to patients as part of a global surgical service. Under this proposal, we would instead pay separately for the certification and recertification of the plan of care for home health

services. Since we are proposing to pay separately for a service that is currently included in our payment for other services, this proposal would increase Medicare expenditures for physicians' services without an adjustment to the physician fee schedule CF. For this reason, we proposed to adjust the physician fee schedule CF to ensure that Medicare payments for physicians' services do not increase as a result of this proposal.

Comment: We received several comments that objected to any budget neutrality adjustment related to the establishment of new codes related to certification and recertification of a plan of care for home health services. According to the AMA, the home health PPS rule published on July 3, 2000 indicates that we want more physician effort devoted to home health services, and not just a continuation of current efforts. The AMA stated that our home health PPS rule indicates an intent to focus on physician certification efforts and education “in order to better involve the physician in the delivery of home health services.” (65 FR 41127).

Response: Although we are establishing new codes to describe certification and recertification of a plan of care for home health services, we disagree that the establishment of these codes constitutes a new requirement to furnish a physicians’

service as a condition of payment for home health services. We note that the proposed regulations applicable to home health services, published on October 10, 1999, would have modified 42 CFR section 424.22 to add a new paragraph (a)(1)(v) to specify that as a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify that the individual is correctly assigned to one of the home health resource groups. However, in response to comments we eliminated this requirement and did not make a modification to the regulation. We also proposed to make a conforming change at paragraph (b)(1) of §424.22 regarding the timing of the recertification. Specifically, we proposed to amend §424.22(b) by replacing the phrase "at least every 2 months" with "at least every 60 days." We believe this is a minor conforming change to the regulation that will have little or no impact on expenditures. While we believe it is beneficial to establish separate codes for the certification and recertification services, the home health regulations do not impose any new requirements on physicians that will increase expenditures. As indicated in our April 2000, Program Memorandum (Provider Education Article: Role of Physicians in the Home Health Prospective Payment System, transmittal B-00-16), the prospective payment system does not introduce change to the plan

of care. It remains the beneficiary's physician's responsibility to develop a plan of care based on his or her intimate knowledge of the medical condition of the home health patient.

The sustainable growth rate determined under section 1848(f) of the Act allows for an adjustment for changes in expenditures that "will result from changes in law and regulations." Since there are no new requirements being imposed upon physicians and there are no regulatory changes that would mandate an adjustment to the SGR, we are making a budget neutrality adjustment to the conversion factor to ensure that expenditures do not increase as a result of this provision. We estimate that paying separately for certification and recertification of a plan of care for home health services will increase Medicare payments without the 0.3 percent offsetting adjustment to the conversion factor that we have applied.

F. Observation Care Codes

We believe that there are not any significant costs for this policy clarification. We believe physicians have not typically been billing for the discharge component of a hospital or observation stay of less than 8 hours. However, physicians who have been billing 99234 through 99236 for stays less than 8 hours in length would see a small reduction in payment. This

policy clarification will give clear guidance to physicians and Medicare contractors in reviewing medical records and would assure consistent payment across contractors.

G. Ocular Photodynamic Therapy and Other Ophthalmological Treatments

As previously stated, we are establishing national HCPCS codes and payment amounts for ocular photodynamic therapy. If we did not establish national codes and pricing for this procedure, carriers that determined that this procedure is covered would use unlisted codes and determine pricing locally. There will be no budget effects associated with establishing national codes and payment amounts for this service since national pricing would substitute for use of unlisted codes and carrier pricing.

H. Electrical Bioimpedance

As stated earlier, we are establishing a national payment amount for electrical bioimpedance. This rule establishes national pricing amounts for a service currently priced by carriers. This change will have little impact on the Medicare program costs.

I. Global Period for Insertion, Removal, and Replacement of Pacemakers and Cardioverter Defibrillators

We proposed to change the global period for certain CPT codes involving the insertion, removal, and replacement of pacemakers

and cardioverter defibrillators from 90 days to 0 days. The proposed changes were not anticipated to result in cost or savings because we proposed to reduce the work and practice expense RVUs to account for any claims that we would receive for post-operative visits that were previously bundled into payment for the 90-day global surgical service. As a result of comments received on the proposed rule, we are not adopting the proposed policy. The global period will remain at 90 days, and we will not implement the proposed reductions to the work and practice expense RVUs. Thus, since there is no change in policy, there are no budget implications of our decision on this issue in the final rule.

J. Antigen Supply

Our change from permitting a physician to bill for a 12-month, as opposed to a 12-week supply of antigen could benefit beneficiaries, since they will be able to obtain a year's supply of medication in a single visit. We believe that this change has no impact on program costs. Also, there is no impact on the beneficiary, since this change only aggregates four prescriptions into one, and the cost to the beneficiary remains the same.

K. Increased Space Allotment in Physical Therapy Salary Equivalency Guidelines

We are making an adjustment to our application of the salary equivalency guidelines that are used to determine the indirect components of the practice expense per hour for physical and occupational therapy. Payments for all outpatient physical and occupational therapy services will increase by 3 and 4 percent, respectively. This change will be budget neutral among all physician fee schedule services.

Other issues mentioned in the preamble are merely discussions or clarifications and, therefore, have no budgetary impact.

Budget-Neutrality

Each year since the fee schedule has been implemented, our actuaries have determined any adjustments needed to meet the budget-neutrality requirement of the statute. A component of the actuarial determination of budget-neutrality involves estimating the impact of changes in the volume-and-intensity of physicians' services provided to Medicare beneficiaries as a result of the proposed changes. Consistent with the provision in the November 1998 final rule, the actuaries would use a model that assumes a 30 percent volume-and-intensity response to price reductions. This year there will be a 5.0 percent increase in the conversion factor resulting from the physician fee schedule update. Since this update will offset any negative payment impacts resulting from this final rule, no volume and intensity

adjustment is being incorporated into the physician fee schedule conversion factor in 2001.

Impact on Beneficiaries

Although changes in physicians' payments when the physician fee schedule was implemented in 1992 were large, we detected no problems with beneficiary access to care. Furthermore, since beginning our transition to a resource-based practice expense system in 1999, we have not found that there are problems with beneficiary access to care.

XI. Federalism

We have reviewed this final rule under the threshold criteria of EO 13132, Federalism, and we have determined that the proposed rule does not significantly affect the rights, roles, and responsibilities of States.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, HCFA amends 42 CFR chapter IV as follows:

Part 410--SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In §410.68, republish the introductory text and revise the introductory text for paragraph (b) to read as follows:

§**410.68 Antigens: Scope and conditions.**

Medicare Part B pays for--

* * * * *

(b) A supply of antigen sufficient for not more than 12 months that is--

* * * * *

PART 414--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

3. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395(hh), and 1395rr(b)(1).

4. Revise §414.22(b)(5)(i) to read as follows:

§414.22 Relative value units (RVUs).

* * * * *

(b) * * *

(5) * * *

(i) Usually there are two levels of practice expense RVUs that correspond to each code.

(A) *Facility practice expense RVUs.* The lower facility practice expense RVUs apply to services furnished to patients in the hospital, skilled nursing facility, community mental health center, or in an ambulatory surgical center when the physician performs procedures on the ASC approved procedures list. (The facility practice expense RVUs for a particular code may not be greater than the non-facility RVUs for the code.)

(B) *Non-facility practice expense RVUs.* The higher non-facility practice expense RVUs apply to services performed in a physician's office, a patient's home, an ASC if the physician is performing a procedure not on the ASC approved procedures list, a nursing facility, *or* a facility or institution other than a hospital or skilled nursing facility, community mental health center, or ASC performing an ASC approved procedure.

(C) *Outpatient therapy services.* Outpatient therapy services billed under the physician fee schedule are paid using the non-facility practice expense RVU component.

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(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: _____

_____

Michael M. Hash

Acting Administrator,

Health Care Financing Administration.

Dated: _____

_____

Donna E. Shalala

Secretary.

BILLING CODE 4120-01-P

Note: These addenda will not appear in the Code of Federal Regulations.

Addendum A -- Explanation and Use of Addenda B

The addenda on the following pages provide various data pertaining to the Medicare fee schedule for physicians' services furnished in 2001. Addendum B contains the RVUs for work, non-facility practice expense, facility practice expense, and malpractice expense, and other information for all services included in the physician fee schedule.

Addendum B—2001 Relative Value Units and Related Information Used in Determining Medicare Payments for 2001

This addendum contains the following information for each CPT code and alphanumeric HCPCS code, except for alphanumeric codes beginning with B (enteral and parenteral therapy), E (durable medical equipment), K (temporary codes for nonphysicians' services or items), or L (orthotics), and codes for anesthesiology.

1. CPT/HCPCS code. This is the CPT or alphanumeric HCPCS number for the service. Alphanumeric HCPCS codes are included at the end of this addendum.

2. Modifier. A modifier is shown if there is a technical component (modifier TC) and a professional component (PC) (modifier -26) for the service. If there is a PC and a TC for the service, Addendum B contains three entries for the code: One for the global values (both professional and technical); one for modifier -26 (PC); and one for modifier TC. The global service is not designated by a modifier, and physicians must bill using the code without a modifier if the physician furnishes both the PC and the TC of the service.

Modifier -53 is shown for a discontinued procedure. There will be RVUs for the code (CPT code 45378) with this modifier.

3. Status indicator. This indicator shows whether the CPT/HCPCS code is in the physician fee schedule and whether it is separately payable if the service is covered.

A = Active code. These codes are separately payable under the fee schedule if covered. There will be RVUs for codes with this status. The presence of an "A" indicator does not mean that Medicare has made a national decision regarding the coverage of the service. Carriers remain responsible for coverage decisions in the absence of a national Medicare policy.

B = Bundled code. Payment for covered services is always bundled into payment for other services not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are incident. (An example is a telephone call from a hospital nurse regarding care of a patient.)

C = Carrier-priced code. Carriers will establish RVUs and payment amounts for these services, generally on a case-by-case basis following review of documentation, such as an operative report.

D = Deleted code. These codes are deleted effective with the beginning of the calendar year.

E = Excluded from physician fee schedule by regulation. These codes are for items or services that we chose to exclude from the physician fee schedule payment by regulation. No RVUs are shown, and no payment may be made under the physician fee schedule for these codes. Payment for them, if they are covered, continues under reasonable charge or other payment procedures.

G = Code not valid for Medicare purposes. Medicare does not recognize codes assigned this status. Medicare

uses another code for reporting of, and payment for, these services.

N = Noncovered service. These codes are noncovered services. Medicare payment may not be made for these codes. If RVUs are shown, they are not used for Medicare payment.

P = Bundled or excluded code. There are no RVUs for these services. No separate payment should be made for them under the physician fee schedule.

-- If the item or service is covered as incident to a physician's service and is furnished on the same day as a physician's service, payment for it is bundled into the payment for the physician's service to which it is incident (an example is an elastic bandage furnished by a physician incident to a physician's service).

-- If the item or service is covered as other than incident to a physician's service, it is excluded from the physician fee schedule (for example, colostomy supplies) and is paid under the other payment provisions of the Act.

R = Restricted coverage. Special coverage instructions apply. If the service is covered and no RVUs are shown, it is carrier-priced.

T = Injections. There are RVUs for these services, but they are only paid if there are no other services payable under the physician fee schedule billed on the same date by the same provider. If any other services payable under the physician fee schedule are billed on the same date by the same provider, these services are bundled into the service(s) for which payment is made.

X = Exclusion by law. These codes represent an item or service that is not within the definition of "physicians' services" for physician fee schedule payment purposes. No RVUs are shown for these codes, and no payment may be made under the physician fee schedule. (Examples are ambulance services and clinical diagnostic laboratory services.)

4. Description of code. This is an abbreviated version of the narrative description of the code.

5. Physician work RVUs. These are the RVUs for the physician work for this service in 2000. Codes that are not used for Medicare payment are identified with a "+."

6. Fully implemented non-facility practice expense RVUs. These are the fully implemented resource-based practice expense RVUs for non-facility settings.

7. Year 2000 Transition non-facility practice expense RVUs. Blended non-facility practice expense RVUs for use in 2000.

8. Fully implemented facility practice expense RVUs. These are the fully implemented resource-based practice expense RVUs for facility settings.

9. Year 2000 transition facility practice expense RVUs. Blended facility practice expense RVUs for use in 2000.

10. Malpractice expense RVUs. These are the RVUs for the malpractice expense for the service for 2000.

11. Fully implemented non-facility total. This is the sum of the work, fully implemented non-facility practice expense, and malpractice expense RVUs.

12. Year 2000 transition non-facility total. This is the sum of the work, transition non-facility practice expense, and malpractice expense RVUs for use in 2000.

13. Fully implemented facility total. This is the sum of the work, fully implemented facility practice expense, and malpractice expense RVUs.

14. Year 2000 transition facility total. This is the sum of the work, transition facility practice expense, and malpractice expense RVUs for use in 2000.

15. Global period. This indicator shows the number of days in the global period for the code (0, 10, or 90 days). An explanation of the alpha codes follows:

MMM = The code describes a service furnished in uncomplicated maternity cases including antepartum care, delivery, and postpartum care. The usual global surgical concept does not apply. See the 1999 Physicians' Current Procedural Terminology for specific definitions.

XXX = The global concept does not apply.

YYY = The global period is to be set by the carrier (for example, unlisted surgery codes).

ZZZ = The code is part of another service and falls within the global period for the other service.