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Part II

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Health Care Financing Administration

42 CFR Part 405, et al.

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999; Final Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 410, 413, 414, 415, 424, and 485

[HCFA–1006–FC]

RIN 0938–AI52

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999

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

ACTION: Final rule with comment period.

SUMMARY: This final rule makes several policy changes affecting Medicare Part B payment. The changes that relate to physicians' services include: resource-based practice expense relative value units (RVUs), medical direction rules for anesthesia services, and payment for abnormal Pap smears. Also, we are rebasing the Medicare Economic Index from a 1989 base year to a 1996 base year. Under the law, we are required to develop a resource-based system for determining practice expense RVUs. The Balanced Budget Act of 1997 (BBA) delayed, for 1 year, implementation of the resource-based practice expense RVUs until January 1, 1999. Also, BBA revised our payment policy for nonphysician practitioners, for outpatient rehabilitation services, and for drugs and biologicals not paid on a cost or prospective payment basis. In addition, BBA permits certain physicians and practitioners to opt out of Medicare and furnish covered services to Medicare beneficiaries through private contracts and permits payment for professional consultations via interactive telecommunication systems. Furthermore, we are finalizing the 1998 interim RVUs and are issuing interim RVUs for new and revised codes for 1999. This final rule also announces the calendar year 1999 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 1999 Medicare physician fee schedule conversion factor is $34.7315.

DATES: *Effective date:* This rule this rule is effective January 1, 1999.

Applicability date: Part 405 subpart D is applicable for private contract affidavits signed and private contracts entered into on or after January 1, 1999.

This rule is a major rule as defined in Title 5, United States Code, section 804(2). Pursuant to 5 U.S.C. section 801(a)(1)(A), we are submitting a report to the Congress on this rule on October 30, 1998.

Comment date: We will accept comments on interim RVUs for selected procedure codes identified in Addendum C and on interim practice expense RVUs for all codes as shown in Addendum B. Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 4, 1999.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1006–FC, P.O. Box 26688, Baltimore, MD 21207–0488.

If you prefer, you may deliver your written comments (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 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1006–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 offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT:

Roberta Epps, (410) 786–4503 (for issues related to outpatient rehabilitation services).

Stephen Heffler, (410) 786–1211 (for issues related to the Medicare Economic Index).

Anita Heygster, (410) 786–4486 (for issues related to private contracts).

Jim Menas, (410) 786–4507 (for issues related to Pap smears and medical direction for anesthesia services).

Robert Niemann, (410) 786–4569 (for issues related to the drugs and biologicals policy).

Regina Walker-Wren, (410) 786–9160 (for issues related to physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives).

Craig Dobyski, (410) 786–4584 (for issues related to teleconsultations).

Stanley Weintraub, (410) 786–4498 (for issues related to practice expense relative value units and all other issues).

SUPPLEMENTARY INFORMATION:

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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 regulation's impact appears throughout the preamble and not exclusively in part IX.

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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:

AANA: American Association of Nurse Anesthetists
ABC: Activity based costing
ABN: Advance Beneficiary Notice
AHE: Average hourly earnings
AMA: American Medical Association
ANCC: American Nurses Credentialing Center
ASA: American Society of Anesthesiologists
ASOPA: American Society of Orthopedic Physician Assistants
AWP: Average wholesale price
BBA: Balanced Budget Act of 1997
BLS: Bureau of Labor Statistics
CAAHEP: Commission on Accreditation of Allied Health Education Programs
CF: Conversion factor
CFR: Code of Federal Regulations
CMSAs: Consolidated Metropolitan Statistical Areas
CORF: Comprehensive outpatient rehabilitation facility
CPEPs: Clinical Practice Expert Panels
CPI: Consumer Price Index
CPI–U: Consumer Price Index for All Urban Consumers
CPS: Current Population Survey
CPT: [Physicians'] Current Procedural Terminology
CRNA: Certified Registered Nurse Anesthetist
DME: Durable medical equipment
DMEPOS: Durable medical equipment, prosthetics, orthotics, and supplies
DRG: Diagnosis-related group
EAC: Estimated acquisition cost
ECI: Employment Cost Index
ES–202 Data: Bureau of Labor Statistics from State unemployment insurance agencies
ESRD: End-stage renal disease
FDA: Food and Drug Administration
FMR: Fair market rental
FQHC: Federally qualified health center
GAAP: Generally accepted accounting principles
GAF: Geographic adjustment factor
GPCI: Geographic practice cost index
HCFA: Health Care Financing Administration
HCPAC: Health Care Professionals Advisory Committee
HCPCS: HCFA Common Procedure Coding System
HHA: Home health agency
HHS: [Department of] Health and Human Services
HMO: Health maintenance organization
HPSA: Health professional shortage area
HRSA: Health Resources and Services Administration
HUD: [Department of] Housing and Urban Development
IPLs: Independent Physiologic Laboratories
MedPAC: Medicare Payment Advisory Commission
MEI: Medicare Economic Index
MGMA: Medical Group Management Association
MSA: Metropolitan Statistical Area
MSA: Medicare Supplemental Insurance
MVPS: Medicare volume performance standard
NAIC: National Association of Insurance Commissioners
NBCOPA: National Board on Certification for Orthopedic Physician Assistants
NCCPA: National Council on Certification of Physician Assistants
NPI: National provider identifier
OBRA: Omnibus Budget Reconciliation Act
OTIP: Occupational therapist in independent practice
PC: Professional component
PHS: Public Health Service
PMSA: Primary Metropolitan Statistical Area
PPI: Producer price index
PPS: Prospective payment system
PTIP: Physical therapist in independent practice
RBRVS: Resource Based Relative Value Scale
RHC: Rural health clinic
RUC: [AMA's Specialty Society] Relative [Value] Update Committee
RN: Registered nurse
RVU: Relative value unit
SMS: Socioeconomic Monitoring System
SNF: Skilled nursing facility
TC: Technical component
TEFRA: Tax Equity and Fiscal Responsibility Act
UPIN: Uniform provider identifier number

I. Background

A. 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 because of changes resulting from a review of those 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 this tolerance is exceeded, we must make adjustments to the conversion factors (CFs) to preserve budget neutrality.

B. Published Changes to the Fee Schedule

In the June 5, 1998, proposed rule (63 FR 30820), we listed all of the final rules published through October 31, 1997 relating to the updates to the RVUs and revisions to payment policies under the physician fee schedule. In the June 5, 1998 proposed rule (63 FR 30818), we discussed several policy options affecting Medicare payment for physicians' services including resource-based practice expense RVUs, medical direction rules for anesthesia services, and payment for abnormal Pap smears. Also, we discussed the rebasing of the Medicare Economic Index from a 1989 base year to a 1996 base year. Further, based on BBA, we proposed revising our payment policy for nonphysician practitioners, for outpatient rehabilitation services, and for drugs and biologicals not paid on a cost or prospective payment basis. In addition, based on BBA, we discussed implementing new payment policies for certain physicians and practitioners who opt out of Medicare and furnish covered services to Medicare beneficiaries through private contracts. And finally, based on BBA, we discussed teleconsultation services.

This final rule affects the regulations set forth at 42 CFR part 405, which consists of regulations on Federal health insurance for the aged and disabled; part 410, which consists of regulations on supplementary medical insurance benefits; part 414, which consists of regulations on the payment for Part B medical and other health services; part 415, which pertains to services furnished by physicians in providers, supervising physicians in teaching settings, and residents in certain settings; part 424, which pertains to the conditions for Medicare payment; and part 485, which pertains to conditions of participation: specialized providers.

II. Specific Proposals for Calendar Year 1998; Response to Comments

In response to the publication of the June 5, 1998 proposed rule, we received approximately 14,000 comments. We received comments from individual physicians, health care workers, and professional associations and societies. The majority of the comments addressed the proposal related to the resource-based practice expense policy.

The proposed rule discussed policies that affect 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 will 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 1999. We discuss in detail the effects of these changes in the Regulatory Impact Analysis (section IX).

For the convenience of the reader, the headings for the policy issues in this section correspond to the headings used in the June 5, 1998 proposed rule. More detailed background information for each issue can be found in the June 5, 1998 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 (Public Law 103–432), enacted on October 31, 1994, required us to develop a methodology for determining resource-based practice expense RVUs for each physician's service that would be effective for services furnished in 1998. In developing the methodology, we were required to consider the staff, equipment, and supplies used in providing medical and surgical services in various settings.

The legislation specifically required that, in implementing the new system of practice expense RVUs, we apply the same budget-neutrality provisions that we apply to other adjustments under the physician fee schedule.

On August 5, 1997, the President signed the BBA into law. Section 4505(a) of BBA delayed the effective date of the resource-based practice expense RVU system until January 1, 1999. In addition, BBA provided for the following revisions in the requirements to change from a charge-based practice expense RVU system to a resource-based method.

Instead of paying for all services entirely under a resource-based system in 1999, section 4505(b) of BBA provided for a 4-year transition period. The practice expense RVUs for the year 1999 will be the product of 75 percent of charge-based RVUs (1998) and 25 percent of the resource-based RVUs. For the year 2000, the percentages will be 50 percent charge-based and 50 percent resource-based. For the year 2001, the percentages will be 25 percent charge-based and 75 percent resource-based. For subsequent years, the RVUs will be totally resource-based.

Section 4505(e) of BBA provided that, for 1998, the practice expense RVUs be adjusted for certain services in anticipation of the implementation of resource-based practice expenses beginning in 1999. Practice expense RVUs for office visits were increased.

For other services whose practice expense RVUs (determined for 1998) exceeded 110 percent of the work RVUs and were provided less than 75 percent of the time in an office setting, the 1998 practice expense RVUs were reduced to a number equal to 110 percent of the work RVUs. This limitation did not apply to services that had a proposed resource-based practice expense RVU in the June 5, 1998 proposed rule that was an increase from its 1997 practice expense RVU.

The total of the reductions under this provision was less than the statutory maximum of $390 million. The procedure codes affected and the final RVUs for 1998 were published in the October 31, 1997 final rule (62 FR 59103).

Section 4505(d)(2) of BBA required that the Secretary transmit a report to the Congress by March 1, 1998, including a presentation of data to be used in developing the practice expense RVUs and an explanation of the methodology. A report was submitted to the Congress in early March 1998. Section 4505(d)(3) required that a proposed rule be published by May 1, 1998, with a 90-day comment period. For the transition to begin on January 1, 1999, a final rule must be published by October 30, 1998.

BBA also required that we develop new resource-based practice expense RVUs. In developing these new practice expense RVUs, section 4505(d)(1) required us to—

- Utilize, to the maximum extent practicable, generally accepted accounting principles that recognize all staff, equipment, supplies, and expenses, not just those that can be tied to specific procedures, and use actual data on equipment utilization and other key assumptions;
- Consult with organizations representing physicians regarding the methodology and data to be used; and
- Develop a refinement process to be used during each of the four years of the transition period.

2. Proposed Methodology for Computing Practice Expense Relative Value Units

(See Addendum B in the June 5, 1998 proposed rule (63 FR 30888) for a detailed technical description of the proposed methodology.)

In the June 5, 1998 proposed rule (63 FR 30827), we proposed a methodology

for computing resource-based practice expense RVUs that uses the two significant sources of actual practice expense data we have available: the Clinical Practice Expert Panel (CPEP) data and the American Medical Association's (AMA's) Socioeconomic Monitoring System (SMS) data. This 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 seen as a ''top-down'' approach.

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 by the physicians in the practice. The practice expenses per hour for the specialty are an average of the practice expenses per hour for the respondent physicians in that specialty.

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 the Medicare claims data. The primary sources for the physician time data were surveys submitted to the AMA's Specialty Society Relative Value Update Committee (RUC) and surveys done by Harvard for the initial establishment of the work RVUs.

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

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.

- For group one, which includes 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 group two, which includes administrative labor, office expenses, and all other expenses, a combination of the group one cost allocations and the physician fee schedule work RVUs were used to allocate the cost pools.
- 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.

Other Methodological Issues

Professional and Technical Component Services

Using the methodology described above, the professional and technical components of the resource-based practice expense RVUs do not necessarily sum to the global resource-based practice expense RVUs since specialties with different practice expenses per hour provide the components of these services in different proportions. We made two adjustments to the methodology, depending on the specific HCFA Common Procedure Coding System (HCPCS) code, so that the professional and technical component practice expense RVUs for a service sum to the global practice expense RVUs.

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 expenses tables from the SMS survey data, it was necessary to crosswalk these specialties to the most appropriate SMS specialty category. (See Table 3 in the June 5, 1998 proposed rule (63 FR 30833) for a listing of all proposed crosswalks.)

We also made the following adjustments to the practice expense per hour data:

- We set the medical materials and supplies practice expenses per hour for the specialties of ''Oncology'' and ''Allergy and Immunology'' equal to the medical materials and supplies practice expenses per hour for ''All Physicians,'' stating that we make separate payment for the drugs furnished by these specialties.
- 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 Physicians'' 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.
- Because we believed that the use of the average practice expenses per hour should create the appropriate practice expense pool for radiology, we did not attempt to differentiate the practice expenses per hour for radiologists according to who owned the equipment.

Time Associated With the Work Relative Value Units

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

For services such as radiology, dialysis, and physical therapy, and for many procedures performed by independent physiological laboratories and the nonphysician specialties of clinical psychologist and psychologist (independent billing), we calculated estimated total physician times for these services 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 Current Procedural Terminology (CPT) codes 00100 through 01996 using the base and time units from the anesthesia fee schedule and the Medicare allowed claims data.

We received the following comments on our proposed methodology to calculate resource-based practice expense RVUs:

Top-Down Methodology

Comment: Most of the physician specialty societies commenting on our proposed general methodology supported the use of the top-down approach as the most reasonable methodology for developing resource-based practice expense RVUs, and the most responsive approach to the requirements of BBA. This was echoed by comments from several nonphysician organizations, the Association of American Medical Colleges, and the Medical Group Management

Association, as well as several hundred individual commenters.

These commenters supported the top-down method for a variety of reasons:

- It reflects the relative values of physicians' actual practice expenses.
- It uses the best available sources of aggregate practice expense data.
- It recognizes specialty-specific indirect costs.
- It does not rely upon arbitrary, distorting data adjustments such as ''linking'' and ''scaling.''
- It is conducive to refinement.

MedPAC also agreed that this approach is necessary, because of limitations in the CPEP process and because the top-down approach assures that all practice costs are reflected in the RVUs.

However, several organizations, mainly representing primary care physicians and supported by comments from individual physicians, opposed the use of a top-down methodology to develop practice expense RVUs. They argued that the top-down approach is not resource-based but, rather, rewards higher paid physicians who have spent more in the past, regardless of the extent to which these expenditures contributed to patient care. Thus, the commenters claimed that the top-down approach perpetuates the inequities in the current charge-based practice expense RVUs that the implementation of a resource-based practice expense system was supposed to correct.

One commenter also claimed that the top-down approach is not responsive to the requirements of BBA, as the methodology is not based on generally accepted accounting principles. Further, the commenter argued that this new proposal is not more responsive to the concerns of the medical community in general but, rather, only benefits those specialties whose income was projected to decline under the bottom-up approach.

A specialty society representing clinical oncology opposed the top-down methodology because—

- It does not actually measure appropriate input resource costs and thus pays for inefficiencies;
- It overpays hospital-based and underpays office-based services; and
- The RVUs for individual codes cannot be refined because of the use of macro-specialty per hour costs.

There were several comments that expressed concern about the more specific impacts of the methodology. A major primary care organization pointed out that, under the 1997 proposed rule, an internist would have had to provide only 15 midlevel established patient office visits to obtain the practice expense reimbursement of a single coronary triple-bypass graft, compared to 40 visits under our current proposal. One organization opposed the use of the top-down approach because of the estimated reduction in payments to radiology and radiation oncology. Another commenter, representing pathologists, expressed concern that because pathology received small gains under the bottom-up method, but a 10 percent reduction under the top-down, there are possible flaws in the top-down methodology.

A few of the above comments specifically recommended that we adopt a new bottom-up approach that is responsive to the BBA, the General Accounting Office (GAO), and the concerns of the medical community. Another organization commented that both top-down and bottom-up methodologies are inherently flawed, and that we should consider an entirely new payment algorithm using type of practice. One of the major primary care organizations concluded that the top-down methodology is only a reasonable starting point that will need to be improved during refinement in order to meet the original intent of improving practice-expense payments for undervalued primary care and other office-based services.

Response: As we stated in our proposed rule, BBA requires us to ''utilize, to the maximum extent practicable, generally accepted cost accounting principles which recognize all staff, equipment, supplies, and expenses, not just those which can be tied to specific procedures****'' We still believe that the top-down methodology is more responsive to this BBA requirement. By using aggregate specialty practice costs as the basis for establishing the practice expense pools, the top-down method recognizes all of a specialty's costs, not just those linked to specific procedures.

We also believe that the other reasons outlined in the proposed rule for preferring the top-down method are still valid. It answers many of the criticisms and questions from the medical community and the GAO regarding the bottom-up method's indirect practice expense allocation method, treatment of administrative costs, and use of caps and linking.

However, we agree that a possible weakness of the top-down approach is that it may perpetuate historical inequities in the current charge-based practice expense RVUs. More highly paid physicians would presumably have more revenues that could subsequently be spent on their practices. We believe this issue should be discussed during the refinement process.

Comment: One major organization commented that we will need to develop an alternative method for new and revised codes that are not included in the SMS data because having multiple methods would lead to questionable validity.

Response: It will not be necessary to develop an alternate methodology for refinement of new and revised codes. Once direct inputs are assigned to the new and revised codes, allocation to these codes will follow the same methodology used for all other services. (See Section II.A.4, Refinement of Practice Expense RVUs.)

Comment: Two major primary care organizations expressed concern that we did not consult with the physician community about our intention to abandon, rather than refine, our originally proposed bottom-up approach, since they had assumed we would only be modifying our original methodology. They commented that this is of greater concern in light of BBA's requirement that we consult with physicians regarding our methodology and of GAO's recommendation that we refine, with no mention of replacing, the bottom-up method. One of the comments stated, that as the GAO found the bottom-up method acceptable, their society would like the GAO's assurance that the new method is sound.

Response: We believe we carried out the BBA requirement to consult with physician organizations. There were extensive consultations with physicians, including the validation panels, the cross specialty panel, and the indirect cost symposium. During the course of each of these meetings, physicians and others pointed out serious problems with the bottom-up methodology. We have had two multispecialty meetings this year to explain our proposed methodology and have also had numerous meetings and discussions with many specialty societies. During all these meetings we carefully listened to all points of view and to suggestions for developing the new proposal. Following this lengthy consultation process, we published our new proposal with a 90-day comment period. This provided further opportunities for all interested groups to review and comment on this proposal.

It is true that the GAO did not recommend that we totally replace our bottom-up approach. It is our understanding that the GAO was not asked to review alternative methods. In any case, their report did not recommend against adopting a new methodology. Their report did point out

several significant weaknesses in our original approach that we believed were better responded to by adopting a top-down methodology.

Comment: One organization urged that we publish the practice-expense RVUs three ways, using a top-down, a bottom-up, and a hybrid approach that uses SMS data for indirect costs and CPEP data for direct costs. The bottom-up and hybrid approaches should reflect the recommendations previously received relating to scaling, linking, and the treatment of administrative costs. This could provide a basis for developing comments that compare the interim practice expense RVUs with those derived from a modified bottom-up approach. The commenter stated that we should be open to considering arguments for a change in the interim practice expense RVUs based on a group's determination that the values under the bottom-up approach were more accurate.

Response: We believe that we proposed the methodology for developing resource-based practice expense RVUs that best responds to the requirements of the Social Security Act Amendments of 1994 and BBA. From a practical standpoint, it would be very difficult to deal with the inconsistencies between RVUs for various services that have been derived from totally different methodologies.

SMS Data

Comment: Almost all specialty society commenters, and many individual commenters, raised questions concerning shortcomings in the SMS data, though several commented that SMS is the most appropriate data source to use in developing specialty-specific practice expense RVUs. As we noted in the proposed rule, the AMA itself pointed out that the survey had not been designed to support the development of practice expense RVUs. The AMA also stated that the sample size, the response rate, and the fact that data was collected on the physician level, rather than the practice level, raised methodological issues. Many commenters echoed these concerns, and many raised what they saw as further general methodological problems:

- MedPAC expressed concern about three types of potential errors in the SMS data: the sampling error and nonresponse error originally identified in our proposed rule and measurement error. Some of this measurement error could occur because the survey measures physician-level rather than practice-level costs, as noted above. In addition, there could be measurement error by using a self-reported survey if no mechanism exists to verify the information provided.

MedPAC suggested that we could reduce these errors through additional data collection, perhaps implementing a subsample of SMS survey participants, through an analysis of nonresponse error that compares respondents with nonrespondents, through AMA's plans to do a practice-level survey every other year, and through considering methods, other than actual audits, to verify survey responses.

- Several of the smaller specialties, such as maxillofacial, pediatric, vascular and thoracic surgeons, cardiology and gynecology subspecialties, geriatricians, and pulmonologists expressed concern with the validity and reliability of SMS data for those specialty and subspecialty groups not adequately represented in the SMS survey. A commenter also stated that academic and hospital-based specialties, such as critical care and neonatology, were not appropriately represented. Many specialty societies requested that we consider practice expense data obtained by under-represented specialty and subspecialty groups.
- Several nonphysician specialties, though supporting the use of SMS data, raised the need to modify the survey to include nonphysicians in the future. A commenter stated that, because nonphysicians were not represented in the SMS survey, we have been forced to make an educated guess about which specialties they most resemble. Another commenter pointed out that the SMS data contains no information about osteopathic physicians.
- Several specialties, regardless of their overall sample size, expressed concerns about the combining together of subspecialties with differing practice costs. For example, organizations representing cardiologists commented that it is not known how many in their sample were providing evaluation and management services, as opposed to performing equipment intensive procedures that have much higher costs. Two specialty societies representing nuclear physicians, along with several hundred individual commenters, objected to the small sample of this subspecialty, with its high costs related to the use of radiopharmaceuticals, being combined with radiologists into a single practice expense pool. The comments recommended that we increase nuclear medicine's practice expense RVUs by 20 percent.

Similarly, a vascular surgery organization objected to being combined with cardiothoracic surgeons, who made up 75 percent of the sample and whose practice style differs substantially from vascular surgeons. An organization representing pediatrics expressed concern that pediatric subspecialties were grouped together with their adult counterparts, such as gastroenterology. The AMA commented on this point that it plans refinements for future surveys to enhance the utility of the data.

- Several commenters noted that the survey consisted of physician-owned practices, despite the trend toward more physicians working as employees, resulting in a possible bias toward solo or small group practices. For example, one commenter stated that the majority of emergency room physicians now work as employees or under contract. Another commenter asserted that the majority of pediatricians list their status as ''employed.'' The AMA commented, in this regard, that a key refinement to the SMS survey will be the development of a practice-level survey to complement the current process.
- One commenter questioned our assumption that physician respondents to SMS share practice expenses equally with all other physician owners in the practice, since there is no data to show that this is the prevalent method.
- An organization representing nurses commented that issues related to changes in acuity and case mix in ambulatory care are not being addressed, particularly as they pertain to the increased professionalization of clinical staff types. The organization argued that there is a need to incorporate into the survey process a clearer distinction between the types of clinical staff that are employed based on specialty practice.
- Concerns were raised by some commenters that the SMS data did not always include the actual costs of a given specialty. Several organizations representing radiologists, radiation oncologists, and cardiologists commented that the methodology employed by the SMS survey consistently underestimated the actual costs of equipment. Organizations representing emergency room physicians, supported by the comment from the AMA, argued that the significant costs of both stand-by time and uncompensated care are not reflected in the SMS data and that these costs need to be recognized.

A gastroenterology specialty society asserted that the SMS data grossly understated actual expenses when compared to its own study. Two commenters stated that costs for home visits, such as travel expenses and insurance, are not adequately represented in the data. One organization commented that the SMS

data fails to adequately incorporate resources, including billing, nursing time, and transportation costs for audiologists utilized in settings such as skilled nursing facilities.

One commenter stated that the added costs for compliance with federal initiatives, such as anti-fraud and abuse efforts and the new evaluation and management documentation guidelines, are not yet reflected in the SMS data. These costs should be recognized during the refinement process and included in future surveys.

• On the other hand, several commenters argued that costs were included in the SMS data that should be excluded because they are paid for separately from the physician fee schedule. One commenter pointed to separately reimbursable supplies and drugs, and another to the costs of taking physician staff into the hospital, as examples of costs included in SMS that could lead to a double payment by Medicare. A society representing vascular surgeons commented that the technical component of noninvasive vascular laboratory testing falls into this ''gray zone.''

• A national specialty society commented that the AMA analysis of the ''zero'' responses by specialty by cost categories (that is, those cost categories where respondents indicated there were no costs) shows that a significant percentage of pathologists' responses for direct cost categories are zero as compared to the ''zero'' response rates for all physicians. The comment requested that the SMS pathology data be cleared of all ''zero'' responses for all cost categories, not just for the total cost category, prior to the calculation of mean costs. For the purpose of calculating practice expense per hour for pathology, the society said, we should only use data from pathologists who incur a particular cost.

• There were a number of comments concerning the SMS data on the specialty-specific physician patient care hours, which is one of the variables used to compute the practice expense per hour for each specialty:

• Many specialty societies stated their concern that in the calculation of the specialty-specific practice expense per hour, specialties working the longest hours are disadvantaged. One commenter pointed out that practice expense is not uniformly distributed over the course of a given day; there are less costs when patient care takes place after, rather than during, office hours.

Another commenter argued that our approach assumes that all of the patient care hours in the SMS survey are reflected in our claims data. However, the commenter stated, much time spent in patient care activities is not billable, such as the involvement of transplant surgeons in patient care after the initial assessments but prior to the actual transplants.

One specialty society stated that hospital-based physicians' hours of work are probably overstated, as they will include total time spent in the facility and not just hours of providing patient services. One commenter questioned both the accuracy of the SMS data on hours worked per week, as well as our assumption that the level of practice expense incurred increases proportionally with the hours spent in patient care. An organization stated that physician reports of number of hours are less reliable than the reports of costs and are prone to overstatement. For these reasons, five specialty societies recommended using a standardized work week, usually a 40-hour week, for all specialties.

• Many other specialty groups argued equally vehemently against any standardization of the patient care hours. One group commented that subjective adjustments to the SMS data, especially those which reallocate practice expenses among specialties, should be avoided. The comment added that suggestions that a standardized 40-hour work week be imposed on the data should be rejected because the proposal is driven by an arbitrary, subjective presumption that cross-specialty practice expense variations are ''too large.''

Another group argued that, as many physicians work more than a 40-hour week, such an adjustment would introduce additional error into the data and distort the relationship between different specialties' practice expenses per hour.

• Three organizations were concerned about the advantage given to specialties that use nonphysician practitioners who are not reimbursable. In such cases, the physician would incur practice expense costs, but the time of practitioners would not be included in the physician patient care hours in the denominator of the practice expense per hour calculation.

On the other hand, another commenter stated that we should not adjust the SMS data for midlevel practitioners, such as optometrists or audiologists, as physician practices employing midlevel practitioners are likely to be more complex than a physician-only operation.

• One specialty society commented that the demographics of the SMS survey are not clear, as there are no assurances that the sample is not biased towards one particular area of the country and does not exclude some areas.

Response: We believe that most of the above comments identified important areas for needed future improvement in our data collection efforts on aggregate specialty-specific practice expense. However, although the SMS survey was not initially intended to be used to develop practice expense RVUs, we believe it is the best available source of data on actual multispecialty practice costs that allows us to recognize all staff, equipment, supplies, and expenses, not just those that can be tied to specific procedures. Many specialties supported this.

For example, a specialty society commented, ''As with any complex database, the AMA SMS database is not perfect. It is, however, the best available source of data for aggregate practice expenses.'' The Medical Group Management Association (MGMA) stated in its comment that, ''The SMS survey data is the most appropriate and only primary data set in existence to determine specialty specific costs pools.''

We also need to point out that many of the weaknesses in the SMS data could well be found in any other survey, whether undertaken by us, some other national group, or a medical specialty society. Problems with sample size and response rate have plagued other previous attempts to gather reliable data on practice expenses. Problems with measurement error may be a serious impediment for survey data that is collected with the purpose of influencing the level of a given specialty's practice expense pool. In fact, we believe one advantage of the current SMS data is that they were collected before the 1997 and 1998 proposed rules were published.

We recognize that some specialties are under-represented or not appropriately represented in the SMS data and some are not included at all. We also acknowledge that additional data may need to be obtained and some adjustments made. One of our most important tasks during the immediate refinement period will be to work with the AMA and the medical community to consider possible ways to improve the representativeness of the aggregate specialty-specific data so that sampling error is decreased. As part of the refinement, we will also need to develop strategies to eliminate as many sources of nonresponse and measurement error as possible. (For further information on our refinement efforts to improve the accuracy of our

data, see Section II.A.4, Refinement of Practice Expense RVUs.)

As indicated earlier, we believe an advantage of the SMS data we used is that it was collected prior to the proposed rule. In fact, it was collected prior to the original proposal in 1997 that was delayed by BBA and that would have resulted in large redistributions among specialties.

We are very concerned, though, about the potential biases that may exist in any subsequent survey data collected by the SMS process or other surveys. We especially believe there is a problem in using data collected and submitted to us by individual specialties. We believe it is more appropriate to use data collected at the same time by an independent surveyor for a wide variety of specialties that both gain and lose under the proposal.

Further, now that it is widely known how these survey data are being used, every specialty has an incentive to ensure that their data are as high as possible in future surveys. We agree with MedPAC that it may not be possible for Medicare to audit these data and that it is essential that alternatives be established by SMS and others. Perhaps specialty data that significantly changes in a future survey should be selectively audited by SMS through an independent auditor or other appropriate entity before being considered for use by us. We will consult with physician groups and others about this during the refinement process.

Comment: One national organization suggested the use of MGMA survey data either as a supplement or alternative to SMS in the future.

Response: We do not believe that the MGMA survey could currently be used as an alternative to SMS. As we noted in our proposed rule, due to selective sampling and low response rate, this survey is not representative of the population of physicians and cannot be used to derive code-specific RVUs. This view is based on consultations with MGMA representatives. However, we do believe that this survey data can be used as one way to validate the general accuracy of the SMS data. We have analyzed the MGMA data and have concluded that, in general, it supports the relative specialty-specific ranking of the practice expense per hour data derived from the SMS survey.

Comment: One specialty society recommended using median, instead of mean, values to calculate each specialty's practice expense per hour. This comment argued that the use of medians would eliminate outliers and is statistically more appropriate.

However, three other organizations specifically commented supporting our decision to use mean SMS data rather than median data. These comments asserted that, particularly with a small sample, use of the median would obscure any major differences in practice costs within a specialty.

Response: We will continue to calculate the practice expenses per hour by using the mean values for each specialty, at least for the purposes of this final rule. This is another issue that can be revisited during the refinement period.

Comment: Organizations representing emergency room physicians, as well as several hundred individual commenters, claimed that the SMS data seriously under-represented the true practice costs of emergency care. The commenters stated that the SMS data, as noted above, did not include costs of uncompensated care, much of it mandated under the Federal Emergency Medical Treatment and Active Labor Act (Public Law 99–272), nor stand-by expenses.

In addition, the comments argued, the SMS data failed to capture a representative cross-section of their types of practice arrangements; the SMS survey focused on physician owners, but the majority of emergency room physicians work as employees or under contract. Therefore, one commenter asserted, SMS did not include the largest single expense for most emergency physicians: the costs associated with employment by practice management firms, which can total between 30–40 percent of the physician's fee.

One of the specialty societies included with its comments the results of a study it commissioned, which showed that the mean practice expense per hour for emergency physicians was $27.33, more than double the $13 per hour based on SMS, even without including uncompensated care. If we are not willing at this time to substitute this survey data for that from the SMS, the organization recommended, with support from a comment from the AMA, that we crosswalk emergency medicine to the practice expense per hour for ''All Physicians,'' which is $67.50.

Response: Though many specialties must deal with the issue of uncompensated care, we do agree that it may pose a particular problem for emergency physicians, who are obligated under law to treat any patient regardless of the patient's ability or willingness to pay for treatment. Therefore, the amount of patient care hours spent on uncompensated care could be significantly higher for emergency medicine than for any other specialty. These issues require further examination. In the meantime, we will make an adjustment in our calculation of the practice expense per hour for emergency medicine by using the ''All Physicians'' practice expense per hour to calculate the administrative labor and other expenses cost pool. We will continue to calculate the clinical labor, supply, equipment, and office cost pools using the SMS-derived data, as it seems unlikely that, as a hospital-based specialty, emergency medicine's costs for these categories would approximate those of the average physician.

Comment: Many commenters argued that the reductions published in the June 5, 1998, NPRM for services without work RVUs were inappropriate. The commenters represented a wide spectrum of specialties including radiology, radiation oncology, cardiology, independent physiological and other laboratories, psychology, audiology, dermatology, and others. These comments focused on the fact that AMA does not survey some of the entities that provide these services. They argued that the CPEP data are flawed and the indirect allocation methodology is biased.

Response: Although it is true that the AMA does not survey the entities that provide some of these services, this does not necessarily mean that these services are inadequately represented in the SMS data. If these services (or in the case of technical component services, the associated global services) are provided in the practices of physician owners surveyed by the SMS in the same proportion as they are reflected in our claims data, the practice expense per hour calculations and the practice expense pools are reasonable.

If the CPEP data accurately contain the direct cost inputs for these services, then the direct practice expense pool is being allocated appropriately. With regard to the indirect allocation methodology, we are modifying it to increase the weight of the direct costs in the allocation, as discussed elsewhere.

However, the possibility exists that inaccuracies in the CPEP data for these services are causing the substantial reductions seen in the NPRM. Therefore, because we are not altering the CPEP at this time, as an interim solution until the CPEP data for these services have been validated, we have created a practice expense pool for all services without work RVUs regardless of the specialty that provides them. We allocated this practice expense pool to procedure codes using the current practice expense relative value units.

While we are not convinced by the comments that were received to date regarding a bias in the SMS survey data against these services, we acknowledge those concerns and will examine this issue during the refinement process.

Comment: The College of American Pathologists (CAP) requested that patient care time included in the SMS data that is spent in autopsies and supervision of technicians and paraprofessionals be excluded from the patient care hours used to calculate the practice expense per hour for pathology services. The commenter stated that these are Part A services for which pathologists rarely incur any direct costs. The AMA supported these adjustments and estimated the percentage of total pathology patient care hours attributable to autopsy and supervision services at 6 and 15 percent, respectively.

CAP also asked that some portion of the patient care hours category of ''personally performing nonsurgical laboratory procedures including reports'' be eliminated for 1999 when determining pathologists' total patient care hours, as the SMS data includes both Part A and Part B services. CAP stated that we should work with the CAP and the AMA to determine the appropriate adjustment.

Response: Since pathologists have more Part A reimbursement than any other specialty, we will decrease the number of patient care hours by 6 percent for autopsies and 15 percent for supervision services. However, until we have more information about the appropriate adjustment for ''personally performing non-surgical laboratory procedures including reports,'' the hours for those services cannot be eliminated from our calculations. This point, as well as the general issue of nonbillable hours, should be revisited during refinement.

Comment: Many specialty societies have commented on specific problems with the SMS data that affect their own specialty and have requested that we supplement or replace the SMS data with data provided with their comments.

Response: There is not sufficient time before publication of the final rule to begin to validate either the methodology or findings of the submitted data. Since changes in any specialty's practice expense per hour would have an impact on other specialties, we do not believe it would be equitable to make any sweeping changes without the adequate review that the refinement process can achieve. In addition, we stated in our proposed rule that, for those larger specialties included in the SMS survey, ''we are unlikely to make any changes in the final rule****'' Therefore, we will continue to use the SMS-derived practice expense per hour for these specialties, but will ensure that all of the submitted data will be considered during the refinement process.

CPEP Data

Comment: Though one major specialty society commented that the CPEP data, in general, is relatively sound, many comments pointed out problems with the CPEP process and with the data derived from that process:

- One group commented that the CPEPs did not have adequate representation from practice managers; that there was no uniform policy dealing with issues such as duplication of time or efficiencies that might result from performing more than one task at a time; and that there was inadequate time allotted for CPEPs to meet.
- Several subspecialties pointed out that they were not included in the CPEP process and that this could have led to the undervaluing of their services.
- Several commenters recommended that we use the CPEP data as validated and refined by the validation panels.
- One organization commented that the CPEP data are flawed since only 200 codes were reviewed by validation panels.
- One primary care group argued that we should not abandon edits and modifications to raw CPEP data, as many codes are performed by more than one specialty, and inaccuracies in the CPEP data can affect several specialties.
- Two organizations commented that the CPEPs used what is now obsolete salary and benefits data, at least for sonographers and vascular technologists. One of these comments pointed out that for some codes, a different cost was computed for the same equipment. Another specialty society recommended that a review of prices and quantities for supplies and equipment be included as part of the refinement process.
- Two commenters were concerned that the CPEP data include expenses that can be billed separately. A primary care specialty society argued that we should edit out all direct inputs for services to hospital patients. The comment mentioned that since these services are paid for outside of the practice expense RVUs, failure to exclude these inputs can distort relativity across categories of services such as surgical services and office visits.
- One commenter clarified that the costs of therapy aides are a part of practice expense and should be reflected in the CPEP data, while the services of therapy assistants are included in the work RVUs.

Response: We are aware that the raw CPEP data we have used in our proposed methodology need further review. We also share many of the concerns raised by those commenting on the issue. However, we believe that the CPEP resource estimates, which were developed by practitioners representing all the major specialties, are the best procedure level data available at this time.

Under our top-down methodology, the CPEP inputs are used solely to allocate each specialty's practice expense pool to the procedures performed by that specialty. We have always believed that the relative input estimates within families of codes for each specialty's CPEP data were generally appropriate. In addition, the most contentious CPEP values were the varying estimates for the administrative staff times, and these values are not utilized in our top-down approach.

We chose not to apply the edits, caps, or linking that had originally been proposed in our 1997 proposed rule as part of our bottom-up methodology. These edits had met with severe criticism from the medical community and were questioned by the GAO. We also did not use the revised inputs from the validation panels we held in October 1997, as these panels only came to consensus on about 200 codes, and we were not convinced that all of the revised values were correct. However, we know that there is much needed improvement in the CPEP data, and the identification and correction of any CPEP errors whether in staff times, supplies, equipment, or pricing will be a major focus of our refinement process.

Comment: One specialty society commented that we erred in not incorporating increases in staff time recommended by validation panels. Partly as a result, the practice expense RVUs for gastroenterologists' out-of-office billing, scheduling, and record keeping are inadequate.

Another commenter stated that there were discrepancies in the administrative data for skilled nursing facility services, with subsequent visit codes being assigned only half of the billing time of initial visits. A third commenter requested that we standardize the administrative staff types according to the validation panels' recommendations. Three commenters stated that we do not account for the costs of maintaining an office full-time when the physician is providing services out of the office.

Response: As stated above, under our proposed methodology, CPEP administrative staff times have no effect on the practice expense RVUs calculated for any code. The costs of maintaining an office while the physician is providing services in a facility should be captured in the SMS cost data and, thus, are a part of each specialty's practice expense pool. As these would be indirect costs, they would be included in the practice expense for each service by use of our allocation methodology, which utilizes both directs costs and the physician work RVUs.

Comment: Almost 30 specialty societies submitted specific CPT code-level changes for the CPEP input data for clinical and administrative labor time, supplies, and equipment for just under 3000 CPT codes. In addition, many commenters included lists of codes with practice expense RVUs that were considered anomalous, either within a code family, or in relation to comparable codes. We also received comments from several organizations with recommendations for revised crosswalks for those codes not valued by the CPEPs, as well as recommended in-office inputs for some codes that are now being done in the office, but were only given practice expense RVUs for the facility setting.

Response: We had intended to make the CPEP revisions requested by a given specialty as part of the final rule if the recommendations appeared reasonable and if there would be no significant impact on any other specialty. However, given the huge volume of recommended revisions—over a third of the codes in the fee schedule would be affected—acceptance of the recommended changes across the board would almost certainly have a spill-over impact on many subspecialties and between sites-of-service.

We believe it would be more responsible and fair to allow the medical specialties to participate collectively in the needed revisions as part of the refinement process. The deferral of the CPEP revisions is in no way a reflection on the effort and thought that the commenters obviously expended in arriving at their recommendations. All the code-specific comments referred to above will be considered at the start of the refinement period. (See Section II.A.4, Refinement of Practice Expense RVUs)

Comment: Many organizations, representing both surgical and primary care specialties, expressed concern that we averaged CPEP data for the same procedures valued by more than one CPEP. Different rationales were offered for this concern:

- Averaging could have disturbed the relative rankings of codes within CPEPs.
- Straight averaging significantly overstated the costs of evaluation and management services.
- Averaging CPEP costs altered practice expense relationships within the evaluation and management family of services, particularly with respect to emergency department evaluation and management codes.
- The inclusion of estimates from those not performing the procedures, including nonphysicians, could have distorted the values for those services.

Likewise, different solutions were offered to answer the concerns:

- One specialty society recommended that we link the CPEP data rather than relying on straight averages.
- Two organizations recommended using frequency-weighted averages.
- Five groups recommended that the CPEP costs for redundant codes be based on the inputs from the dominant specialty's CPEP panel.

Response: As we are making no other changes in the CPEP data for this final rule, we will continue to use straight averaging for the redundant CPEP codes for the purposes of this final rule. This issue will be considered further during refinement.

Comment: Two commenters requested the inclusion in practice expense of the procedure-related supplies which are brought into a skilled nursing facility (SNF). One of these commenters made the same request for home visits.

Response: Home visits are to be paid using the non-facility RVUs. Therefore, any supplies that would be used are already included in the payment. As for the SNF setting, this is an issue for refinement. We would need more information about the supplies and why the SNF is not responsible for providing them.

Comment: The American College of Surgeons sent a list of new crosswalked codes where CPEP data had inadvertently been duplicated in our database.

Response: We thank the commenter for pointing out this discrepancy, and these duplications have been deleted.

Physician Time

Comment: One major specialty society recommended that efforts be undertaken to move toward greater consistency in physician time data. The commenter was concerned that since these data are derived from eight different sources using different methodologies, our inflation of the Harvard time data raises even more concern about consistency.

Three major organizations, two representing primary care and the other a surgical specialty, recommended that we use the unadjusted Harvard and RUC survey data. One reason given was the implication for the work RVUs of any proposed revisions to the time data. The RUC commented that, while the RUC physician time data may be greater than Harvard time data for the same codes, it may be incorrect to assume that all Harvard time data should be increased. The RUC and several other organizations requested that we provide a description of the methodology we used to make adjustments to the data in both the RUC and Harvard physician time databases so they can comment on the validity of the changes.

Response: The physician time data used for the development of the practice expense pools are based on the Harvard resource-based RVUs study and RUC survey data that were developed as part of the refinement of the work RVUs. Both sets of data were based on physician surveys. However, the RUC data, gathered in the process of refining the work values of many CPT codes, are more current and, on average, exceeded the original Harvard values by 25 percent. As a matter of consistency and fairness to those services not yet refined by the RUC, we increased the Harvard time data in proportion to the increases for related services. A detailed description of the methodology we employed to make all adjustments in physician time will be placed on the HCFA Homepage.

We still believe this adjustment is appropriate and we will continue to use the adjusted values in our calculations for this final rule. However, as the time values attributed to each procedure play an important role in the determination of each specialty's practice expense pool, we believe that ensuring the increased accuracy and consistency of physician time data should be addressed as part of the refinement of the practice expense RVUs.

Comment: Three surgical specialty societies commented that evaluation and management times have been artificially inflated due to rounding. A small increase in time would disproportionately inflate high volume procedures that take little time.

Response: In our proposed rule, we expressed concern that imprecision in the time estimates for any high volume services that have relatively little time associated with them may potentially bias the practice expense methodology in favor of the specialties that perform these services. We stated at that time that this issue should be examined as

part of the refinement of the resource-based practice expense RVUs.

Comment: There were several other comments regarding the accuracy of the physician time data:

- The RUC acknowledged that some of the RUC physician time data may not be absolutely precise.
- One specialty society, as well as the AMA, pointed out that there are some problems with the accuracy of the physician time data for psychotherapy services. For example, the times assigned to psychotherapy codes that include evaluation and management services are equal to and, in some cases, less than the psychotherapy codes that do not include these services.
- One commenter stated that the physician time data, as computed in the Harvard studies, are not current and are likely to be inappropriate for use in computing practice expense RVUs.
- The American College of Surgeons commented that physician time for pediatric surgery codes is based on erroneously low physician time data from the original Harvard study, rather than the time data from the special study of pediatric services performed by the same Harvard study team for the American Pediatric Surgical Association in 1992. The latter data were used as the basis for the work RVUs assigned to 48 pediatric surgical services.
- A surgical specialty society commented that the physician time does not compensate its members for longer hours and cited examples of nonbillable time, such as standby time for cardiac catheterization and supervision of residents and interns. The society suggested that this be considered during refinement.
- One commenter stated that travel time for home visits is not included in either the work or practice expense RVUs. The commenter suggested that travel time for house calls should be equal to the work equivalent of the lowest office service times 3, for an average of 15 minutes. Further, a modifier should be used to cover instances where travel exceeds the average.
- The American Society of Transplant Surgeons identified physician times for several services that it believes are inaccurate and recommended adjusted times for these services.

Response: As stated above, we will ensure that all identified anomalies and inaccuracies in the physician time data are considered as part of the refinement process.

Comment: The American College of Radiology commented that for our top-down approach we had used a level three office visit (99213) as a benchmark for estimating physician time for radiology codes. They suggested that it would be more appropriate to use the intravenous pyelography procedure (CPT 74400) instead of the office visit used in our methodology.

Response: Although we agree that 99213 may be an inappropriate benchmark since it is not often performed by radiologists, we are not convinced that the average work per unit time of codes on the radiology fee schedule is equivalent to CPT 74400. Instead, we are using the weighted average work per unit time for CPT 71010 and 71020 as the benchmark. These two services represent over approximately one-third of the total allowed services in the radiology fee schedule, while CPT 74400 represents less than two-tenths of one percent. We will work with the medical community to develop time estimates for radiology procedures that will make the imputation of time from the work estimates unnecessary.

Comments: The American Occupational Therapy Association commented that the practice expense pool for occupational therapy codes was understated because the time values of 15 minutes that we arbitrarily assigned were too low. They included a list of time values we should use for each code.

The American Hospital Association also objected to the reductions in times for outpatient rehabilitation codes and urged the use of the actual surveyed times for all procedure codes in the range 97001 through 97770.

Response: We believe that the time of 15 minutes we assigned to these codes is appropriate and does not lead to an underestimation of the practice expense pool for outpatient rehabilitation services. The outpatient rehabilitation codes in this range are timed codes and are billed in 15 minute increments. Also, we have been told by some physical therapy associations that at times, some of the 15 minute period time may be performed by therapy aides or assistants. (Note: We plan to review this issue during a future five-year review of work RVUs.) Finally, it is common for these timed codes to be billed in multiple units during one therapy session. Thus, any therapist's work prior to or after the visit is spread across more than one unit, rather than applied to each unit.

Crosswalk Issues

Comment: The American Academy of Maxillofacial Prosthetics (AAMP) and the American College of Prosthodontists commented that crosswalking is not valid for maxillofacial prosthetic codes since this specialty does not correspond to any other medical specialty included in the SMS data and its practice expense values are much higher than other medical specialties in the SMS survey. AAMP submitted several studies from its own organization and from the American Dental Association, as well as two studies published in professional journals that report the results of polls of prosthodontic practitioners, including information on overhead expenses. The AAMP recommended that this data be used to calculate its practice expense per hour.

Response: We agree that maxillofacial prosthetics does not correspond closely with any other medical specialty. It also is not a separately-identified specialty in either the SMS survey or the Medicare claims database.

Though the AAMP submitted survey data compiled by both its own organization and the American Dental Association, the format, definitions, and methodology of these surveys were not consistent with those of the SMS survey. For example, the 1993 AAMP survey did not survey practice expense, but rather the ''percent overhead of gross collections for 1992.'' The American Dental Association surveys counted dentist shareholder and employee dentist income as practice expense in many tabulations.

Because of these methodological differences from the SMS data, we are not able at this time to use the information in the submitted surveys to calculate a comparable practice expense per hour for maxillofacial prosthetics.

For this final rule we will create a practice expense pool for the maxillofacial prosthetic codes (CPT 21076 through 21087) and crosswalk this pool to the practice expense per hour for ''All Physicians.'' We had imputed physician times for these services in our proposed rule. However, we are now using the physician times utilized in calculating the work RVUs for the same services. In addition, until the CPEP data for these codes can be validated, we will allocate the practice expense pool to the specific services using the current RVUs. We hope to work with the specialty society as part of the refinement process in order to develop a reliable method of deriving accurate practice expense RVUs for maxillofacial prosthetics.

Comment: The American Optometric Association (AOA) disagreed with our crosswalk of optometry to the average practice expense per hour for ''All Physicians,'' that results in a practice expense per hour of $67.50. The commenter stated that AOA understands that the crosswalk decision

was based, at least in part, on the 1997 survey conducted by AOA which had been provided to us. This survey has been conducted regularly since 1990 and was included with the comment, along with a study commissioned by the AOA entitled ''Results of the First National Census of Optometrists.'' Using data from this survey and study, AOA computed an $89.53 practice expense per hour for optometry, significantly higher than the average for ''All Physicians.''

Response: As in the above request, the data submitted by AOA are not easily comparable to the SMS data. For example, the AOA calculation used medians rather than means, and retirement and fringe benefits were not counted as median net income, but rather as practice expense. It is therefore not possible, without further information, consultation, and analysis, for us to calculate a practice expense per hour that would be comparable with that of other specialties. During the refinement period we will be working with specialties not represented in the SMS survey to identify the data needed to enable us to determine accurate practice expense RVUs for their services.

Comment: Although generally supporting the crosswalk to General Internal Medicine, the American Chiropractic Association (ACA) submitted data from the 1997 survey results of ACA's biannual survey of the chiropractic profession. This survey shows considerably lower direct patient care hours than SMS shows for General Internists. Therefore, the ACA requested that we use its data to calculate the practice expense per hour for Doctors of Chiropractic, stating that we should accept specialty societies' data over SMS data if they were collected in a comparable manner.

Response: The survey submitted by the commenter indicated that the patient care hours worked by chiropractors are significantly lower than those of general internists to whom chiropractors' practice expense per hour is crosswalked. However, the hours of direct patient care a week shown in the survey were defined more narrowly than in the SMS data. For example, the 29 hours of patient care a week calculated in the submitted survey did not include the hours spent for documentation, administration, and billing, activities that we have considered to be included in the direct patient care hours for other specialties. In addition, there are insufficient details in the survey for us to determine its comparability to the SMS data and we will maintain the crosswalk for chiropractors for this final rule. We do intend, however, to revisit this issue during the refinement process.

Comment: The American Podiatric Medical Association, Inc. (APMA) objected to its crosswalk to general surgery because it believes that there is little similarity between the two specialties based on site-of-service and types of services provided. General surgery services are typically performed in the facility setting, while the high volume podiatry services are almost entirely done in the office. In addition, the comment stated that podiatrists work fewer hours than general surgeons.

The comment also included the results from APMA's 1996 and 1998 surveys of podiatric practice, as well copies of the surveys themselves. According to the comment, these surveys show that the actual practice expense per hour for podiatry is $91.50 and APMA recommends that we use this data in place of our proposed crosswalk.

The American Academy of Orthopaedic Surgeons also disagreed with the crosswalk for podiatry, but recommended that podiatry be crosswalked to orthopaedic surgery in the short run, as 70 percent of the codes billed by podiatrists are those that are shared with orthopaedic surgery.

Response: Because of significant methodological differences between the submitted surveys and the SMS data (for example, only gross and net incomes are surveyed) we are not able at this time to calculate a practice expense per hour in total, let alone for each of the different cost pools.

However, we are persuaded that the crosswalk to general surgery is not appropriate for the reasons cited in the comment, and we are changing the crosswalk to ''All Physicians.'' We will be working with all specialties not represented in the SMS data to ensure that we obtain comparable information to calculate their practice expenses per hour.

Comment: The Joint Council of Allergy, Asthma, and Immunology stated that, in calculating the allergists' practice expense per hour, we reduced the supply category practice expense per hour to that of ''All Physicians,'' because we believed that we made a separate payment for the drugs used. However, this is not true for immunotherapy drugs provided by allergists, as the cost of these drugs is included in the practice expense RVUs. Therefore an adjustment needs to be made.

Response: The commenter is correct and the adjustment has been made to the medical supplies practice expense per hour.

Comment: The American Society of Clinical Oncology commented that since the SMS supply cost data for chemotherapy codes included the costs of expensive chemotherapy drugs, which are paid for separately, we used the lower supply costs for ''All Physicians'' for their supply cost pool. The commenter argued that this fails to recognize that, in addition to the cost of the drugs, chemotherapy administration has extra supply costs in excess of that for ''All Physicians.'' Also, although chemotherapy drugs are generally among the costliest drugs, the cost of drugs was probably included in other specialties' supply costs as well, and all specialties should be treated in the same manner.

The Association of Community Cancer Centers, the Society of Gynecologic Oncologists, and the American Society of Hematology also disagreed with our adjustment for drug costs, as did the AMA, which called our method of correcting for the double counting of drugs inequitable and imprecise. The American Society of Hematology recommended increasing the supply per hour costs to 125 percent of the ''All Physicians'' level.

Response: It is true that other specialties may have some drug costs included in their SMS supply cost data, but we believe that the total costs for chemotherapy drugs are far greater than are the drug costs included for any other specialty. Failure to make an adjustment for these high drug costs would lead to a gross distortion in the supply cost pool for oncology.

We also are not convinced that the other supply costs for oncologists would necessarily exceed that of ''All Physicians,'' and we will continue to crosswalk oncology's supply costs to that category's practice expense per hour. We do agree that during refinement we need to consider development of a methodology for removing separately billable supplies and services from the SMS data so that the Medicare program avoids making duplicate payments. We also will work with the oncology specialty to ensure that their practice expense per hour for the supply category adequately reflects the actual costs of other oncology supplies.

Comment: The American Association of Oral and Maxillofacial Surgeons objected to the crosswalk of oral surgery and maxillofacial surgery to the practice expense per hour of ''All Physicians.'' They recommended a crosswalk to either otolaryngology or plastic surgery, as most of the medical procedures billed

by oral and maxillofacial surgeons can be crosswalked to these two specialties. The commenter argued that because of their significantly higher practice expenses, oral and maxillofacial surgery should not be in the same practice expense pool as manipulative therapists and optometrists, as this dilutes the practice expenses for these surgical services. In addition, the 1996 Harvard Study grouped oral and maxillofacial surgery under otolaryngology and plastic surgery.

Response: We do not currently have sufficient data to make such a change in our crosswalk. This is an issue that can be addressed during the refinement period.

Comment: The American College of Cardiology and the American Society of Echocardiography disagreed with the crosswalk of Independent Physiologic Laboratories (IPLs) to ''All Physicians.'' The comment recommended that IPLs' practice expense per hour be crosswalked to cardiologists, as 60 percent of IPL billings are in the 93000 series and for the 13 highest volume IPL codes, cardiologists account for 40 percent of claims. The Society of Vascular Technology/Society of Diagnostic Medical Sonographers also expressed concern that our crosswalk of IPLs did not adequately recognize their costs and recommended that we use the figure of $176 per hour based on the studies cited in the comment.

Response: As discussed above, we will be creating a separate practice expense pool for all services without physician work, which will include those technical component services done by IPLs and by cardiologists.

Comment: The Society of Gynecologic Oncologists requested that we consider using multiple crosswalks to determine practice expense per hour for specialties that provide interdisciplinary care. The comment stated that the true reflection of practice expense per hour for a gynecologic oncologist is a hybrid of the practice expense per hour for the specialties of obstetrics and gynecology and oncology.

Response: It is not clear whether this is desirable or what data would be used to weight such a split between more than one specialty. Many physicians belong to more than one specialty or subspecialty. This is another issue that can be discussed during the refinement period.

Comment: The American Geriatrics Society disagreed with our crosswalk of geriatrics to the General Internal Medicine practice expense per hour. The comment stated that geriatricians typically have higher costs than internists because of the need for more office space and more health care professionals on staff. Since many geriatricians are family physicians, geriatrics should be cross-walked to family practice.

Response: We believe that geriatricians are typically more like internists than family practitioners, so for the final rule we will not change the crosswalk. However, we are open to receiving data that would demonstrate that a crosswalk to family practice would be more appropriate.

However, we would note that geriatrics is a relatively small specialty and the services performed by them are frequently done by other specialties. Thus, changes in the practice expense per hour data for geriatricians would not likely have a significant impact on the RVUs for services they perform.

Comment: One commenter made recommendations for revisions or additions to our proposed crosswalks for several nursing subspecialties. Another specialty society commented that under the physician fee schedule we have chosen to pay nonphysician practitioners a percentage of the physician reimbursement, and crosswalking to specialties with higher practice expense per hour rates than general internal medicine or general surgery is not logical or reasonable. Another organization also recommended that data from nurse practitioners and physician assistants be excluded from the practice expense pool calculations.

Response: We will further consider appropriate crosswalks for nursing subspecialties during the refinement period.

Comment: The American Hospital Association and the American Occupational Therapy Association recommended that we crosswalk all of the practice expense pools for outpatient rehabilitation services to the ''All Physicians'' practice expense category, rather than using the salary equivalency guidelines for the administrative, office, and other pool.

Response: We believe that using the ''All Physicians'' practice expense per hour for the administrative, office, and other pool would considerably overstate the actual practice expense for occupational therapy. We have carefully examined outpatient therapy practice costs for the development of the salary equivalency guidelines, and believe that these better approximate the actual expenses for this cost pool. We will continue to use the salary equivalency guidelines to calculate this portion of the practice expense pool for occupational therapy for this final rule.

Comment: The American Speech-Language Hearing Association commented that it is not appropriate to use the practice expense per hour data from physicians that perform audiology tests and it submitted a 1993 survey, ''Audiology Services—Scale of Relative Work,'' as part of its comments.

Response: As we stated above, we are creating a single practice expense pool for all services, such as audiology, that have no work RVUs. This practice expense pool, created by using the average clinical staff time per procedure from the CPEP data and the ''All Physicians'' practice expense per hour, raises practice expense RVUs for audiology services relative to those previously proposed. However, during the refinement process we will be considering all data submitted on any of these services, including the study submitted with the above comment.

Calculation of Practice Expense Pools—Other Issues

Comment: Several organizations commented on potential problems with the Medicare claims data, which are used as one component of the specialty-specific practice expense pool calculation.

- Many commenters were concerned about reliance on Medicare claims data to determine the size of each specialty's practice expense pool. The comments claimed that to the extent that the Medicare population is not representative of the general population, there is a bias against specialties whose patient population does not match Medicare's. Several organizations, representing the gamut of medical specialties, urged us to work during the refinement period with organizations for whom we have no, or inadequate, historical claims utilization information and to acquire nationally representative claims data that include Medicare, Medicaid, and private payer data.

One of these commenters recommended that, if this is not feasible, we should conduct sensitivity analyses to explore the influence Medicare service utilization patterns may have on private payers. The specialty-specific utilization data are crucial for the final step of volume-weighted averaging that brings the individual specialty scales onto one scale, particularly when involving services performed very frequently by specialties that see relatively few Medicare patients.

For example, the comment argued, to the extent that the cost estimates for evaluation and management (E&M) services provided by obstetricians and gynecologists and pediatricians differ

significantly from those of specialties that account for the bulk of E&M services provided to Medicare patients, the use of an all-payer claims database would probably yield different RVUs for E&M services.

• Several surgical specialties urged that we clean the Medicare claims data to eliminate obvious errors, such as data showing a sometimes significant number of nonsurgeons or physician assistants performing complex surgeries that can only be performed by surgical specialties. This misreporting can decrease a specialty's practice expense pool and should either be reassigned or excluded during refinement.

One of the commenters recommended that Medicare claims data be reviewed for the existence of a second listed surgical specialty identifier. In addition, physician assistants' claims should use the -AS modifier, and calculations should use only the time that is assigned to the intraoperative period.

• Three specialty organizations commented that many physicians' self-designated specialties are incorrectly classified in our claims data. For example, many cardiologists and geriatricians may bill as internists, which may affect the respective practice expense pools. Until these data become more accurate, one of the commenters recommended that the specialty practice expense pools be recalculated on an annual basis.

• An organization representing transplant surgeons commented that, as transplant surgery is not a designated specialty in the Medicare claims database, many transplant surgeons designate themselves as general surgeons, who have the lowest practice expense per hour of any surgical specialty. The comment argued that this has led to a significant underestimation of the costs associated with transplant surgery.

Response: We would be interested in receiving any reliable national utilization data on the procedure code level though, to date, we are not aware of the existence of such a data source. We plan during the refinement period to work with the medical community in order to pinpoint problems in the Medicare claims data, to develop strategies to improve their accuracy, and, if possible, to find reliable supplemental data for those specialties not appropriately represented in the Medicare database.

Comment: One organization commented that the Medicare frequency numbers for occupational therapy codes will be understated because BBA requires that all outpatient therapy services be paid under the Medicare Physician Fee Schedule beginning January 1, 1999.

Response: We disagree. We have not included estimates for frequencies of expected services of outpatient therapy services in computing the practice expense RVUs. BBA specified that we pay for these services using the physician fee schedule. BBA did not incorporate these services into the fee schedule.

Comment: Many organizations representing radiation oncology, as well as numerous individual commenters, argued that we erroneously combined the SMS radiation oncology survey data with that of radiology. The commenters argued that these two specialties should be dealt with separately, as radiation oncology utilizes different codes and has considerably higher costs than radiology.

Response: We had combined radiation oncology and radiology together into one practice expense pool because of the small sample of radiation oncologists in the SMS data. However, we now agree with the commenters that these are two different specialties with differing practice costs. Therefore, we have separated them into two separate practice expense cost pools in order to calculate the practice expense per hour for each of the specialties. For radiology, excluding radiation oncology, the total practice expense per hour is $55.90. This is comprised of $17.90 for nonphysician payroll per hour ($9.70 for clerical payroll), $12.80 for office expense, $4.50 for supply expenses, $7.70 for equipment expense, and $12.90 for other expenses. For radiation oncology, the total practice expense per hour is $68.30. This is comprised of $23.70 for nonphysician payroll per hour ($9.20 for clerical payroll), $11.30 for office expense, $6.20 for supplies expense, $11.00 for equipment expense, and $16.20 for other expenses.

Allocation of Practice Expense Pools to Codes

Comment: Several organizations commented on our use of work RVUs as part of the allocation formula for indirect practice expense costs:

• A primary care specialty group stated that we should not allocate the indirect practice expenses using the work RVUs, since there is no reason to believe that the costs of providing the service, such as the cost of utilities, would vary by the intensity, where the costs would vary by time. We should, therefore, use time rather than work in our indirect allocation.

Another primary care organization commented that using work as one allocator for indirect expenses inappropriately gives surgical procedures with higher work RVUs substantially higher administrative costs for billing activities than is given to evaluation and management services. We should develop a standardized method to address administrative staff costs.

• Five other organizations argued that allocating indirect costs based on a combination of direct costs and physician work RVUs is inappropriate and treats unfairly chemotherapy and radiation oncology services as well as other technical component services, since they typically are assigned no work RVUs. Various recommendations were made by these commenters to rectify what they see as discrimination against these technical component services:

+ Indirect costs should be based on direct costs.

+ Physician time or clinical staff time should be used instead of work.

+ We could allocate 50 percent of the indirect costs based on direct costs and 50 percent based on physician work or time.

+ As an alternative for chemotherapy services, work could be imputed by using the work to time ratio for other hematology or evaluation and management services.

One commenter recommended that we vary the indirect cost allocation methodology in recognition of the practice patterns of particular specialties.

• One accounting organization commented that the use of work REUS is arbitrary and argued for the use of total dollars actually spent to perform the procedures, not indirect splits, suggesting the use of Activity Based Costing as a preferable methodology.

Response: In this final rule, we will use an allocation method for the final rule that is basically similar to our proposed allocation method. It is widely recognized by accountants and others that there is no single best method of allocating indirect expenses to individual services. If we used physician time as an allocator of indirect expenses, we would be using the same values, whose accuracy have already been questioned by some commenters, both to create the practice expense pools and to allocate these pools to individual services. If we used only direct costs, we would be giving full weight to CPEP values that have not yet been refined. We agree that the use of physician work as an allocator is not preferable in the long term. It likely provides maximum advantage to hospital-based services in which the

physician incurs relatively few direct costs.

For this final rule, we are making a technical change to the allocation method for indirect costs by using direct costs and the work REUS scaled using the Medicare conversion factor instead of a factor calculated using the physician time data. Because of questions raised by commenters concerning the time data adjustments, we believe that it is more appropriate to convert the work REUS into dollars using the Medicare conversion factor (expressed in 1995 dollars, consistent with the AMA SMS survey data). This will give somewhat less weight to work while, at the same time, avoiding a major methodological change until it has been examined further. We intend to work with the medical community during refinement so that we ensure that our allocation methodology is both appropriate and equitable.

Comment: Many major specialty societies, both primary care and surgical, commented that we should not apply a different methodology for allocating the practice expense pools to the radiology codes than we do to all other codes. One commenter argued that multiplying the current charge-based practice expense RVUs for radiology codes by some percentage cannot yield a resource-based system.

Organizations representing urologists, pulmonologists, cardiologists, and ophthalmologists commented that the uniform reductions made in the radiology codes to maintain relative values assumed that all radiology services are done only by radiologists, when many of these procedures are performed by these other specialties. A commenter stated that decisions regarding the practice expense values for radiology codes done predominantly by other specialists should not be made by one specialty. These organizations recommended that the practice expense RVUs for their codes be established using the allocation methodology used for all other services.

One specialty society, representing diagnostic vascular testing, commented that the use of the existing radiology relatives to allocate practice expense to the code level results in significantly larger decreases in the technical component than in the professional component of their services. The commenter recommended that if we continue to use the radiology relatives, then we should reduce the professional components of the codes more than the technical components because practice expenses are greater for the technical component than for the professional component.

The AMA supported the use of the radiology relative values for actual radiology services, but recommended that this methodology should be applied only to services that are performed predominantly by radiologists.

The American College of Radiology endorsed the radiology relativity of the radiology RVUs without exception, and they would oppose the exclusion of individual radiology procedures since this is inconsistent with the concept of radiology relative values. They argued that maintaining the relativity of the radiology fee schedule—

- Is consistent with generally accepted accounting principles because it is based on surveys and physician panels;
- Is widely accepted;
- Solves rank order anomalies caused by raw CPEP data;
- Simplifies the derivation of the professional component, technical component, and global practice expense RVUs;
- Is mandated by law, as the Omnibus Budget Reconciliation Act of 1989 stated that for radiology services ''the Secretary shall base the relative values on the relative values developed under section 1395m(b)(1)(A)****''; and
- They also argue that we have recognized and honored the statutory obligation to maintain the relationships in the radiology relative value scale.

Another national organization representing diagnostic imaging services also suggested keeping the radiology fee schedule as the allocator for radiology, rather than the direct costs from the CPEP data, as there would be even greater reductions on codes we allocated using the CPEP relatives.

Response: Because the majority of specialties that perform radiology services object to the use of the current practice expense RVUs for radiology services, we cannot continue to use these RVUs. However, since we are not making changes to the CPEP data for this final rule and since the American College of Radiology has not had sufficient opportunity to comment on the CPEP data because of our proposed use of the current radiology RVUs, we are using the current radiology RVUs to allocate the direct cost pools of the specialty radiology until such time as the CPEP data for radiology services have been validated. We will not use the current radiology RVUs for any other specialty.

It should be noted that radiology services or components of radiology services that lack work RVUs are handled as described in the section on services without work RVUs. This alters the impact of using the current radiology RVUs for the specialty radiology since we set the global portion of a radiology service equal to the sum of the technical and professional components.

Comment: One specialty society commented that, for one important high volume pathology service, the proposed total professional component practice expense RVU payment would be $11.37, approximately $2 short of the administrative labor costs alone. The commenter wanted more information on how our method splits administrative costs between the professional and technical components. The commenter requested that we provide a data set of the RVUs for administrative labor, office expenses, and other expenses that result from our allocation method, with a break-out of the professional and technical component RVUs for services that have both components, so that the appropriateness of the allocation method can be evaluated.

Response: Our methodology was described in the proposal, and we also provided additional detailed data files that we used to develop the proposed values. We will try to make additional data available if the request is further specified.

Comment: The American College of Cardiology expressed concern that, though it might be necessary to weight average the allocation to codes according to the practice expense per hour of the different specialties performing the service, this defeats the intent of Congress to recognize actual costs and could also lead to negative incentives. The commenter suggested that this is an issue that we and the specialties should pursue.

The American Society of Echocardiography more specifically commented that we should not include in the calculations for cardiovascular diagnostic tests the even more unrepresentative data for internists coding for these procedures. The society maintained that because of the low equipment costs for internists, this blend dilutes the RVUs allocated to these codes.

Response: The statute is very specific that Medicare is not to pay specialty differentials. Therefore, weight averaging of the CPEP inputs among specialties that do a service seems appropriate.

Other Issues

Comment: Many commenters, representing a broad spectrum of specialties, expressed concern that reductions in payment for specific services could have a negative impact on access to care. Many of these

commenters recommended that we monitor access and quality of care issues that may arise as a result of the implementation of a resource-based practice expense system.

Response: Maintaining access to high quality health care for Medicare beneficiaries is, and will continue to be, a high priority, and we will monitor available relevant data. However, we do not anticipate that the implementation of resource-based practice expense RVUs should lead to any major impediments to access to care. Any impacts of this new system are being transitioned in over a 4-year period, during which we will be refining both the practice expense per hour data and the direct cost inputs. We will be working closely with the medical community during this refinement period, and we are confident that we will achieve a resource-based practice expense system that will maintain our beneficiaries' access to the best possible medical care.

Comment: One commenter was concerned about how the monthly capitated payment for end-stage renal disease (ESRD) services was handled under the top-down approach. The commenter argued that, though the ''building block'' process used for the work RVUs for these services does not translate perfectly for practice expense values, this approach should still be utilized to calculate the practice expense RVUs. In addition, the commenter questioned our choice of CPT 99213, a mid-level office visit, to calculate physician time for ESRD services.

Response: We allocated the practice expense pool to ESRD services using the CPEP inputs, as we did for almost all other services. We also believe that the intensity of an average evaluation and management service provides a reasonable estimate of physician time. These issues can be further analyzed during refinement.

Comment: Two commenters noted that costs associated with the supervision of diagnostic tests were not included in the technical component amounts.

Response: In separate carrier manual instructions, we are revising the level of physician supervision required for many diagnostic services. For example, we are changing the requirements for most ultrasound procedures from personal or direct supervision to general supervision. We believe the required supervision for any remaining services that are at the personal supervision level are generally already reflected in the work RVUs. Therefore, we do not believe that there are additional costs for physician supervision.

Comment: One commenter indicated that there will be a marked increase in the volume of services paid under the physician fee schedule as a result of BBA changes in payment for outpatient therapy services. The commenter maintained that this increase should not adversely affect future budget neutrality adjustments.

Response: Although payment for these outpatient therapy services are based on payment amounts contained in the physician fee schedule, these services are not included as part of the fee schedule pool for budget neutrality calculations.

Comment: One commenter argued that the budget neutrality adjustment is inappropriately applied because it does not recognize the savings provided by the elimination of the facility payments for endoscopic procedures that will move to the office setting.

Response: The statute specifies that there shall be budget neutrality for physician fee schedule services. The budget neutrality adjustment does not take into account payments to facilities.

Comment: Two commenters suggested that any fiscal adjustments made to comply with BBA should be reflected in the conversion factor, or other ratio, rather than be included in the calculation of the practice expense RVUs, so that other payer reimbursement would not be affected.

Response: We do not completely understand these comments, but we believe the request is consistent with our practice of making budget-neutrality adjustments on the conversion factor.

Comment: Several commenters requested additional impact analyses such as—

- Comparison of actual practice expense by specialty with expected practice expense payments, both by amount and by percent, for both our proposed practice expense payments and the current fee schedule practice expense RVUs;
- Comparison of impacts by geographic area, including rural and urban impacts;
- Analysis of impacts on hospital, academic, and community-based physicians;
- Analysis of total Medicare and non-Medicare impact using national claims case mix data; and
- An analysis that would demonstrate to other payers the degree to which our proposed payment rates are less than actual practice costs.

Response: We lack the data to provide some of the requested analyses. For example, we do not have national claims case mix data and are unaware of the existence of such data. With regard to rural and urban impacts, in the June 5, 1998 proposed rule we discussed the limitations of such analyses given the structure of the Medicare payment localities. We are unsure what the commenters are specifically requesting on the issue of actual costs since we have based the resource-based practice expense RVUs on the best available source of multi-specialty actual cost data: the SMS survey. Cost analyses at the individual practice level are problematic since, for example, we do not have physician cost reports, but we are open to concrete suggestions on how to perform such analyses. We also note that the Medicare public use files are an excellent source of data for commenters who wish to perform additional analyses that they believe are possible with the data sources available to us.

Comment: One commenter requested that we make clear to Medicare contractors that hospital-based pathologists who incur technical component costs for nonhospital patients can be paid for both the technical and professional components.

Response: This is a long-standing policy, and we are not aware of any general problems in this regard. However, we would be willing to discuss the issue with individual carriers if the commenter provides more specific information.

Comment: One commenter recommended that we recalibrate the allocation of RVUs to the pools for physician work, practice expense and malpractice, as this allocation has remained constant since the resource-based relative value scale was implemented in 1992.

Response: We are recalibrating the allocation this year to match the Medicare Economic Index (MEI) weights. For example, work goes from 54.2 percent of the total to 54.5 percent, the practice expense portion goes from 41.0 percent to 42.3 percent, and the malpractice portion goes from 4.8 percent to 3.2 percent. (See Section II.D, ''Rebasing and Revising the Medicare Economic Index.'') In order to prevent the work RVUs from changing as a result of this, we are altering only the practice expense and malpractice RVUs. The changes to the practice expense and malpractice RVUs due to this are offset by an adjustment to the conversion factor.

Comment: One commenter recommended that we should limit the magnitude of the changes in physician payments resulting from the shift to resource-based payment for practice

expenses by imposing some reasonable limit on payment increases and decreases for individual services. The commenter maintains that section 1848(c)(4) of the Act, which authorizes the Secretary of Health and Human Services to, ''establish ancillary policies, as may be necessary to implement this section,'' provides statutory authority on which to base such a policy. The comment pointed out that we invoked this section in 1991 with reference to the transition to resource-based payment for physician work.

Response: We believe that Congress intended the transition period to be the mechanism by which we would mitigate the impacts of any changes in payment brought about by the shift to resource-based practice expense. Therefore, we believe it would be inappropriate for us to impose further limits on payment increases or decreases.

Comment: One commenter maintained that the proposal violates both the Regulatory Flexibility Act and the Paperwork Reduction Act of 1980 because the adequate filings required in both of these Acts did not accompany the proposal. Additionally, the commenter stated that we did not cite any evidence to support its contention that a Regulatory Impact Statement is not required.

Response: We had included a Paperwork Reduction Act (PRA) section in HCFA–1006-P that meets the requirements of the PRA of 1980.

One commenter stated that we do not cite any evidence in either of our proposals to support our contention that no regulatory impact statement is required. There may be some confusion about the purpose of an impact statement and the difference between a regulatory impact statement and a regulatory impact analysis (RIA). A regulatory impact statement is a brief rational on why an analysis was not conducted. An RIA is a complete analysis based on recent available data and is more extensive.

An RIA was conducted in the proposed rule of June 5, 1998 (63 FR 30866). Absent this analysis, we would be required to furnish an impact statement. Therefore, there is no violation of either the RIA or Regulatory Flexibility Act requirements.

3. Other Practice Expense Policies

Site-of-Service Payment Differential

As part of the resource-based practice expense initiative, we are replacing the current policy that systematically reduces the practice expense RVU by 50 percent for certain procedures performed in facilities with a policy that would generally identify two different levels (facility and nonfacility) of practice expense RVUs for each procedure code depending on the site-of-service.

Some services, by the nature of their codes, are performed only in certain settings and will have only one level of practice expense RVU per code. Many of these are evaluation and management codes with code descriptions specific as to the site of service. Other services, such as most major surgical services with a 90-day global period, are performed entirely or almost entirely in the hospital, and we are generally providing a practice expense RVU only for the out-of-office or facility setting.

In the majority of cases, however, we will provide both facility and nonfacility practice expense RVUs. The higher nonfacility practice expense RVUs are generally used to calculate payments for services performed in a physician's office and for services furnished to a patient in the patient's home, or facility or institution other than a hospital, skilled nursing facility (SNF), or ambulatory surgical center (ASC). For these services, the physician typically bears the cost of resources, such as labor, medical supplies, and medical equipment associated with the physician's service.

The lower facility practice expense RVUs generally are used to calculate payments for physicians' services furnished to hospital, SNF, and ASC patients. The costs for nonphysicians' services and other items, including medical equipment and supplies, are typically borne by the hospital, by the SNF, or the ASC.

We received the following comments on our site-of-service payment differential proposal.

Comment: We received several comments concerning the appropriateness of our site-of-service proposal:

- Several specialty groups commented that they agreed with eliminating the site-of-service differential and replacing it with two levels of payment.
- A national specialty society representing gastroenterologists, as well as several hundred individual commenters, strongly opposed the elimination of the current site-of-service differential and replacement of it with the facility and nonfacility resource-based practice expense RVUs. The comments argued that we should not have established different practice expense RVUs for facility and nonfacility settings for gastrointestinal endoscopy codes 43234 through 45385 because:
- It is unsafe to do these procedures in the office and will thus jeopardize patient safety;
- It creates an incentive to provide care in the inappropriate office setting; and
- It is not authorized by legislation, is against the intent of BBA to have different payment levels for different settings, and is likely to result in legal challenge.

The commenter recommended that we drop the office and out-of-office differential in practice expense payment.

- One organization commented that our site-of-service proposal will exacerbate the ability to subsidize uncompensated care and suggested exempting teaching physicians from the new site-of-service provision. It also suggested that HCFA should also monitor the effects of the site-of-service policy.
- The AMA, the American Hospital Association, and three other organizations commented that payment differentials should not provide an incentive for physicians and patients to choose one site over another. Some physician groups are concerned that the differential will accelerate the shift of some services from facility to nonfacility settings at the expense of patient safety. They asserted that claims data on changes in place of service should be made available and this issue should be one focus of refinement efforts.

Response: We believe that, to the extent that the differing RVUs for in-office and out-of-office services reflect the relative differences in practice costs for performing those services, we have not created incentives to provide services in inappropriate settings. We are required by both the Social Security Act Amendments of 1994 and BBA to develop resource-based practice expense RVUs, based on physicians' actual costs. All of our data indicate that physicians' practice expenses are higher in the office, where the physician must incur all the costs of staff, equipment, and supplies, than in a facility that provides and is paid separately for these resources. As the facility and nonfacility costs to the physician can vary by a considerable amount, we believe that adopting a single average payment for both sites would consistently underpay in-office procedures, and overpay those performed in a facility and would thus be inherently inequitable, not resource-based, and contrary to the intent of the law. Furthermore, we are not aware of any studies showing that codes 43234 through 45385 are being unsafely performed in offices. We have complete

confidence that physicians will continue to exercise their best clinical judgment as to the most appropriate setting for their patients.

Comment: One specialty society stated its support for the proposed change in the site-of-service payment, as long as it does not result in nonpayment for services actually provided. For example, there are no practice expense RVUs for emergency intubation in the nonfacility setting, though this service may occasionally have to be performed in the office.

Response: If a service for which there are only facility RVUs is performed in the office, the facility rate will be paid.

Comment: The American Urological Association commented that certain codes—50590, 52234, 52235, 52240, 52276, and 52317 were inappropriately assigned nonfacility PERVUs, as it is not safe to perform these services in the office.

Response: We would need more data to demonstrate that performing these services in the office is not appropriate before we would eliminate the nonfacility RVUs. We are willing to review such information during the refinement process. Such information should be submitted to HCFA, Office of Clinical Standards and Quality.

Comment: Two societies representing pulmonologists commented that critical care is listed with facility and nonfacility practice expense RVUs, although it is nearly always performed in an inpatient setting.

One organization representing psychiatrists noted that CPT codes 90816 through 90829 are restricted to the inpatient hospital and partial hospital and residential care settings, and that CPT code 90870, electroconvulsive therapy, would not generally be performed in an office setting. The commenter recommended that the final rule list RVUs for only the facility setting.

Response: We are not deleting RVUs proposed for the nonfacility setting in this final rule, but will be considering this issue during refinement. We would note, however, that services performed in the residential care setting would be paid by using the nonfacility RVUs.

Comment: One commenter pointed out that in our proposed rule we list the services that, by nature of their codes, would only have one level of practice expense; this list includes codes 99321 through 99333 and 99341 through 99350. However, in Addendum C, both facility and nonfacility values are given and the facility values are higher than the nonfacility values for most of these codes. These inconsistencies should be corrected. Another commenter submitted a list of some codes where the facility practice expense RVUs are higher than the in-office values.

Response: We thank the commenters for pointing out these discrepancies. The instances of higher facility RVUs are an artifact of our indirect methodology and reflect the differing mix of specialties performing a service in each setting. We will look at this more closely during the refinement process.

Comment: One specialty society commented that the dual energy x-ray absorptiometry codes have the same practice expense RVUs for both the in-office and out-of-office setting. The comment recommended that the in-office RVUs be adjusted to reflect the high costs of equipment for the office-based physician.

Response: More specific data will be needed on the actual costs of the equipment so that we can address any changes to the CPEP data during the refinement process.

Comment: Three organizations representing outpatient therapy services commented that, though outpatient rehabilitation providers will be paid the nonfacility rate, there are higher costs for providing rehabilitation services in an SNF or hospital than in a doctor's office. These costs are not reflected in the CPEP data and are grossly underestimated in the practice expense RVUs. There should be a special higher site-of-service differential to be applied when outpatient therapy services are furnished in provider settings.

Response: The site-of-service differential is intended to ensure that the Medicare program avoids making duplicate payments to practitioners and facilities for the same services. BBA specified that outpatient therapy services, which prior to January 1, 1999 have been paid by Medicare using a cost reimbursement system, should be paid using the physician fee schedule effective January 1, 1999. As discussed more fully in the June 5, 1998 proposed rule, we believe it would be inappropriate, and inconsistent with how we pay for other services under the fee schedule, to pay a higher rate for these outpatient rehabilitation services when they are provided in an SNF or hospital.

Comment: One specialty organization recommended that we confirm that facility-based practice expenses exclude only those practice expenses that are actually provided and paid for by the facility. We should provide a data file summarizing which resources are deemed to be provided by facilities, so that physician organizations can identify any errors or anomalies in HCFA's assumptions. For example, vitreoretinal physicians must often provide clinical staff for out-of-office procedures, and it is essential that there is a mechanism for the physician to be reimbursed.

Response: The differential between the facility-based and office-based practice expenses is determined by the CPEP inputs for staff labor time, supplies and equipment attributed to each site and the mix of specialties providing the services in each site. We will consider further adjustments to the CPEP inputs during the refinement period.

Comment: The American Speech-Language-Hearing Association commented that the extra costs for patient acuity and travel should be added to the site of service differential.

Response: This is an issue for which specific data is needed and that should be addressed during the refinement period.

Additional Relative Value Units for Additional Office-Based Expenses for Certain Procedure Codes

Usually office medical supplies or surgical services in the physician's office are included in the practice expense portion of the payment for the medical or surgical service to which they are incidental. The November 1991 final rule (56 FR 59522) included a policy for 44 procedure codes that allowed a practice expense RVU of 1.0 to pay for the supplies that are used incident to a physician's service but generally are not the type of routine supplies included in the practice expense RVUs for specific services. This list of procedure codes was expanded in the December 1993 final rule (58 FR 63854). Included in this list of procedures for which an additional amount may be paid for supplies if the procedure is performed in a physician's office are closing a tear duct (CPT code 68761) and billing for a permanent lacrimal duct implant (HCPCS A4263), inserting an access port (CPT code 36533) and billing for an implantable vascular access portal/catheter (A4300), and performing cystoscopy procedures and billing for a surgical tray (A4550).

We proposed to revise this policy under the resource-based practice expense system. We believe the supply costs that this policy is designed to cover were included in the supply inputs identified by the CPEPs and the AMA's SMS survey. Thus, they were included in the practice expense RVUs for each relevant procedure code. Therefore, we proposed to discontinue separate payment for supply codes A4263, A4300, A4550, and G0025.

Below are the comments we have received on this issue:

Comment: While two primary care organizations agreed with our proposal to discontinue separate payment for select supply codes, three other specialty societies opposed elimination of the current payment for these supplies. One comment argued that incident-to supplies were not counted in the CPEP process, and the other that this separate payment is a preferred method of recognizing added costs to physicians.

Response: We believe that the current practice expense RVUs include the payment for these supplies. However, we are willing to consider evidence that the CPEP inputs do not reflect the appropriate use of these supplies for any service during the refinement process.

Comment: The AMA, as well as four physician specialty organizations, recommended phasing out separate payment for supplies during the transition instead of implementing it all at once in 1999.

Response: We agree and we will be phasing out the separate payment for these supplies over the transition period.

Anesthesia Services

Although physician anesthesia services are paid under the physician fee schedule, these services do not have practice expense RVUs. Rather, payment for physician anesthesia services is determined based on the sum of allowable base and time units multiplied by a locality-specific anesthesia CF.

Since the beginning of the physician fee schedule, overall budget neutrality and work adjustments have been made to the anesthesia CF and not to the base and time units. We are following the same process and making an adjustment to the anesthesia CF to move anesthesia services under the resource-based practice expense system. The adjustment to the anesthesia CF is 3.0 percent (phased in other the transition period).

4. Refinement of Practice Expense Relative Value Units

Section 4505(d)(1)(C) of BBA requires the Secretary to develop a refinement process to be used during each of the 4 years of the transition period. In the June 5, 1998 proposed rule, we proposed keeping the practice expense RVUs as interim RVUs until at least the fall of 1999, and possibly beyond 1999, if we believe more time is needed to identify and correct errors. We also solicited recommendations for a refinement process in subsequent years.

In the June 1998 proposed rule, we did not propose a specific process for a long-term refinement process. Rather, we set out the parameters for an acceptable refinement process for practice expense RVUs. Such a refinement process would enable us to do the following:

- Review and refine practice expense and hour data.

We suggested that we would be prepared in the future to refine the practice expense and hour data of those specialties well-represented in the SMS data if we receive compelling evidence that the SMS data are incorrect. We invited comments on potential revisions to the SMS survey or alternative sources of data and on the need to confirm, through audit or other means, the survey data that would be used for long term refinement.

- Obtain and review practice expense and hour data for specialties or practitioners not included in the SMS survey.

We invited comments on the appropriateness of our crosswalks and suggested that any arguments that the practice expense and hour data should be changed would be strengthened by the submission of survey data comparable to the SMS data.

- Address anomalies, if any, in the code-specific Harvard and RUC physician time data.

We proposed that we would not revisit work RVU issues that have been already addressed as part of the 5-year review.

- Address anomalies, if any, in the code-specific CPEP data on clinical staff types and times, quantity and cost of medical supplies, and quantity and cost of medical equipment.

We proposed that the codes identified by commenters as having possible errors during the comment periods of the proposed rule and the final rule will constitute the universe of codes whose code-specific CPEP data should be reviewed, as it was not our intention to review the inputs for all the codes on an annual basis. We also proposed that we obtain the advice of practicing physicians on the appropriateness of recommended changes to the CPEP inputs. We suggested two principal options for obtaining that advice, either HCFA-convened multiple specialty panels or the RUC or new organization like the RUC that includes broad representation across all specialties and includes nonphysician practitioners. The panels would need to meet no later than the summer of 1999 to consider the comments we received on both the proposed rule and the final rule. We invited comments on these options and solicited any other recommendations.

- Refine, as needed, our process of developing practice expense RVUs for codes not addressed by the CPEP process, for example, codes that were new in 1996, 1997, and 1998.

We developed practice expense RVUs for codes that were new in 1996, 1997, and 1998 by comparing the new codes to other comparable codes for which we had actual CPEP data and we invited comments on the appropriateness of our crosswalks. Also, we solicited new code-specific data on clinical staff types and times, quantity and cost of medical supplies, and quantity and cost of medical equipment.

- Develop practice expense RVUs for codes that will be new in 1999 and beyond.

Because of time constraints, we proposed that we develop interim practice expense RVUs for new 1999 codes by preparing a crosswalk of CPEP data from existing codes. Though the practice expense values for these codes will be subject to comment, the interim values will serve as the basis of payment during 1999.

Beyond 1999, we proposed two possible options that could be used to develop practice expense RVUs for new codes. First, we could continue to crosswalk new codes to existing codes and review comments we receive with the assistance of our multiple specialty panels. Second, we could request the RUC or a RUC-like organization to provide recommended practice expense RVUs or recommended inputs before publication of the proposed rule, as we do with work RVUs. We invited comments on these options and solicited any other recommendations. Following are the comments that we have received on our proposal for refinement of the resource based practice expense RVUs:

Comment: The RUC submitted the following comments on the refinement process:

- The RUC stated its interest in reviewing any comments that we receive on the accuracy of the physician time data for specific codes.
- The RUC commented that many members of the RUC, the RUC's Advisory Committee and the Health Care Professionals Advisory Committee (HCPAC) observed or participated in the entire CPEP process. The comment stated that, based on that experience and on extensive subsequent discussion, it became clear that the RUC, through its experience in developing physician work relative value units, should also seek involvement in developing

recommendations on practice expense relative values.

• The RUC comment contained the following proposal for refinement of the CPEP data:

The RUC proposed the development of a new Advisory Committee, the RUC Practice Expense Advisory Committee (PEAC) to review comments on the code-specific CPEP data (that is, clinical staff types and times, quantity and cost of medical supplies, and quantity and cost of medical equipment) during the refinement period. This committee would report to the RUC, which would make final recommendations to HCFA. The committee composition would mirror the RUC and include additional representation from the American Nurses Association, the American Academy of Physician Assistants, the Medical Group Management Association, and four other non-MD and DO organizations to encourage input from nurses and practice managers in the process.

The committee would include one representative from the following organizations:

• Chair (To be selected by the Chair of the RUC);
• American Medical Association;
• American Osteopathic Association;
• CPT Editorial Panel;
• Health Care Professionals Advisory Committee;
• Two rotating seats for the RUC Advisory Committee (currently held by Rheumatology and Child Psychiatry);
• American Academy of Dermatology;
• American Academy of Family Physicians;
• American Academy of Neurology;
• American Academy of Ophthalmology;
• American Academy of Orthopaedic Surgeons;
• American Academy of Otolaryngology—Head and Neck Surgery, Inc.;
• American Academy of Pediatrics;
• American Academy of Physician Assistants;
• American Association of Neurological Surgeons;
• American College of Cardiology;
• American College of Emergency Physicians;
• American College of Obstetricians and Gynecologists;
• American College of Physicians;
• American College of Radiology;
• American College of Surgeons;
• American Nurses Association;
• American Psychiatric Association;
• American Society of Anesthesiologists;
• American Society of Internal Medicine;
• American Society of Plastic and Reconstructive Surgeons;
• American Urological Association;
• College of American Pathologists;
• Medical Group Management Association; and
• Society of Thoracic Surgeons.

Four seats would be added to include other organizations representing nursing or practice managers, for example, National Federation of Licensed Practical Nurses or American Licensed Practical Nurses Association, American Association of Medical Assistants, Association of Surgical Technologists, Professional Association of Health Care Office Managers, and Healthcare Financial Management Association.

Also contributing to this refinement process would be 80 members of the RUC Advisory Committee, representing those specialty societies with a seat in the AMA House of Delegates who have elected to participate in the RUC process. The RUC process will also include input from the HCPAC, which represents audiologists, chiropractors, nurses, occupational therapists, optometrists, physical therapists, physician assistants, podiatrists, psychologists, social workers, and speech-language pathologists.

The RUC has not yet implemented the PEAC, pending the initial response(s) to the proposed rule. However, the RUC has authorized the RUC Chair to convene the PEAC in a timely fashion and requests that we share all comments we wish to have reviewed regarding changes to the CPEP data with the RUC soon after the conclusion of the comment period on the final rule. The RUC would assure that all members of the RUC Advisory Committee and HCPAC Advisory Committee are contacted regarding the comments and will solicit interest in bringing recommendations forward to the PEAC on these comments. Specialty societies would collect additional data and, where possible, form a consensus recommendation with other interested specialty societies or HCPAC organizations. After considering the comments and the specialty society recommendation, the PEAC would present a report with their recommendations to the RUC which would submit its recommendations to us, along with its usual submission of work relative value recommendations, at the end of May.

The RUC comment contained the following proposal for refinement of the crosswalk for 1996, 1997, 1998, and 1999 new codes. The RUC proposes that the PEAC, when constituted, also review any comments on the final rule that are forwarded by us regarding the appropriateness of crosswalks and extrapolated code-specific data for those codes that were new in 1996, 1997, 1998, and 1999. The RUC would encourage specialty societies and HCPAC organizations to collect data or evidence to support new code-specific data on clinical staff types and times, quantity and cost of medical supplies, and quantity and cost of medical equipment for each of those new services that are frequently performed.

The RUC comment also contained the following proposal for the development of practice expense RVUs for codes that will be new in 2000 and beyond. The RUC proposes that recommendations for practice expense RVUs for new codes in 2000 and beyond be developed simultaneously with the work RVU recommendations. After a new code is approved by the CPT Editorial Panel, specialty societies would conduct a survey that would include a section on physician work and a section on direct expense inputs for that service. The specialty society would then present their recommendations on both the work and practice expense RVUs, along with all of their supporting data from the survey, to the RUC to review. The RUC would review both RVUs and submit the recommendations to us in a format similar to its current submission.

The RUC comment stated that the majority of the discussion on the expense inputs would focus on the clinical staff time and, potentially, the comparison between this time and the physician time. This time information will not be available for new codes. If we were to utilize two different processes for work and practice expenses for new codes, it would be necessary to establish a process to reconcile differences in time between the two sets of recommendations. The RUC comment recommended that the RUC process represents the best choice for reviewing this relationship and providing verifiable recommendations. The comment also recommended that for new codes for services performed by nonphysicians only, the RUC HCPAC Review Board would review both work and practice expense RVUs and would submit their recommendations to us directly. Throughout the updating process of practice expense, the RUC will also seek the input of nurses, practice managers, and others who have expertise in physician practice expense.

Comment: Almost all specialty societies and individuals commenting on refinement, as well as MedPAC and the AMA, agreed that the RUC or a group like the RUC should undertake the refinement of the CPEP input data for individual procedure codes, including reviewing our crosswalks for CPT codes new in 1996 through 1999, and recommending practice expense values for codes that will be new in 2000 and beyond. Several specialty societies, while supporting the role of the RUC in handling the complex issue

of refining CPEP data, stated that the RUC would need to include nonphysicians such as practice administrators and nurses in order to accomplish this task, as staff in management roles have more expertise than practitioners on the intricacies of practice management and the details of practice expenses. The American Podiatric Medical Association commented that podiatry must have full participation on an equal basis with other physicians' specialties; membership on the HCPAC would not be sufficient. The American Academy of Audiology has also commented that they want an audiologist to be represented on any group refining RVUs and the American Occupational Therapy Association commented on the need for therapy representatives. The Society of Vascular Technology/Society of Diagnostic Sonographers commented that they would support the use of a RUC-like group only if there would be appropriate representation of technical component service providers; otherwise they would not favor the RUC handling refinement issues.

Response: As previously described, there are four key data items we used for our methodology. Three are needed to develop practice expense ''pools'' per specialty, and the fourth is needed to allocate these aggregate practice cost pools to individual CPT codes. The data sources we used are as follows:

Practice Cost Pools

1. AMA SMS survey data for practice costs per hour, by specialty.
2. Harvard and RUC data for length of time to perform each service
3. Medicare claims frequency data for each procedure.

Allocation to Individual CPT Codes

4. ABT CPEP resource inputs per CPT code.

Refinement requires consideration of three broad types of activities:

1. Review of broad strategy and general methodology issues. Examples of these types of activities include review of the basic methodology, formulas for allocation of indirect expenses, development of criteria for consideration of alternative data sources, survey sample size consideration, development of possible approaches to validate survey data, and other similar methodology issues.
2. Refinement of specialty level practice cost per hour data.
3. Refinement of detailed code level data (CPEP data, procedure time data).

The RUC has proposed to be involved in the refinement process by creating a subcommittee to advise it, referred to as the Practice Expense Advisory Committee (PEAC). It would consist of over 35 members (RUC specialties supplemented by other groups such as MGMA, nurses, practice managers and others). The vast majority of specialties that commented on the refinement process indicated their support for the RUC proposal or for a similar process.

Initial Refinement Process

We continue to believe that our proposed general methodology is sound and responsive to the BBA requirements. We did receive a large variety of comments about broad methodology issues, practice expense per hour data, and detailed code level data. As described elsewhere, we have made some adjustments to our original proposal for a select number of situations in which we were convinced an adjustment was appropriate at this time. We are considering other comments for possible future refinement. The values of all codes will be considered interim for 1999 and for future years during the transition period. Rather than specify a detailed refinement process at this time, we will continue to work with the professional community to further develop the refinement process. We will modify the process as necessary during the period, based on our experiences and recommendations received.

Our plans to start the initial refinement process are as follows:

1. We plan to establish a mechanism to receive independent advice for dealing with broad practice expense RVU technical and methodological issues. We are considering contractor support and/or other ways of obtaining independent advice and assessments of comments that we have already received or will receive in the future about important technical issues, especially those that result in major redistributions among specialties. We welcome continuing advice and specific recommendations from the GAO, MedPAC, and the Practicing Physicians Advisory Council. We will also continue to actively consult with physician and other groups about these issues. We are particularly interested in receiving additional comments and suggestions about methodology from organizations that have a broad range of interests and expertise in practice expense and survey issues. All comments will be considered, but we especially encourage organizations that represent a broad range of physician, practitioner, and provider groups (for example, groups that represent both ''winning'' and ''losing'' specialties) with expertise in practice costs issues to make specific recommendations regarding the following methodology issues:

- *Bias in ''Top Down'' methodology.* Some commenters believe the methodology we are using to establish initial practice expense RVUs is flawed. They indicate that it is inappropriate to pass through costs and that the method will perpetuate inequities among specialties because high revenue specialties have more to spend on their practices. One possible way of dealing with this issue is to further analyze the differences in practice costs per hour by specialty to determine the ''reasonableness'' of these differences. Edits or other adjustments in practice costs data could be established if appropriate.
- Validation of data. It is difficult to establish an unbiased method for refining and validating practice costs data. Data from the SMS survey are self-reported. There could be major incentives in the future for respondents to expand the definition and reporting of ''costs'' for purposes of this methodology. In addition, we would expect that individual specialties would be likely to bring undervalued practice expense RVUs to our attention, but would not have an incentive to report overvalued practice expense RVUs. We welcome comments on the following:
  + What specific methods should HCFA use to validate key components of the data used for establishing practice expense RVUs?
  + What specific approaches should be used to ensure fairness among specialties?
  + Should we, for example, require that the specialty obtain review by an independent auditor before we consider changes in the data?
- Criteria for using alternative survey data. The primary source of practice costs per hour data was the AMA's SMS survey. Some specialties have already requested that alternative, supplementary, or more recent data be used. We welcome comments on what specific criteria should be established for use of these alternative data?
- Allocation of indirect expenses. We allocated indirect expenses to individual CPT codes based on physician work and direct expenses. Some commenters suggest that indirect expenses should be allocated by alternative methods, such as physician time and direct expenses, or just direct expenses. We would welcome your recommendations.

2. RUC/PEAC. We would welcome comments from the RUC/PEAC or any other organization or individual for individual code level data—both for

resource inputs and time data. The RUC and PEAC would function as an entity independent from us, much like the current RUC operates for purposes of providing comments on work RVUs. We also recognize the RUC/PEAC may wish to comment on other aspects of the process, such as methodology. We would consider such comments along with those received from others and would likely discuss them as part of the process described in paragraph 1 above. However, we wish to emphasize that, as in our dealings with the current RUC, we would retain the ultimate authority and responsibility to establish practice expense RVUs.

3. Comments on the refinement process.

We seek comments January 4, 1999 and suggestions on any aspect of the refinement process as described above.

Comment: All but one of the organizations commenting on the issue, as well as many individual commenters, recommended that we keep the practice expense RVUs as interim for the 4 years of the process. One national specialty society recommended we make the revised practice expense RVUs interim for 1 year, only extending the period based on the number of misvalued procedures identified and also ensuring that only changes based on compelling evidence are made.

Response: We stated in our proposed rule that we would keep the practice expense RVUs as interim through at least through 1999. Due to the complexity of the issues that need to be addressed during refinement, we now believe that a longer period could be needed to finalize all the RVUs. Therefore, as stated above, we will be keeping all the RVUs as interim throughout the transition period.

Comment: Many commenters recommended acceptance of information from alternative data sources during the refinement period, including data provided by specialty societies. One commenter suggested that we develop a standard survey instrument for specialties to use. Another organization commented that we should consider using MGMA's cost survey as an alternative source of information that could be used to supplement, validate, or otherwise expose further areas of refinement in the SMS, or perhaps be a substitute for SMS in the future. This comment also stated that we should remain open to challenges about current practice expense per hour calculations from all specialties, even from those larger specialties represented in the SMS survey, in both the short and long term. Many commenters also recommended that we develop a process for validating any supplemental data that we use.

Response: We believe that the refinement process that we outlined above is responsive to these concerns. One of the major purposes of the technical support and advice mentioned will be to help us to determine what additional data, whether from large or small specialties, are needed, whether submitted information is valid, and whether and how alternative sources of data, such as the MGMA survey, can be used to validate the assumptions used to create the practice expense pools.

Comment: One specialty society commented that we should conduct specialty-specific surveys for all HCFA-designated specialties during the refinement period. The comment stated that it is not reasonable for us to put the burden of ''oversample'' costs, which exceed $100,000 on the HCFA-designated specialties that the AMA has chosen not to include in its annual survey sample.

Response: Decisions on what surveys are needed, what the criteria should be for those surveys, who should conduct the surveys, and who should fund them will be made as we address these issues during refinement.

Comment: One organization recommended that the refinement process distinguish between intra-specialty refinement issues that can be resolved within a specialty, and inter-specialty refinement issues which change the cost pool of one specialty with respect to all other specialties.

Response: Again, we believe that our chosen refinement process addresses this concern. The intra-specialty refinement issues will, for the most part, revolve around adjustments to the CPEP data and will be referred to the PEAC for their recommendations. Those issues that affect the relative size of the practice expense pools are generally more fundamental methodological questions for which we will seek technical and methodological input as well as input from the medical community.

Comment: One national organization commented that the SMS data appears to be the best data available for the purpose of determining practice expense RVUs and that SMS data closely mirrors the specialty's own data. The comment recommended that refinement should focus on identifying the proper inputs for particular codes, rather than adjusting the current SMS data, or revamping the design of the survey, which currently does not reflect a bias towards inflating practice expenses for individual specialties.

Response: We agree that the SMS survey is, at present, the best data available for determining aggregate specialty-specific practice costs. We believe one of the purposes of refinement is to pinpoint where appropriate adjustments need to be made in the data that we use. We also agree, as mentioned above, that we will need to develop a system to validate the accuracy of data collected in the future.

Comment: One commenter recommended that we ensure that cost-saving innovations are not discouraged by the refinement process. This means that the practice expense scale should not be refined to immediately reflect the full impact of every cost-saving development, or specialties will be permanently discouraged from implementing such innovations.

Response: We are required by law to develop practice expense relative values that are resource-based. Therefore, we do not believe that we could develop an alternative approach that would only apply to cost-saving innovations. We also do not believe that the use of resource-based practice expense RVUs will have a significant effect on cost-saving innovations; on the contrary, the use of a prospectively determined payment system, in itself, offers an incentive for any individual practitioner to cut costs.

Comment: Two commenters recommended that codes for entirely new procedures and technologies have their practice expense values taken from the all-specialty practice expense pool; two organizations recommended that codes that apply to new technologies to replace current procedures come from the pertinent specialty's pool.

Response: There would be no budget neutrality adjustment for new codes that represent entirely new procedures and technologies. However, we believe that, in the majority of cases (since we would typically expect some type of substitution of new services for more established services) a budget neutrality adjustment would be appropriate. In such a case, we would spread the adjustment across all services. However, new codes that merely replace existing services would only affect the pertinent specialty's pool at the time when the practice expense pools are recalculated.

Comment: A primary care specialty group recommended that we leave undisturbed the Harvard and RUC time data during the refinement period because of the implications for the work RVUs assigned to codes, while a surgical specialty group recommended that we remain open to revising the Harvard physician time data.

Response: The physician time data plays an important role in determining the size of each specialty's practice expense pool and, for this reason, it is important that this data be as accurate as possible. Therefore, we cannot rule out the need for adjustments in the time data during the refinement period. However, according to our chosen refinement process, requests to adjust the physician time data would be initially referred to the RUC. We believe that the RUC will understand the implications that changes in physician times could have for the work RVUs.

Comment: One commenter agreed with our proposal that we address potential bias toward specialties which use more midlevel providers during the refinement period.

Response: This is one of the issues on which we will be seeking input during the refinement period.

Comment: The AMA, supported by comments from two physician specialty groups, recommended that, to avoid confusion, we publish only the blended set of values each year, but make a list of the resource-based practice expense RVUs available to interested parties. Any proposed changes in the resource-based practice expense RVUs could then be published in the spring proposed rules. Four organizations recommended that both sets of RVUs be published throughout the period.

Response: We are publishing both sets of RVUs in Addenda B and C.

5. Reductions in Practice Expense Relative Value Units for Multiple Procedures

Comment: Two commenters expressed agreement with our decision not to propose further multiple procedure reductions. Gastroenterologists stated that multiple procedure reductions should not apply to GI procedures done through different orifices.

Response: Although we have not made a specific proposal with respect to multiple procedures thus far, we may do so in the future. We continue to believe there are efficiencies when more than one service is performed during a single encounter.

6. Transition

The Proposed Rule

The transition to resource-based practice expenses, enacted in section 4505(b) of BBA, requires practice expense RVUs in 1999 to be based 75 percent on the existing charge-based practice expense system and 25 percent on the new resource-based system. In 2000, the shares are 50 percent of the former and 50 percent the latter, and in 2001, the shares are 25 percent and 75 percent, respectively. Beginning in 2002, practice expense RVUs are entirely resource-based.

In our October 31, 1997 final rule (62 FR 59052), we indicated that we would use, as the first factor in the transition formula, the 1998 practice expense RVUs actually used for payment. (''The practice expense RVUs for 1999 will be based on the product of 75 percent of the previous year's practice expense RVUs (1998) and 25 percent of the resource-based practice expense RVUs.'') In response to this statement, we received a comment suggesting that we consider interpreting the law to use 1997 practice expense RVUs as the starting point for the transition. This interpretation would have eliminated from the transition the 1998 changes in practice expenses enacted by section 4505 of BBA. Those commenting contended that the 1998 changes applied only to 1998 and should not be included in the first practice expense factor in the transition formula. Using 1997 RVUs would have resulted in higher payments for certain specialty procedures and lower payments for office visits during 1999, 2000, and 2001. Beginning in 2002, the starting point for the transition does not matter because the transition will be complete and practice expenses will be based entirely on the new resource-based system.

When we developed the proposed rule, we specifically considered the suggestion that we use actual 1997 practice expense RVUs as the starting point for the transition. In the proposed rule we indicated that we did not believe that we could use 1997 practice expense RVUs for several reasons. First, this approach seemed to us contrary to the statute's intent of moving toward a resource-based payment system; also, the interpretation could potentially result in a ''yo-yoing'' of practice expense RVUs for certain services between 1998 and future years. We pointed out that practice expense RVUs for office medical visits, explicitly increased by the Congress in 1998, could be reduced in 1999 only to be increased again when the practice expenses are fully resource-based.

We also stated that we would not use 1997 practice expense RVUs as the starting point for the transition because this result was inconsistent with our construction of similar reductions, enacted in OBRA 1993, to practice expense values for 1994, 1995, and 1996. We also indicated that we would reject the only other possibility, using 1991 practice expense RVUs; using 1991 RVUs would be unacceptable since to do so would exclude the effects of the series of reductions to practice expense RVUs mandated by the Congress between 1993 and 1998 and would instead return the system to outmoded practice expense RVUs established at the very inception of the fee schedule. We indicated that we believed this to be a poor alternative. Basing the transition on data for 1991, from which the original practice expenses were derived, would require us to retrospectively impute charge data for the many new procedure codes that had been added since the beginning of the fee schedule. It also would have been contrary to the statutory scheme, which is moving steadily toward a resource-based payment system. We indicated that adoption of 1991 data for the transition starting point would not gradually transition payments to the new resource-based system, but instead would represent an abrupt change in direction. This result is at odds with the purpose of a transition and inconsistent with other transitions in Medicare. Therefore, the June 1998 rule proposed to use the 1998 practice expense RVUs for purposes of the transition formula in 1999, 2000, and 2001.

We received comments strongly supporting the approach we took in the proposed rule, as well as strongly opposing our approach. These comments centered on section 1848(c)(2)(C)(ii) of the Act. That provision requires practice expense RVUs to be computed by multiplying ''base allowed charges'' by a practice expense percentage. BBA then requires that this ''product'' be used as the first factor in the transition formula. A cross-reference to section 1848(c)(2)(D) of the Act appears to require base allowed charges to be generated from charge data for 1991. However, we believe that a number of other factors demonstrate the irrationality of using data for 1991 as the transition starting point. Using data for 1991 would be a total aberration from the course of the past 7 years of congressional directives to decrease practice expense RVUs from which office-based and visit codes were generally excepted and would turn the clock back without any congressional direction to do so. We have analyzed both the statutory language and the context in which it is found, and we have determined that the best accommodation of the two is to use current 1998 practice expense RVUs as the basis for the transition to the resource-based practice expense system.

We have considered, among other things, that we are authorized by law to make such ancillary policies as are

necessary to implement section 1848 of the Act; that the equation, based on 1991 average allowed charges that the law seems to instruct us to use as the transition starting point, ignores consistent legislative direction since 1993, as well as our consistent implementation; that we have not used the average allowed charge provision since the establishment of practice expense RVUs in 1991, that it has no ready application to the more than 2000 codes developed since 1992, and, therefore, that using 1991 allowed charges for the transition creates a significant administrative burden, unintended by the Congress, particularly given the short time period for implementation; that the language describing the transition formula and the language describing the ''product'' upon which it is based are internally inconsistent; that our implementation of adjustments in accordance with section 1848(c)(2)(G) of the Act is consistent with our implementation of the OBRA 1993 3-year reductions; that the Congress is familiar with our implementation, has amended section 1848(c) of the Act since the implementation, and has not acted legislatively to alter our implementation prospectively. In addition, we note that the Physician Payment Review Commission (PPRC) studied resource-based practice expenses for a number of years, that the Congress is familiar with PPRC's data and analyses, and that the results of our transition are consistent with the results PPRC predicted. In sum, we believe that our construction of the law most appropriately resolves the tensions inherent in the practice expense transition provisions of the BBA.

We address below the specific comments we received with respect to transition issues.

Comment: Some commenters, mainly societies representing surgical specialties, opposed our proposed approach and indicated that our proposal to use the 1998 practice expense RVUs in the transition formula is in conflict with the language and intent of BBA. These commenters argued that section 1848(c)(2)(C)(ii)(I) and (II) of the Act require that the practice expense charge data relied upon in 1991 to establish the 1992 practice expense RVUs be used for the first factor in the transition formula. They also contend that the adjustments to the 1998 practice expense RVUs, required by BBA, were intended to accomplish a one-time redistribution of RVUs from specialty codes to primary care codes and that using these RVUs during the transition would perpetuate the redistribution for three more years. These commenters claimed that this transition would redistribute an estimated additional $490 million from specialists to office-based codes.

These commenters assert that the charge-based factor in the transition must be the formula in section 1848(c)(2)(C)(ii) of the Act that established practice expense RVUs as the product of (I) the base allowed charges for a service, and (II) the practice expense percentage for the service. Base allowed charges are defined in section 1848(c)(2)(D) of the Act as ''with respect to a physician's service, the national average allowed charges for the service . . . for services furnished during 1991, as estimated by the Secretary using the most recent data available.'' (The practice expense percentage is defined in section 1848(c)(3)(C)(ii) of the Act.) Therefore, according to these commenters, the reference in the transition provision that RVUs be determined based on ''such product'' requires us to use 1991 average charges to compute 1999 RVUs.

Response: We disagree with these commenters. We believe that the formula in section 1848(c)(2)(C)(ii) of the Act is internally inconsistent, that it was intended for the establishment of the original practice expense RVUs, that it has no ready application to the 2,000 codes new or revised since 1991, and that it produces results inconsistent with the balance of section 1848(c)(2)(C) of the Act. The commenters' construction of the law would eviscerate the changes the Congress made to practice expense RVUs since 1993 and would require that we revert to the beginning of the program in the absence of congressional direction to do so.

First, we believe that the reference to ''such product'' in section 1848(c)(2)(C)(ii) of the Act supports our view that the Congress contemplated that the first factor in the transition formula would be based on RVUs and not on 1991 average allowed charges. Under the commenters' reading, the transition formula requires that in 1999 we multiply 75 percent of a product based on average allowable charges and 25 percent of the resource-based RVUs. However, ''average allowed charges'' are expressed as dollar figures, while the resource-based factor is expressed in RVUs. This internal inconsistency suggests that the Congress contemplated instead that both factors in the formula would be expressed in RVUs and that we would use current RVUs produced under section 1848(c)(2)(C) of the Act for the first factor in the transition.

Moreover, although the Congress has not repealed section 1848(c)(2)(C)(ii)(I) and (II) of the Act, the provisions have not been applied in the fee schedule computations since 1992 when the first practice expenses were established. The language of the provisions indicate the inappropriateness of their application here. Thus, section 1848(c)(2)(D) of the Act, incorporated by reference, provides for use of average allowed charges ''as estimated by the Secretary using the most recent data available.'' This language would seem to require us to use 1998 data to recompute 1991 charges, surely an unintended result. In addition, in 1993, the Congress required us to compute practice expenses RVUs on a basis other than that contained in section 1848(c)(2)(C)(ii) of the Act: effective January 1, 1994, section 1848(c)(2)(E) of the Act provided for a ''[r]eduction in practice expense relative value units for certain services.'' The Congress did not explicitly state that the amendment applied notwithstanding the existing language of section 1848(c)(2)(C)(ii) of the Act; instead, the amendment operated without recourse to that provision at all. The amendment envisioned that reductions would be made to the ''relative value units [being] applied'' at that time, not to charges for 1991. At the end of the period for which reductions were specified in section 1848(c)(2)(E) of the Act, practice expense RVUs did not revert to 1992 values based on 1991 charges; RVU changes produced by section 1848(c)(2)(E) of the Act were permanent and carried forward into the next year's (1997) practice expense RVUs. These more recent and more specific provisions added by the Congress in subsequent years obviously control over the original provision, and the commenters' argument, if adopted, would wipe out the effects of these intervening changes in the law. We believe that it is far more rational and consistent with congressional intent to harmonize the computation during the 4-year transition period with recent legislative changes rather than reverting back to a system from 1991 that has been unused since that time.

Section 1848(c)(2)(G) of the Act, like section 1848(c)(2)(E) of the Act, provides specified reductions for specified services for a particular year to lower excessively high practice expense RVUs; it explicitly raises low RVUs attributable to office visit codes. Section 1848(c)(2)(E) of the Act also provides that ''the aggregate amount of reductions'' to practice expense RVUs for services furnished in 1998 cannot exceed $390 million. We believe that the Congress intended that RVU changes resulting from application of section

1848(c)(2)(G) of the Act be treated in the same way as we had treated changes resulting from application of section 1848(c)(2)(E) of the Act, that is, that the RVU changes produced by section 1848(c)(2)(G) of the Act would be permanent and carried forward into the next year's fee schedule.

Accepting the comments advocating use of the 1991 average allowed charges in the transition formula would present other difficulties. We did not establish average allowed charge RVUs for codes new or revised since 1991. Thus, using 1991 average allowed charges in the transition would require us to retroactively impute average allowed charges for procedure codes that did not exist in 1991. This would be a significant administrative burden, particularly given the obligation to have these amendments implemented by January 1, 1999.

We believe that the Congress intended that we devote our efforts to developing the resource-based practice expense system and refining practice expense RVUs, rather than to creating a set of imputed charges for new codes to be used only for the transition. BBA explicitly requires the Secretary to develop a process to refine resource-based practice expense RVUs during each year of the transition (see section 4505(d)(1)(C) of the Act). On the other hand, there is no mention of our refining what 1991 national average allowed charges would have been for more than 2,000 new codes. It is unlikely that the Congress contemplated that we would pursue the imputation of 1991 charges in the limited time we had to retool the resource-based practice expense system, especially given that the imputed values would have no utility after 2001.

Additionally, we note that section 1848(c)(4) of the Act provides authority for us to ''establish ancillary policies (with respect to the use of modifiers, local codes, and other matters) as may be necessary to implement this section.'' We view this situation as one appropriate for the application of the ancillary policies provision. We believe, as we have noted, that the statutory language and the context in which it appears are at odds and create an ambiguity that we must resolve based on the design of the section as a whole and the congressional policies underlying it, and we are using section 1848(c)(4) of the Act for that purpose. In order to rationally implement section 1848(c) of the Act, we will use 1998 RVUs for the first factor in the transition formula.

Comment: The surgical specialty societies argue that implementing section 1848(c)(2)(G) of the Act in the same manner as section 1848(c)(2)(E) of the Act is prohibited because the ''adjustments in relative value units for 1998'' are limited to $390 million and that including the reduced practice expense RVUs in the base for the transition makes reductions total more than $390 million.

Response: We do not agree with that statement. We believe that the commenters are misreading the limitation on the ''aggregate'' reallocation; that limitation applies only to amounts attributable to services furnished in 1998. The law requires us to ''increase the practice expense relative value units for office visit procedure codes during 1998 by a uniform percentage which [HCFA] estimates will result in an aggregate increase in payments for such services equal to the aggregate decrease in payments'' for the overpriced practice expenses. The provision simply contemplates that we add the increase for each service and assure that the total of all increases is equal to the total of all decreases in payments for the overpriced practice expenses. This provision does not restrict the use of the 1998 practice expense RVUs in future years. To read the law as these commenters suggest would be to reverse years of intentional redistribution of practice expense RVUs mandated by the Congress.

Comment: Primary care groups who commented on the proposed rule asserted that the 1998 ''down payment'' (the increased practice expense RVUs for office visit codes created by section 1848(c)(2)(G)) of the Act was a step in the direction of the ultimate resource-based system. On the other hand, a surgical group believed that we were biased because we presumed that a resource-based practice expense RVU system would lead to a reduction in most specialty codes and a corresponding increase in primary care codes.

Response: The trend in practice expense RVU redistributions under a resource-based system is clear, and section 1848(c)(2)(G) of the Act is another step in that progression, consistent with the preceding redistributions which the Congress mandated in 1993. The direction of payment changes for major categories of service—increases for medical visits and reductions for surgical procedures—has been mandated by the Congress, implemented by HCFA, and known to the public for some time. The exception of office-based services from the 1993 practice expense RVU reductions clearly indicated that the Congress intended a relative redistribution toward those services. While the Congress could not know, on a procedure-by-procedure basis, the impact of the new resource-based system, it was cognizant of the general direction of a resource-based system before it enacted section 121 of the Social Security Act Amendments of 1994, mandating resource-based practice expense RVUs.

Establishment of a resource-based system for practice expenses has been discussed for some time. In 1992, the PPRC, a statutorily established Commission that provided advice and recommendations to the Congress, issued a report titled ''Practice Expenses Under the Medicare Fee Schedule: A Resource-Based Approach'' (Number 92–1). That report described the Commission's research on a resource-based alternative for calculating practice expense RVUs. It showed the direction of the projected redistributions. The report showed that RVUs for the category of evaluation and management services (medical visits or primary care services) would increase and the category of surgical procedures would decrease.

In its 1993 Annual Report to the Congress, the Commission specifically recommended that the Congress enact a resource-based system for payment of practice expenses. The report, at page 147, indicated:

> The Commission has long questioned the appropriateness of these charge-based practice expense and malpractice expense relative values as part of the Medicare Fee Schedule. Since it suggested the OBRA 89 approach as an interim measure in the *Annual Report to Congress 1989*, the Commission has been working to develop methods for calculating practice expense and malpractice expense relative values that are more consistent with the reform goals of resource-based payments (PPRC 1989). This work has lead to the identification of methods for calculating these two components that the Commission thinks are more appropriate than the OBRA 89 formulas. Both the practice expense and malpractice expense methods have been described in previous reports to Congress, and each is the topic of a special research report issued by the Commission (PPRC 1992b; PPRC 1992c).

In the same report, the Commission specifically recommended:

> The Congress should revise the practice expense component of the Medicare Fee Schedule so that it will be resource-based. Practice expense relative values should be based on data about the direct costs incurred in delivering each service and an incentive-neutral formula to allocate indirect costs. A transition to new practice expense relative values should be introduced beginning in 1997. This date will allow for completion of the current fee schedule transition process

and for development and refinement of the resource-based approach.

Id. This report also showed the impact of a resource-based system for four major categories of services. The Commission estimated that the total payment for evaluation and management services would increase by 12 percent, that diagnostic procedures would decrease by 19 percent, that surgical global services would decrease by 29 percent and that technical procedures would not be changed. (These impacts reflect the total Medicare payment; when measured relative to the practice expense component alone, there would be greater percentage changes.) Thus, the PPRC reports put the Congress on notice about the direction of changes under a resource-based system.

The Congress, in section 13513 of OBRA 1993, enacted reductions in the practice expense component payment to move toward resource-based practice expense RVUs. (The Congress also used these reductions to achieve savings in the Medicare program.) The Congress specifically exempted from reduction any services that were performed at least 75 percent of the time in an office setting. Therefore, the impact of the reductions fell on surgical procedures, and the largest impact occurred for those procedure codes for which the practice expense RVUs most exceeded work RVUs. The structure of section 1848(c)(2)(E) of the Act—reduction of one-quarter of the amount of excess practice expense in each of 3 years—was itself a transition to moderately reduce practice expense RVUs for non-office-based codes rather than to decrease them precipitously.

Section 121 of the Social Security Act Amendments of 1994 required us to develop and implement resource-based practice expense RVUs effective January 1, 1998. Section 4505 of the BBA postponed the change to resource-based values, but included another round of reductions for certain non-visit codes. We agree with the comment that the 1998 payment changes were simply another step in the ongoing process moving payments in the direction of the resource-based practice expense system.

Comment: Groups representing primary care physicians supported our proposal, stating that using 1997 RVUs for the transition would cause some RVUs to ''ping-pong'' between 1998 practice expense RVUs and the transition years. Some commenters opposing the transition policy in the proposed rule stated that the ''yo-yoing'' of practice expense values around the transition was not inconsistent with the statutory scheme.

Response: We agree that it is inconsistent with the statutory scheme to create sharp reversals in practice expense RVUs. A transition in the direction of a resource-based practice expense system began in 1993, and a one-time upward spike in RVUs for surgical procedures, which ignores the changes previously made, would be inconsistent with congressional intent and with the very purpose of a transition.

In response to comments on our proposed rule, we have examined the impact of the transition more precisely for a limited set of procedures. While this example is illustrative only, it shows that using 1991 average allowed charges in the transition formula (disregarding the 1998 redistribution, the OBRA 1993 practice expense payment reductions, and all budget neutrality adjustments) would result in marked payment spikes in 1999 for procedures whose fully-implemented resource-based practice expense RVUs are lower than their 1998 practice expense RVUs.

The chart below illustrates the changes in practice expense RVUs for each year from 1992 through 1998 and the estimated practice expense RVUs for 1999, 2000, 2001, and 2002, using data for 1991 and 1998 RVUs as alternative starting points for the transition. The chart shows the figures for cataract removal and intraocular lens insertion (CPT code 66984); the practice expense RVUs for cataract surgery decreased under both the OBRA 1993 and BBA reductions. Practice expense RVUs for cataract surgery will decrease between 1998 and 2002 when the resource-based system is fully implemented. The chart shows that there would be smooth, moderate decreases between 1998 and 2002, as we understand the Congress to have intended, if the 1998 practice expense RVUs are used in the transition formula. The chart also shows that there would be large increases in 1999 practice expense RVUs (compared to 1998 and even compared to earlier years) if the transition practice expense RVUs were based on 1991 average allowed charges. There would indeed be spikes in Medicare payments unless the 1998 practice expense RVUs are used in the transition formula, as we understand the Congress to have intended, during 1999, 2000, and 2001.

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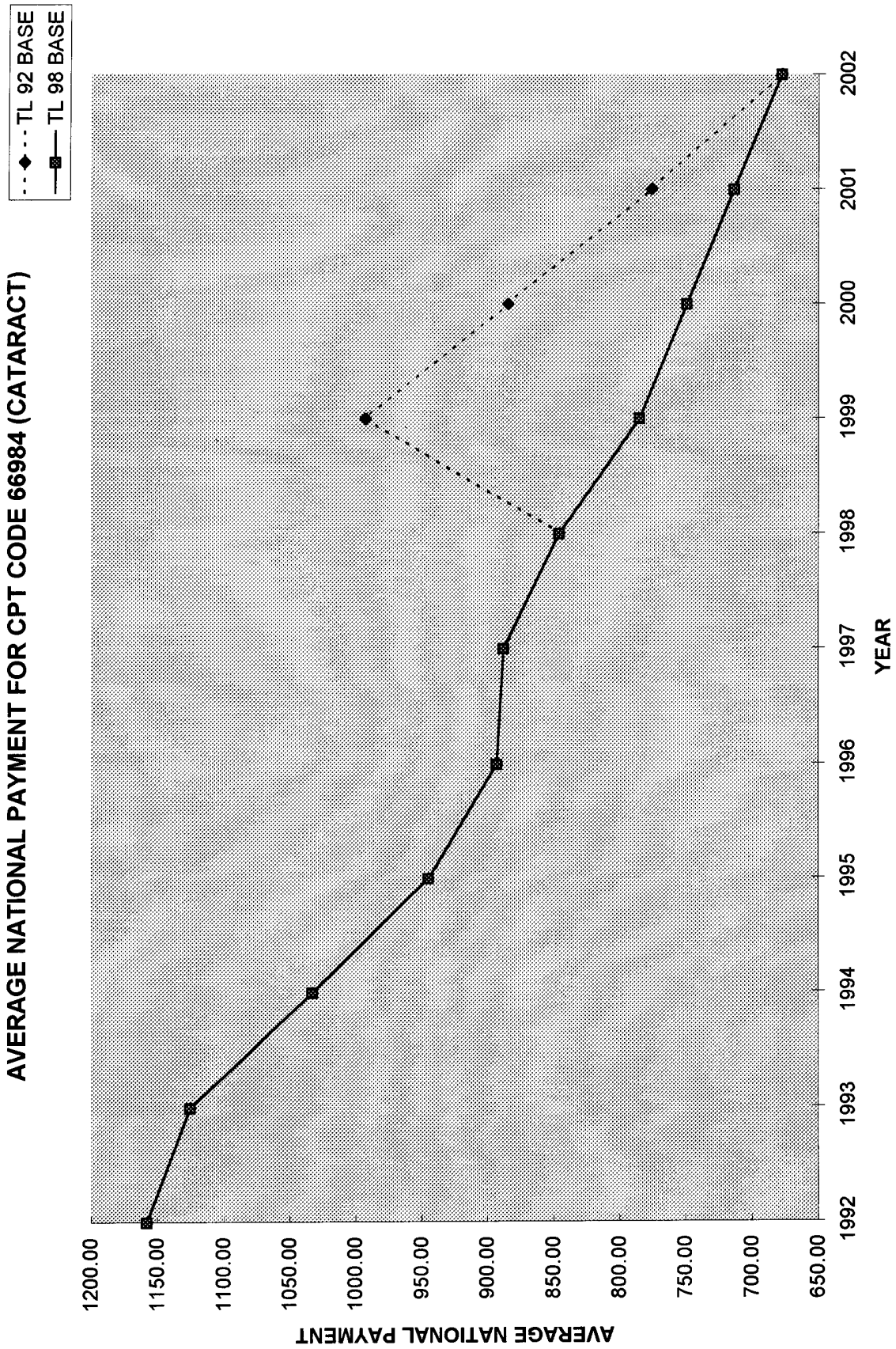

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Comment: Commenters opposing the proposed policy stated that the legislative history does not indicate that the Congress shares our concern about sharp changes in the redistribution of practice expense RVUs.

Response: We believe, instead, that the shape of the reductions made by section 1848(c)(2)(G) of the Act evidences the Congress' concern on this point. That provision explicitly exempted from reduction any procedure if the in-office or out-of-office practice expense RVUs would have increased under our June 1997 proposed rule. Thus, the Congress specifically chose not to reduce RVUs for a procedure if they were subsequently to be increased under the resource-based system. In this way, the law reflects congressional intent to avoid perverse shifts in practice expense RVUs during the transition.

Comment: Commenters opposed to the proposed rule also suggested that the OBRA 1993 changes codified at section 1848(c)(2)(E) of the Act were intended by the Congress to be temporary and apply only during 1994, 1995, and 1996.

Response: We disagree; the provisions were scored legislatively as permanent reductions, and we note that we implemented the OBRA changes in that way. Moreover, the Congress has acquiesced in our implementation of section 1848(c)(2)(E) of the Act. As discussed earlier, the OBRA 1993 reductions for practice expenses were designed to achieve Medicare savings while moving the system in the direction it would ultimately move under a resource-based system, greater relative payments for office-based procedures. The Congressional Budget Office and the Administration ''scored'' section 13513 of OBRA as having permanent savings, from which it can be inferred that the payment reductions were permanent. Until we received this comment in response to the proposed rule, it had not been suggested that our implementation of section 1848(c)(2)(E) of the Act was contrary to congressional intent. In fact, the Congress has since amended section 1848(c) of the Act without legislatively altering our implementation of section 1848(c)(2)(E) of the Act. We believe that the Congress' failure to take contrary legislative action on our implementation of section 1848(c)(2)(E) of the Act indicates that we have implemented that provision as the Congress intended.

Comment: One specialty society commented that there should be no transition for services that are new in 1999 and beyond.

Response: The law is silent as to whether there should be a transition for new services in 1999 and beyond. However, we agree with the commenter and will not provide a transition for codes representing services that are new beginning in 1999.

Comment: One specialty society suggested that we consider asking the Congress for additional transition time due to the disruption caused by the year 2000 computer systems overhaul.

Response: For 1999, we plan to make routine provider payment updates and other BBA changes. These pose minimal risks to contractors' year 2000 (Y2K) efforts and, therefore, can be done. Routine updates between October 1, 1999 and April 1, 2000 may need to be delayed because they would occur during a critical timeframe in late 1999 and early 2000 when final Y2K testing and refinements must be accomplished. We will actively consult with interested professional groups, the Congress and other parties as we develop our plans to achieve Y2K compliance while causing minimum disruption in fee schedule updates.

Comment: A surgical group suggested that we limit the magnitude of the changes in physician payments by imposing some reasonable limit on payment increases and decreases for individual services. They argue that such an approach is advisable because of what they believe is uncertainty about the accuracy of the resource-based RVUs.

Response: We do not believe that it is appropriate to place limits on increases or decreases in payments as a result of the implementation of the new system. We believe that the Congress addressed concerns about the accuracy of new values by explicitly providing for a transition and requiring a refinement process to be used each year of the transition. We believe that, in so doing, the Congress indicated its view of the appropriate contours of relief from the effects of redistribution of practice expense RVUs.

Resolution

We have considered all of the comments on our proposal to use 1998 practice expense RVUs in the formula for the 1999, 2000, and 2001 transition to fully resource-based practice expense values. We believe that use of 1998 practice expense RVUs is most consistent with the statutory design for resource-based practice expense and that using 1991 average allowed charges for this purpose would be antithetical to this scheme and to the purpose of providing a smooth transition. Thus, we are using the current, 1998, practice expense relative values in the transition formula for 1999 through 2001.

Revisions to the Regulations

We are revising § 414.22 (Relative value units (RVUs)), paragraph (b), (Practice expense RVUs), to state that for services beginning January 1, 1999, the practice expense RVUs will be based on a blend of 75 percent of practice expense RVUs used for payment in 1998 and 25 percent of the relative practice expense resources involved in furnishing the service. For services beginning January 1, 2000, the practice expense RVUs will be based on a blend of 50 percent of the 1998 PE RVUs and 50 percent of the relative practice expense resources involved in furnishing the service. For services beginning January 1, 2001, the practice expense RVUs will be based on a blend of 25 percent of the 1998 practice expense RVUs and 75 percent of the relative practice expense resources involved in furnishing the service. For services beginning January 1, 2002, the practice expense RVUs will be based on 100 percent of the relative practice expense resources involved in furnishing the service.

There will be only one level of practice expense RVUs per code for the following categories of services: those that have only the technical component of the practice expense RVUs; only the professional component practice expense RVUs; certain evaluation and management services, such as hospital or nursing facility visits that are furnished exclusively in one setting; and major surgical services. For other services, there will be two different levels of practice expense RVUs per code. The lower practice expense RVUs will apply to services furnished to hospital or ASC or SNF patients. The higher practice expense RVUs will apply to services furnished in a physician's office or services other than visits but performed in a patient's home and services furnished to patients in a nursing facility or an institution other than a hospital, ASC, or SNF.

Result of evaluation of comments: Based on our evaluation of all comments received on our proposed resource-based practice expense methodology, we have made the following modifications:

- Creation of a separate pool for services with work RVUs equal to zero. We created a separate practice expense pool for services with work RVUs equal to zero (including the technical components of services with professional and technical components) using the top-down methodology except we used the average clinical staff time

from the CPEP data (since these codes by definition do not have physician time) and, as an interim measure, we used the current 1998 practice expense RVUs to allocate the direct cost pools (clinical labor, medical supplies, and medical equipment). For services with professional and technical components paid under the physician fee schedule, the global practice expense RVUs are set equal to the sum of the professional and technical components.

• Allocation of the indirect cost pool. In the indirect allocation methodology, we are converting the work RVUs to dollars using the Medicare conversion factor (expressed in 1995 dollars for consistency with the SMS survey years).

• SMS based practice expenses per hour. For the specialty of emergency medicine, we are using 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 pathology, we are removing the supervision and autopsy hours reimbursed through Part A of the Medicare program from the practice expense per hour calculation.

For the specialty of podiatry, we are using the ''All Physician'' practice expenses per hour to create the practice expense cost pools.

For the specialty of allergy/immunology, we are using the ''allergy/immunology'' supply practice expenses per hour to create the supply practice expense pool.

We are splitting the ''radiology'' practice expenses per hour into ''radiation oncology'' practice expenses per hour and ''radiology other than radiation oncology'' practice expenses per hour and using these split practice expenses per hour to create practice expense cost pools for these specialties.

• Corrections to code crosswalks. We had inadvertently crosswalked some codes in settings where CPEP data existed. We have removed these crosswalks.

• Use of the current practice expense relatives for radiology services. For the specialty of radiology, we are using the current practice expense relatives for radiology services, as an interim measure, to allocate radiology's direct practice expense cost pools. For all other specialties that perform radiology services, we are using the CPEP relatives for radiology services in the allocation of that specialty's direct practice expense cost pools. Note that radiology services or components of radiology services that lack work relative value units are handled as described above under ''Creation of a separate pool for services with work relative value units equal to zero.''

• Physician's time for radiology codes. For radiology codes for which we lacked Harvard or RUC survey data, we calculated the physician's time using the average work per unit time of CPT codes 71010 and 71020.

• Maxillofacial prosthetics. For maxillofacial prosthetics, we are using the ''All Physician'' practice expenses per hour to create practice expense cost pools and, as an interim measure, allocating these pools using the current practice expense RVUs.

B. Medical Direction for Anesthesia Services

General Requirements

The conditions for payment of medical direction for anesthesia services are included in § 415.110 (Conditions for payment: Medically directed anesthesia services). Before January 1999, the regulations referred to these conditions as applying to services furnished directly or concurrently. The reference to services furnished directly is not correct. It suggests that the physician personally performing the anesthesia services only has to provide the same kind of services as the physician medically directing the anesthesia service. In fact, the physician personally performing the anesthesia service must perform the entire anesthesia service alone. This policy is included in § 414.46(c)(1)(i) (Additional rules for payment of anesthesia services, Physician personally performs the anesthesia procedure). Therefore, we are deleting the reference in § 415.110 to services furnished directly.

The December 1995 final rule (60 FR 63152) allows the physician's medical direction of a certified registered nurse anesthetist (CRNA) performing a single anesthesia service. However, this provision did not take effect until January 1, 1998. This policy was incorporated in § 414.46(d)(iii) (Additional rules for payment of anesthesia services, Anesthesia services medically directed by a physician). A program memorandum explaining this policy was issued to the Medicare carriers in January 1998.

In the June 1998 proposed rule, we proposed revising § 415.110 (Conditions for payment: Medically directed anesthesia services) so that it is consistent with § 414.46(d)(iii) by stating that medical direction can apply to the single anesthesia service furnished by a CRNA.

The law provides that the payment allowance for the physician's medical direction furnished on or after January 1, 1998, is 50 percent of the fee schedule amount that would have been paid if the anesthesia service was furnished by the physician alone.

Both the ASA and the American Association of Nurse Anesthetists (AANA) have pointed out that our medical direction requirements are outdated and too restrictive. The requirements are oriented to the administration of a general anesthetic, which was the predominant mode of practice when the regulations were originally implemented. There are other types of anesthesia, such as regional, spinal or epidural anesthesia, and monitored anesthesia care, that are becoming more common and for which the Associations argue, the current requirements are not completely appropriate. For example, in monitored anesthesia care, there is no definable emergence as there is for general anesthesia.

Also, the AANA has advised us that requiring the presence of the anesthesiologist for induction for all cases may not be appropriate and may delay the start of surgery and result in the inefficient use of operating room time. In addition, the ASA has advised us that neither the regulations nor the operating instructions explain the level of documentation required by the anesthesiologist to support the payment for the medical direction service. The ASA believes that the lack of instructions for medical documentation and the concerns about payment audits have reportedly prompted anesthesiologists to overly document anesthesia records.

The ASA and the AANA reached substantial consensus on a revised recommended set of medical direction requirements. The only area that they had a difference of opinion was with respect to the pre-anesthetic exam and evaluation. The ASA favored the requirement that the physician personally perform the examination and the AANA initially favored the requirement that the physician ensure that the examination and evaluation be performed by a qualified individual. We chose the proposed language as a compromise position. We reviewed their recommendations and proposed revising our regulations in § 415.110 (Conditions for payment: Anesthesia services) to reflect current anesthesia practice arrangements. Namely, we proposed to—

• Provide that the physician either perform the pre-anesthesia examination and evaluation or review one performed by another qualified individual;

• No longer require the physician to be present during induction and emergence on all anesthesia cases; and

• Require that the physician—

+ Monitor the course of anesthesia at intervals medically indicated by the nature of the procedure and the patient's condition;

+ Remain physically present in the facility and immediately available for diagnostic and therapeutic emergencies; and

+ Provide indicated post-anesthetic or ensure that it is provided by a qualified individual.

SUMMARY OF PROPOSED CHANGES TO MEDICAL DIRECTION REQUIREMENTS

For each patient the physician—		
	Current regulations	Proposed regulations
(i)	Performs a pre-anesthetic examination and evaluation	Performs a pre-anesthetic examination and evaluation, or reviews one performed by another qualified individual permitted by the State to administer anesthesia.
(ii)	Prescribes the anesthesia plan.	Participates in the development of the anesthesia plan and gives final approval of the proposed plan.
(iii)	Personally participates in the most demanding procedures in the anesthesia plan including induction and emergence.	Personally participates in the most demanding aspects of the anesthesia plan.
(iv)	Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in program operating instructions.	Ensures that any aspect of the anesthesia plan not performed by the anesthesiologist is performed by a qualified individual as specified in operating instructions.
(v)	Monitors the course of anesthesia at frequent intervals	Monitors the course of anesthesia at intervals medically indicated by the nature of the procedure and the patient's condition.
(vi)	Remains physically present and available for immediate diagnosis and treatment of emergencies.	Remains physically present in the facility and immediately available for diagnostic and therapeutic emergencies.
(vii)	Provides indicated post-anesthesia care	Provides indicated post-anesthesia care or ensures that it is provided by a qualified individual.

Comment: Almost all commenters recommended that we drop the proposed medical direction requirements and retain the current requirements. They pointed out that the proposed regulations would significantly relax the requirements for physician involvement in the provision of anesthesia care when a qualified nonphysician anesthetist is providing these services. They believe these changes would be to the detriment of patients and would diminish the current standards of care. The focus of these commenters' concerns was on the proposed requirements that the medically directing physician—(1) Could review a pre-anesthetic examination and evaluation performed by a qualified individual permitted by State law to administer anesthesia; and (2) ensure that indicated post-anesthesia care is provided by a qualified individual.

Several commenters also pointed out that the proposed requirement that the physician participate in the most demanding procedures in the anesthesia plan could be construed as meaning that the medically directing physician does not have to participate in any aspect of anesthesia care. Commenters also objected to the proposed requirement that the physician remain physically present in the facility and immediately available for diagnostic and therapeutic emergencies. The commenters pointed out that the proposed requirement is too lax and could be interpreted to mean the medically directing physician could be located anywhere in the facility.

Response: The medical direction requirements specify the activities that the medically directing physician, who is usually an anesthesiologist, must perform in order for the carrier to allow payment for a physician's service under the physician fee schedule. The medical direction requirements are not quality of care standards. As one commenter pointed out, these requirements are minimum requirements. Practicing anesthesiologists can, if they choose, furnish a level of services beyond the minimum standards.

As we noted in the proposed rule, we had decided to propose revised medical direction requirements because of concerns that the ASA and the AANA presented. We had asked the ASA and AANA to work together, to the extent practicable, to come up with a revised set of medical direction requirements. In February 1998, we met with both groups and heard their views and concerns. At that time, with the exception of the first proposed requirement that the CRNA be able to furnish the preanesthesia exam and evaluation and have the medically directing physician review it, it was our understanding that the leadership of both groups agreed to the uniform revised requirements.

However, because of concerns raised by their membership, the ASA and several State anesthesiologist societies are now requesting, for the most part, that we retain the current requirements, established in 1983.

We have decided to retain the current requirements (that is, requirements (i) and (ii), and (iv) through (vii)) in the preceding table and make only one technical revision in requirement (iii) at the present time. We will study the medical direction issue further and may propose to make a change in the future. The technical revision pertains to the requirement that the physician participate in the most demanding procedures in the anesthesia plan including, induction and emergence. We published a final rule in the **Federal Register** on March 2, 1983 (48 FR 8928) in which the current requirements for medical direction were included to implement section 108 of TEFRA of 1982. Since general anesthesia was the usual mode of practice for anesthesia services, the requirement reflected this practice. However, since 1983, other types of anesthesia care, such as regional anesthetics and monitored anesthesia care have become more common. One of our objectives was to revise the current requirement so that it is consistent with current anesthesia practices. As a result, we have decided that the medically directing physician must be present at induction and emergence for general anesthesia. That final requirement is as follows: The medically directing physician participates in the most demanding

aspects of the anesthesia plan, including, if applicable, induction and emergence.

Documentation Requirements

The current regulations do not specifically include medical record documentation requirements for medical direction. The proposed regulations state that the physician inclusively documents in the patient's medical record that the conditions set forth in paragraph (a)(1) of § 415.110 have been satisfied, specifically documenting personal participation in the most demanding aspects of the anesthesia plan.

The ASA asked initially that we include the medical documentation requirements in the regulations so that physicians, carrier staff, and other claims/medical record auditors have a clear and uniform understanding of the documentation requirements.

In addition, within the past 2 years, we have established medical documentation requirements for teaching physicians, including teaching anesthesiologists, that specify the amount of documentation needed to support the claim for the physician's service when the attending physician is involved in a medical/surgical case with a resident. We sought to establish some level of reasonable documentation for the medically directing physician considering that—(1) The teaching anesthesiologist is paid as if he or she personally performed the anesthesia service alone (that is, 100 percent of the fee); (2) the medically directing anesthesiologist is paid 50 percent of the total fee; and (3) the documentation requirements for the teaching anesthesiologist, as found at § 415.178, are that the record demonstrates the physician's presence or participation in the administration of the anesthesia. The operating instructions in MCM section 15016 specifically require that the teaching physician document in the medical records that he or she was present during the critical (or key) portions of the procedure, including induction and emergence. The teaching anesthesiologist's presence is not required during the preoperative or postoperative visits with the beneficiary.

Comment: The AANA asked that we revise the medical documentation requirements to require that the physician alone personally document the record; the Association stated that the CRNA should not have to document the physician's participation since the CRNA may not agree concerning the extent of the physician's participation in the case.

Response: We believe the proposed regulation text accomplishes this objective since it clearly says the physician must document the medical record. However, for purposes of further clarity, we will accept the commenter's recommendation.

Comment: The ASA asked us if their interpretation of the proposed medical documentation requirement is correct. ASA interprets the provision as allowing an anesthesiologist to state in the medical record that the medical direction standards have been met, without enumerating each such standard, and as requiring the anesthesiologist to specify in the record those demanding aspects of the case in which he or she personally participated.

Response: We understand the ASA's concerns about the medical direction requirements. We do not wish to make the act of medical documentation overly burdensome to the anesthesiologist. However, the medical record must include an amount of documentation to enable a medical records' auditor to conclude that the physician was sufficiently involved to support the payment of a medical direction fee.

The medical direction requirements specify certain functions or services that the physician must perform and cannot delegate to the directed qualified individual. We do not believe it is onerous to require the medically directing physician to document that he or she performed the pre-anesthetic exam and evaluation, provided indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where indicated. We also expect that there would be some indication in the record that the medically directing physician was present during some portion of the anesthesia monitoring.

Limited Activities Permitted During Medical Direction

The preamble to the final regulations (48 FR 8928) to implement section 108 of TEFRA of 1982 allows the medically directing physician to respond to medical emergencies and obstetrical patients in labor and also continue to furnish medical direction. The specific preamble language is as follows:

''We do not expect that a physician who is directing the administration of anesthesia to four surgical patients would be involved *routinely* in furnishing any additional services to other patients. However, addressing an emergency of short duration in the immediate area, or administering an epidural or caudal anesthetic to ease labor pain, or periodic rather than continuous monitoring of an obstetrical patient, would not substantially diminish the scope of control exercised by the physician in directing the administration of anesthesia to surgical patients. However, the carriers will review hospital records to ensure that such circumstances do not occur frequently, are of short duration, and do not constitute a diminution of the physician's involvement in the surgical procedure.''

In addition, the preamble addressed the specific question of whether the medically directing physician could perform certain routine tasks, such as receiving patients entering the operating suite for the next surgery, checking on or discharging patients in the recovery room and handling scheduling matters. The preamble included the following response to this comment:

''We agree that a physician may appropriately receive patients entering the operating suite for the next surgery while directing concurrent anesthesia procedures. However, checking or discharging patients in the recovery room and handling scheduling matters is not compatible with our reimbursing the physician on a reasonable charge basis (now physician fee schedule basis) for directing concurrent anesthesia procedures. The time devoted to such activities potentially can be extensive and would diminish the degree of involvement in the concurrent care beyond levels acceptable for purposes of reasonable charge reimbursement (now physician fee schedule payment).'' This continues to be our position.

Comment: Some commenters asked whether the policy of allowing certain other activities during medical direction would continue since the proposed regulation did not specifically address this matter. Also, the ASA asked whether this list of activities was exclusive or whether other similar services of short duration could be performed without violating the medical direction payment standards. The ASA did not provide examples of the kinds of services they would consider ''other limited services of short duration.''

Response: We believe this comment goes beyond our proposal. We will continue the policy enunciated in the preamble to the final TEFRA section 108 regulations. We will not expand or limit the current policy until we receive and have our medical staff evaluate information from the anesthesia societies on the specific services or the kinds of circumstances for which they are seeking an expansion of the policy. We invite comments on this issue.

Result of evaluation of comments: We have decided to include the following

set of requirements for medical direction in § 415.110 of this final rule. For each patient, the physician—

(i) Performs a pre-anesthetic examination and evaluation;

(ii) Prescribes the anesthesia plan;

(iii) Personally participates in the most demanding aspects of the anesthesia plan, including, if applicable, induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in program operating instructions;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated post-anesthesia care.

Also, the physician directs no more than four anesthesia services concurrently and does not perform any other services while he or she is directing the single or concurrent services so that all of the conditions for medical direction are met. The physician can attend to medical emergencies and perform other limited services as allowed by Medicare instructions and still be deemed to have medically directed anesthesia procedures.

The physician alone inclusively documents in the patient's medical record that the medical direction requirements have been met, specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence, where applicable.

C. Separate Payment for a Physician's Interpretation of an Abnormal Papanicolaou Smear

As stated in the proposed rule (63 FR 30841), with the exception of services to hospital inpatients, we do not allow separate payment for a physician's interpretation of an abnormal Pap smear. Under our proposed rule, separate payment may be allowed for a physician's interpretation of the abnormal Pap smear furnished for any patient on or after January 1, 1999.

About 10 percent of Pap smears are abnormal and are interpreted by a physician, usually a pathologist. If a physician interprets an abnormal Pap smear for a patient, other than a hospital inpatient, payment for a physician's interpretation (and the underlying test) is made under the clinical laboratory fee schedule payment for the Pap smear test. The physician negotiates with the laboratory for payment for the physician's service.

The College of American Pathologists requested that we recognize separate payment for a physician's interpretation of an abnormal Pap smear in all settings. We believe this would establish an understandable and uniform definition of physicians' services across sites. Therefore, we proposed recognizing, under the physician fee schedule, separate payment for a physician's interpretation of an abnormal Pap smear in all settings.

The Pap smear test may be furnished by a hospital or an independent laboratory. For hospital inpatients, the Pap smear test is paid to the hospital on a prospective payment basis. For other than hospital inpatients, the Pap smear test is paid under the clinical laboratory fee schedule to the hospital laboratory or independent laboratory. For services to hospital patients, the Pap smear interpretation usually is furnished by the hospital pathologist who can bill for the professional component of the service. If the independent laboratory's pathologist furnishes the Pap smear interpretation, payment can be made to the pathologist or the independent laboratory if it is an appropriate reassignee.

We received 25 comments from individuals and organizations on our proposal to recognize separate payment for a physician's interpretation of an abnormal Pap smear. All of the commenters supported our proposal.

Comment: Several commenters stated that our policy in section 15020 of the Medicare Carriers Manual that allows separate payment for a physician's interpretation of a Pap smear for a hospital inpatient only as long as there is an abnormality, is too restrictive. They pointed out that regulations implementing the Clinical Laboratory Improvement Amendments at § 493.1257(c)(1) require a pathologist to confirm all Pap smears identified by the screening personnel as showing an abnormality. This includes, by regulation, all smears thought to show ''reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papilloma virus-associated changes) or malignant category.''

Response: Our regulation will permit separate payment for a physician's interpretation of an abnormal Pap smear in all settings as long as—(1) The laboratory's screening personnel suspect an abnormality; and (2) the physician reviews and interprets the smear.

We contrast these services with other services of laboratory physicians that we considered hospital services. For example, the services of the physician that involve the review of Pap smears as part of the laboratory's quality control assurance procedures are considered hospital services and payable only to the hospital. Such services include reviewing slides that are considered normal by the cytotechnologist but are routinely reviewed by a pathologist, because of the risk status of the patient, as part of a random sample selected for quality review.

Comment: Two commenters recommended that we treat a physician's interpretation of an abnormal blood smear similar to the interpretation of an abnormal Pap smear.

Response: This comment is outside the scope of our proposal. Our proposal did not address abnormal blood smears. However, we will look into this issue next year as part of our review of physician fee schedule policies.

Comment: One commenter pointed out that the percentage of Pap smears that are abnormal or thought to be abnormal by the cytotechnologist and that require a physician's interpretation can vary considerably from geographical area to area and among laboratories within an area. The commenter wanted to point out that the fact that some laboratory-specific percentages of Pap smears that are interpreted to be abnormal are above 10 percent is not necessarily indicative of unacceptable utilization levels.

Response: We appreciate the commenter's clarification. In our proposal, we stated that ''about 10 percent of Pap smears are abnormal and are interpreted by a physician.'' We note that the 10 percent is a national estimate and that differences among laboratories could vary from this amount based on the population that the laboratory serves.

Result of evaluation of comments: We are allowing separate payment for a physician's interpretation of a Pap smear to any patient (that is, hospital or nonhospital patient) as long as—(1) The laboratory's screening personnel suspect an abnormality; and (2) the physician reviews and interprets the Pap smear.

D. Rebasing and Revising the Medicare Economic Index

Background

The Medicare Economic Index (MEI) represents a weighted sum of the annual price changes of the inputs used to produce physicians' services. It attempts

to present an equitable measure for the changes in the costs of physician time and operating expenses. The MEI now in use was rebased and revised as stipulated in a final rule published in the **Federal Register** (57 FR 55896) on November 25, 1992.

The MEI is comprised of two broad components, which are physician net income and physician practice expenses. Physician net income is comprised of wages, salaries, and benefits. The physician practice expense portion is comprised of six major categories: (1) Nonphysician employee compensation, including the wages and salaries and benefits of nonphysician employees in physicians' offices; (2) office expenses; (3) medical materials and supplies; (4) professional liability insurance; (5) medical equipment; and (6) other professional expenses.

We believe that it is desirable to rebase and revise the index periodically, in order that the expense shares and proxies will reflect approximate current conditions. Therefore, we are rebasing the MEI to reflect 1996 physician expenses. We chose 1996 as the base year for two main reasons: (1) The 1996 data were the most recent available data for most of the data sources we are using; and (2) the 1996 data were representative of the changing distribution of physician earnings and practice expenses over time. We have selected what we believe is the most appropriate proxy for each expense category. We will continue to adjust the physician and nonphysician employee compensation for economy-wide labor productivity, to avoid accounting for both physician practice productivity and economy-wide productivity in the physician update framework.

We determined the number and composition of expense categories based on the criteria used to develop the previous MEI expenditure weights and our other input price index expenditure weights (for more information on these criteria, see the November 25, 1992 final rule (57 FR 55900)). To determine the expenditure weights, we used currently available, valid data sources on physician earnings and practice expenses.

While we consulted numerous data sources, we used five sources to determine the rebased and revised MEI expenditure weights: (1) The 1997 American Medical Association Socioeconomic Monitoring System (AMA SMS) survey (1996 data); (2) the March 1997 Bureau of Labor Statistics (BLS) Employment Cost Index; (3) the 1992 Bureau of the Census Asset and Expenditure Survey (the latest available); (4) the 1996 Bureau of the Census Current Population Survey; and (5) the *Medical Economics* continuing survey published October 1997 (1996 data). No one data source provided all of the information needed to determine expenditure weights according to our criteria.

Rebasing and Revising the Medicare Economic Index

In the June 5, 1998 **Federal Register** (63 FR 30841), we published a proposed rebased and revised MEI. In that rule, we discussed in detail the methodology and data sources used to rebase and revise the MEI. The final rebased and revised MEI will have a 1996 base year and use the same data sources we proposed in the June 5, 1998 rule. Therefore, the weights and price proxies in this final rule are the same as those we proposed and are shown in Tables 1 and 2.

TABLE 1.—REVISED MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	Weights		Proposed price proxies
	1989 [1]	1996 [1 2]	
Total	100.000	100.000	
Physician Earnings [4]	54.155	54.460	
Wages and Salaries	45.342	44.197	AHE–Private [3].
Benefits [5]	8.813	10.263	ECI–Ben: Private [3].
Physician Practice Expenses	45.845	45.540	
Nonphysician Employee Compensation	16.296	16.812	
Employee Wages and Salaries	13.786	12.424	
Prof/Tech Wages	3.790	5.662	ECI–W/S: Private P&T [3].
Managers Wages	2.620	2.410	ECI–W/S: Private Admin [3].
Clerical Wages	5.074	3.830	ECI–W/S: Private Clerical [3].
Services Wages	2.233	0.522	ECI–W/S: Private Service [3].
Craft Wages	0.069	.....	
Employee Benefits [5]	2.510	4.388	ECI–Ben: Priv. White Collar [3].
Office Expenses	10.280	11.581	CPI(U)–Housing
Medical Materials and Supplies	5.251	4.516	PPI Drugs/PPI Surg. Appl/CPI(U) Med Sup.
Professional Liability Insurance	4.780	3.152	HCFA–Prof. Liab. Phys. Prem. Survey.
Medical Equipment	2.348	1.878	PPI–Medical Instruments and Equip.
Other Professional Expense	6.890	7.601	
Automobile	1.400	1.300	CPI(U)–Private Transportation.
All Other	5.490	6.301	CPI(U)–All Items less Food and Energy [1].

[1] Due to rounding, weights may not sum to 100.000 percent.

[2] Sources: Socioeconomic Monitoring System 1997 Survey of Physicians, Center for Health Policy Research, American Medical Association; Anne L. Finger, ''What it costs to run a practice,'' *Medical Economics,* October 27, 1997; U.S. Department of Labor, Bureau of Labor Statistics; and U.S. Department of Commerce, Bureau of the Census, 1992 Asset and Expenditure Survey, and 1997 Current Population Survey.

[3] Net of change in the 10-year moving average of output per man-hour for the nonfarm business sector.

[4] Includes employee physician payroll.

[5] Includes paid leave.

TABLE 2.—PERCENT DISTRIBUTION OF NONPHYSICIAN PAYROLL EXPENSE BY OCCUPATIONAL GROUP: 1996

BLS occupational group	Expenditure shares [1]
Total	100.000
Professional and Technical Workers	45.570
Managers	19.399
Clerical Workers	30.831
Service Workers	4.199

[1] These weights were derived from the 1996 Current Population Survey, U.S. Bureau of the Census.

The time series of percent changes in the current and rebased MEI are presented and compared in Table 3.

TABLE 3.—ANNUAL PERCENT CHANGE IN THE CURRENT AND REVISED MEDICARE ECONOMIC INDEX

Years ending June 30	Current MEI 89-base percent change	Revised MEI 96-base percent change	Difference
1985	3.3	3.2	0.0
1986	3.3	3.1	−0.2
1987	3.0	2.8	−0.2
1988	3.6	3.5	−0.1
1989	3.4	3.4	0.0
1990	3.0	3.2	0.2
1991	3.2	3.3	0.1
1992	2.8	2.7	−0.1
1993	2.1	2.2	0.1
1994	2.1	2.1	0.0
1995	2.0	2.0	0.0
1996	2.0	1.8	−0.2
1997	2.2	2.2	0.0
1998	2.5	2.3	−0.2
Average: 1985–1998	2.7	2.7	0.0

The CY 1999 increase in the MEI, one of the components used to update the physician fee schedule, is 2.3 percent.

We received numerous Comments on the rebased and revised MEI. Each Comment, with a response, is provided below. The Comments are organized into four major sections: index structure, expenditure weights, price proxies, and productivity adjustment.

Index Structure

Comment: A commenter believed we should re-examine the structure of the MEI, rather than make minor changes to an index that was developed in 1972 when physicians were paid reasonable charges.

Response: The structure of the MEI consists of weights associated with each of the cost categories, price proxies for each of the cost categories, and an overall adjustment for changes in productivity. The 1996-based MEI structure is identical to the revised structure we proposed on September 9, 1991 that was based on issues discussed at a public conference on March 19, 1987, thoroughly reviewed by the industry through a public Comment period, and ultimately adopted in 1992. This commenter did not offer any specific recommendations for change, and we know of no structural change we could make to improve the MEI. Consequently, the structure of the MEI will remain the same.

Comment: A commenter suggested that we indicate in the annual physician fee schedule proposed rule what the forecasted MEI would be under the different options considered and under the agency's final recommendation. The commenter noted that forecast data generally are provided when the agency updates the hospital market basket.

Response: The physician fee schedule is updated by a statutory-specified formula equal to the MEI plus or minus an update adjustment factor. The agency does not consider various options and make an update recommendation. The MEI for a year is based on changes in prices for prior periods. The performance adjustment is based on actual data; no options are considered. Thus, the situation for physician updates is not analogous to the hospital update process where changes in hospital payments are based on forecasts of the hospital market basket increase in the upcoming Federal fiscal year. In the case of physicians, the changes in the physician payment levels are based on the most current historical and performance data available.

Comment: A commenter believed that we should establish a regular schedule for updating weights of various elements of the MEI so that the index reflects the most recent data and information available.

Response: In the past, more frequent rebasing would have resulted in little or no difference in the update factors. For this current rebasing, the 1989-based MEI and the 1996-based MEI grew at the same rate on average between 1985–1998 as shown in Table 3. We will continue to monitor changes in the structure of physician costs as they might affect the MEI and we will update and rebase as needed.

Comment: A commenter believed that the MEI should contain an adjustment reflecting the fact that different inputs are used when services are provided by a SNF.

Response: Part of the fundamental design of the Medicare fee schedule is that payment is based on the service performed without regard to the place where the service is performed. The MEI is consistent with that design and provides a single national factor to update payments under the fee schedule, regardless of the site of service or the specialty of the health professional.

Expenditure Weights

Comment: One commenter was concerned that the proposed MEI does not reflect adequately the much larger portion of practice expenses the average obstetrician-gynecologist pays for professional liability insurance as compared to other specialties. The commenter pointed out that professional liability consists of 6.88 percent of the obstetrician-gynecologist's practice expenses, but only 3.2 percent of the practice expense of all physicians.

Response: The purpose of the MEI is to recognize the aggregate ''pure price'' increase of providing physicians'' services, regardless of specialty or site of service. Therefore, all input costs across all specialties are considered when determining the appropriate cost weights. The resulting cost weights, along with the price proxies and productivity adjustment, are used to calculate a national average percent change in the inputs used to provide physicians' services. This national average percent change is used to update the national payments under the fee schedule. We recognize that professional liability expenses as a portion of total expenses are above the average for some specialties and below the average for other specialties. However, differences in regional or specialty costs are accounted for by the GPCI or the RVU weight, respectively.

The only change to the professional liability insurance price proxy is that premiums are now collected for $1 million/$3 million of coverage on a quarterly basis, as opposed to premiums for $100,000/$300,000 of coverage on an annual basis. We continue to survey the same professional liability insurers that we surveyed for the 1989-based MEI.

Price Proxies

Comment: Several commenters suggested the price proxy for the physician earnings component should be the Employment Cost Index (ECI) for professional and technical workers, rather than the average hourly earnings (AHEs) for total nonfarm workers, for two reasons. First, the rationale for using a proxy of a highly heterogenous group no longer exists under the current payment system. Thus, our concern regarding circularity (increases in physician fees, which are tied to prevailing charges, are linked to

increases in physician payments) is no longer an issue. Second, earnings of professional workers are used as the proxy for the physician work component in the GPCI while AHEs for total nonfarm workers are used for physician earnings in the MEI. The commenter believes that we should use earnings for professional workers as the proxy in the MEI to be consistent with the GPCI.

Response: The commenters have raised issues that need to be clarified regarding the most fair and relevant price proxy to use for the physician work component of the MEI. The commenters are correct that circularity does not now exist between charge levels for individual physicians and subsequent Medicare fee levels for all physicians in the aggregate. However, paying based on a fee schedule does not override the need for us to continue to use fair and relevant price proxies.

We believe that the current price proxy, AHEs in the nonfarm business economy, is still the most appropriate proxy to use for the physician work component. AHEs continue to best meet the criteria of the 1972 Senate Finance Committee report shown in the June 5, 1998 **Federal Register** (63 FR 30844), including the criterion of ''fairness to all concerned.'' AHEs are also the best general earnings wage variable of which we are aware for our specific purpose. As a measure of equitable payment increases, AHEs reflect the impact of supply, demand, and economy-wide productivity for the average worker in society. By using the AHEs as the price proxy for physician time, the physician wage component captures this parity in rates of increase for physicians and the average worker in society.

The ECI for professional and technical workers includes occupations like engineer, architect, mathematical and computer scientist, and other types of technicians. Excess supply or excess demand for professional and technical workers on average can cause their wages to move differently than wages are moving in the overall economy or for a specific professional and technical occupation, such as a physician. Consequently, the ECI for professional and technical workers does not necessarily provide a good normative indicator of the percent increases in general earnings. Therefore, the ECI for professional and technical workers would fail to meet the criteria of fairness in the Senate Finance Committee report.

The commenters are correct that the proxy for physician work time in the GPCI is different than the price proxy in the MEI. This design reflects the different purposes of the GPCI and the MEI. The GPCI determines how total outlays are allocated among localities based on relative input price levels for each locality, or the ''pieces of the pie.'' Thus, the GPCI price proxy needs to validly reflect the relative levels of the specific category being proxied. The MEI, on the other hand, determines the aggregate increase in total outlays, or the ''size of the pie.'' These different purposes require that different proxies be used. Thus, the purpose of the proxy in this case is to measure the normative change in physician earnings. Our other input price indexes (market baskets), like the prospective payment system (PPS) hospital market basket and the HHA market basket, also use different price proxies than the geographic adjustment variable for similar reasons.

We are going to carefully monitor the price proxy used for physician work time in the MEI to ensure that it continues to be the most appropriate price proxy available for that purpose.

Comment: Several commenters suggested that the nonphysician employee compensation component of the MEI should be adjusted using a price proxy that reflects the increased skill mix of staff in physicians' offices.

Response: The MEI is a Laspeyres (fixed-weight) index that measures the normative ''pure price'' increase associated with physicians' services. Our other input price indexes, for hospitals, home health agencies, and skilled nursing facilities, are Laspeyres indexes as well. Changes in skill mix are appropriately captured in the volume-and-intensity adjustment in the fee schedule update, as they are with similar update formulas for our other payment programs, for example, PPS hospitals. By capturing skill mix shifts in the volume-and-intensity adjustment, we are able to appropriately separate quantity and ''pure price'' effects in the update framework. If we included positive and negative skill mix shifts in the MEI, there would be double-counting. Therefore, we will not adjust for changes in skill mix for the nonphysician employee compensation components of the MEI.

Comment: A commenter recommended that we adjust the office expense component using a price proxy based on inflation in commercial rents rather than inflation as measured by the housing component of the CPI for urban consumers.

Response: The CPI–U for housing is a comprehensive measure of changes in the cost of housing, including rent, owners' equivalent rent, insurance, maintenance and repair services, fuels, utilities, telephones, furnishings, and housekeeping services. Note that the GPCI also uses a consumer rather than a commercial rent index. The GPCI uses an index of Fair Market Rents (FMR) published by the Department of Housing and Urban Development for use in the Section 8 rental subsidy program because a valid indicator of commercial rents was not available. This measure does not meet the criterion of timeliness to be used in an input price index as it is only available prospectively on an annual basis. It would not represent historical data or be available quarterly like the rest of the proxies in the MEI.

Comment: One commenter questioned why we proposed using wholesale price changes, as measured by producer price indices (PPI), to measure cost changes for medical supplies and equipment. The commenter believed most physician practices are small entities that are unlikely to be able to purchase supplies and equipment at wholesale prices.

Response: In revising and rebasing the MEI, we selected wage and price proxies based on relevance, reliability, fairness, timeliness, and length of time a series had been established. Relevance means that the price proxy should represent price changes for goods or services within the expense category. We believe that use of the PPI for medical instruments and equipment appropriately captures price changes for the offices of physicians. Note that movement in the PPI at any given time is followed within a few months by approximately the same movement in the CPI. If this were not true, retailers would soon be out of business as their expenses rose but their revenues did not. Movement in the PPI essentially drives movement in the CPI, albeit with a slight lag. An increase in the wholesale level for a commodity will be followed by the same approximate increase in the retail level. Over time, the PPI does not move faster or slower than does the CPI. As mentioned in our June 5, 1998 proposed rule (63 FR 30846), use of the PPI for medical instruments and equipment as the price proxy for medical equipment is consistent with the 1989-based MEI.

Productivity Adjustment

Comment: A commenter proposed the elimination of the productivity adjustments to both the physician and nonphysician personnel components. The commenter believed the validity of the proposed MEI is compromised severely by this productivity adjustment.

Response: The Medicare fee schedule is appropriately adjusted for ''pure price'' inflation using a price index that approximates a price change in a freely functioning, competitive market. In

such a market, competitive forces lead to increased efficiencies (productivity). Therefore, a competitive output price does not rise as fast as a competitive input price, with the difference reflecting this increased efficiency (productivity). Thus, the input prices in the MEI need to be appropriately adjusted for productivity to approximate a freely functioning, competitive output price change. The PPS hospital input price index (market basket) is similarly adjusted for productivity, but the adjustment is included as a separate component of the PPS update framework.

The commenter believed that using economy-wide labor productivity to make the adjustment to the MEI input prices was inappropriate because physician productivity is lower than economy-wide productivity. While it is true that service industry productivity tends to be lower than economy-wide productivity, there is wide variation in productivity among specific sectors of the service industry. For physicians, the substantial influence they have over the volume and intensity of services provided to their patients allows them to increase output and, therefore, productivity.

The commenter provided information on the declining number of patient contacts per physician as evidence of declining productivity. To estimate productivity per physician, however, the large increase in volume and intensity of services per contact has to be accounted for. An approximation of the change in volume and intensity of physicians' services is the increase in allowed charges per enrollee in excess of the MEI increase (shown in the 1998 Annual Report of the Board of Trustees of the Federal Supplementary Medical Insurance Trust Fund). The increase in allowed charges per enrollee from Table II.F3. of this report has exceeded the MEI increase by 3.1 percentage points in 1994, 5.8 percentage points in 1995, and 2.1 percentage points in 1996. These data show that volume-and-intensity increases for physicians' services are still high relative to economy-wide productivity, which has historically grown around 1 percentage point annually on a 10-year moving average basis.

Economy-wide labor productivity increases automatically result in economy-wide wage rate increases as less worker time or other inputs are needed to produce the same outputs. Thus, the AHEs wage variable implicitly includes productivity increases in the overall economy. The productivity adjustment to the MEI factors out these economy-wide productivity increases. However, an individual physician practice still benefits from its own productivity increases in excess of economy-wide productivity increases. This means each individual physician practice is allowed to reap the rewards of having high productivity. Thus, it is both technically correct and fair to both providers and payers to adjust the MEI input prices by economy-wide productivity increases.

Result of Evaluation of Comments

As proposed, we rebased the MEI to 1996. We used the same data sources (for base year weights and price proxies) and methodology as explained in the June 5, 1998 proposed rule. The percent change in the MEI for CY 1999 is 2.3 percent.

III. Implementation of the Balanced Budget Act

In addition to the resource-based practice expense relative value units, BBA provides for revisions to the payment policy for drugs and biologicals, includes a provision allowing private contracting with Medicare beneficiaries, institutes payment for outpatient rehabilitation services based on the physician fee schedule, and changes the policy for nonphysician practitioners and for teleconsultations.

A. Payment for Drugs and Biologicals

Before January 1, 1998, drugs and biologicals not paid on a cost or prospective payment basis were paid based on the lower of the estimated acquisition cost (EAC) or the national average wholesale price (AWP) as reflected in sources such as the Red Book, Blue Book, or Medispan. (For purposes of this discussion, we will use the term ''drugs'' to refer to both drugs and biologicals). Examples of drugs that are paid on this basis are drugs furnished incident to a physician's service, drugs furnished by pharmacies under the durable medical equipment (DME) benefit, and drugs furnished by independent dialysis facilities that are not included in the end-stage renal disease (ESRD) composite rate payment.

Section 4556 of BBA established payment for drugs not paid on a cost or prospective payment basis at the lower of the actual billed amount or 95 percent of the AWP, effective January 1, 1998. In this final rule, we are revising the current regulations at § 405.517 to conform to this statutory change. This regulation is removing the EAC and provide for payment at the lower of the actual charge on the Medicare claim or 95 percent of the AWP.

Also, we are revising the method of calculating the AWP. Our current regulations provide that, for multiple-source drugs, the AWP equals the median AWP of the generic forms of the drug. The AWP of the brand name products is ignored on the presumption the brand AWP is always higher than the generic AWPs. While this may have been true when the policy was first promulgated, it is not always true now. Therefore, the AWP for multiple-source drugs would equal the lower of the median price of the generic AWPs or the lowest brand name AWP.

Comment: We received some comments on the proposed methodology for determining the AWP in the case of multi-source drugs. Some commenters suggested we use the average AWP instead of the median AWP. Others objected to the use of the lowest brand AWP saying that in all cases all AWPs, both generic and brand, should be used. One commenter stated that the law does not distinguish brand AWP from generic AWP; therefore, we should not make this distinction.

Response: We agree that the law does not define the term ''average wholesale price,'' and, therefore, does not distinguish brand AWP from generic AWP or average versus median price. However, we believe it is within our general authority in implementing the statute to define terms that do not have explicit statutory definitions. We believe that when there is an array of charges, the median is an appropriate measure of central tendency. This is consistent with many other areas of the program in which the median is used. With respect to distinguishing between brand and generic AWPs, as we stated in the final rule titled ''Medicare Program; Fee Schedule for Physicians'' Services (BPD–712–F),'' published in the **Federal Register** on November 25, 1991 (56 FR 59502), when this policy was promulgated, the brand AWP was believed to be always greater than the generic AWPs (56 FR 59507). Now there is evidence from the Office of Inspector General (OIG) in its report titled ''The Impact of High-Priced Generic Drugs on Medicare and Medicaid'' (OEI–03–97–00510) that this is no longer true. From a series of OIG reports spanning the past 10 years, it is clear that the AWP is higher than the amount typically paid for drugs by physicians who bill the program. It is also true that when a brand AWP is lower than the median generic AWP, typically there are also other generic AWPs that are as low as or lower than this brand AWP. We believe, therefore, that the payment allowance resulting from this methodology will be adequate.

Comment: Some commenters objected to a payment allowance of less than the AWP. One commenter alleged that not all physicians can buy drugs at less than retail prices. Another commenter stated that only large physician practices can obtain bulk purchase discounts. Another commenter suggested that we monitor access to drugs. Another suggested that we study actual acquisition costs before implementing the limit of 95 percent of AWP. Two commenters stated that physicians should not be burdened with maintaining price controls or cost containment or tracking the prices of drugs. Physicians should only be responsible for choosing the best drug and not be responsible for the cost of the drug. Furthermore, if physicians are not paid sufficiently for the drugs they now inject, they will stop injecting drugs and refer patients to the hospital instead. This will cost the program much more.

Response: First, the law now requires that the Medicare program limit its payment allowance to 95 percent of the AWP. Furthermore, there are numerous reports by the OIG over the past 10 years showing that significant discounts from the AWP are common and are not related to bulk purchases. In the absence of evidence to the contrary of the OIG findings, we believe it is reasonable to set the payment limit as we have proposed. With respect to the comment that physicians will refer patients to hospitals for injections, we believe that for the reasons stated and because payment for outpatient hospital services will be changed to a prospective payment basis, this will not occur.

Comment: One commenter stated that our definition of ''brand'' should be ''the product of the innovator company.'' The commenter objected to considering other manufacturers' products that are marketed under a proprietary name other than the generic chemical name of the drug as a ''brand.''

Response: Our definition of ''brand'' is any product that is marketed under a name other than the generic chemical name of the drug. If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand. We do not limit the definition of ''brand'' to the innovator company product or any product manufactured under a direct license from the innovator. Furthermore, we believe that it is an unreasonable administrative burden to require our contractors to determine which of the thousands of AWPs they must look up, to also determine which of those are innovator drugs or licensed by the innovator company.

Comment: Two commenters supported our proposal stating that our proposal was consistent with the statute.

Response: We agree with this comment.

Comment: A commenter stated that radiopharmaceuticals are drugs, but because of their unique nature they do not have AWPs. Therefore, the commenter recommended that we pay for radiopharmaceutical drugs at the billed amount.

Response: We agree that radiopharmaceutical drugs do not have AWPs, and, therefore, require a different pricing methodology. However, we do not agree that these drugs should be paid at the amount billed to the program. Currently, our contractors determine an allowance for these drugs that is reasonable in light of prices paid by physicians who use them. We will continue this policy of local pricing by our contractors.

Result of evaluation of comments: We are adopting our proposal with further clarifications. The Medicare allowed charge for drugs and biologicals is the lower of 95 percent of the median generic AWP or 95 percent of the lowest brand AWP. A ''brand'' product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological. The allowed charge for drugs and biologicals that do not have an AWP is determined by the local Medicare contractor considering the prices paid by physicians and suppliers who use them.

B. Private Contracting with Medicare Beneficiaries

Section 4507 of BBA 1997 amended section 1802 of the Act to permit certain physicians and practitioners to opt-out of Medicare and to provide through private contracts services that would otherwise be covered by Medicare. This rule conforms the regulations to sections 1802(b) and 1862(a)(19) of the Act. In addition, this rule contains ancillary policies that we believe are necessary to clarify what it means when a physician or practitioner ''opts-out'' of Medicare, and to otherwise effectuate the Congress'' intent in enacting section 4507 of BBA 1997.

The private contracting provision is effective for private contracts entered into on, or after, January 1, 1998. We implemented private contracting through a series of operating instructions for Medicare carriers and information that carriers were instructed to provide to physicians and practitioners.

The Medicare claims submission and private contracting rules apply only when a physician or practitioner furnishes Part B Medicare-covered services to a beneficiary who is enrolled in Medicare Part B. The private contracting rules do not apply to individuals who have only Medicare Part A, to individuals who are age 65 or over but who do not have Medicare, or to services that Medicare does not cover.

General Issues

State of Law Before Section 4507 of the BBA

Comment: Some commenters disagreed with our view that private contracting is not valid except as specified in section 4507 of the BBA. They believed that section 1848(g) of the Act does not preclude private contacting. In addition, they believed that the claims submission requirements apply only to ''services for which payment is made'' under the fee schedule and, therefore, by definition, do not apply if no claim is submitted.

Response: We continue to believe that under the Act, private contracts between beneficiaries and physicians or practitioners are not enforceable unless they meet the requirements of section 4507 of the BBA. The mandatory claims submission rules of section 1848(g)(4) of the Act specify that: ''For services furnished on or after September 1, 1990, within 1 year after the date of providing a service for which payment is made under this part on a reasonable charge or fee schedule basis, a physician, supplier or other person (or an employer or facility in the cases described in section 1842(b)(6)(A))—

- (i) Shall complete and submit a claim for such service on a standard claim form specified by the Secretary to the carrier on behalf of a beneficiary, and
- (ii) May not impose any charge related to completing and submitting such a form.''

Because there must be a claim to Medicare before payment can be made, the meaning of the phrase ''. . . for which payment is made on a reasonable charge or fee schedule *basis* . . . (emphasis added)'' must be to define the universe of claims to which the mandatory claims submission rules apply as being those services for which Medicare makes payment on a fee schedule or reasonable charge basis once a claim is submitted. The only exceptions the law provides to the mandatory claims submission rules are those found in the private contracting provisions of section 1802(b) of the Act and those implied by the phrase ''on

behalf of the beneficiary.'' In addition, one cannot omit the word ''basis'' and argue that the claims submission requirement applies only to services for which ''payment is made under this part on a reasonable charge or fee schedule.'' The word ''basis'' has meaning and was specifically included because it defines a universe of services to which the provision applies. The clear intention of the claims submission provision is to apply to all services for which payment is made under part B on a reasonable charge or fee schedule *basis*, but not to include services for which payment is made under part B on a reasonable cost basis (for example, hospital outpatient department services).

The phrase ''. . . for which payment is made . . .'' cannot, as commenters contend, mean that the mandatory claims submission rules apply only if payment is actually made in an instant case. That reading would mean the mandatory claims rules would never apply where no payment was made because of the absence of a submitted claim, rendering the mandatory claims provision meaningless.

Moreover, the limiting charge rules of section 1848(g)(1)(A) of the Act establish explicit limits on the charges of a nonparticipating physician or nonparticipating supplier or other person who does not accept payment on an assignment-related basis for a physician's services furnished to an individual who is enrolled in Part B. The only exception to these limits is that found in the private contracting provisions of section 1802(b) of the Act.

Comment: Commenters disagree that the limiting charge applies in the absence of a claim. They believe that if the claims submission rule can be waived by the beneficiary, then the limiting charge rule can also be waived by the beneficiary.

Response: As noted above, there is specific language in section 1848(g) of the Act that indicates that the physician, supplier, or other person must submit the claim ''on behalf of the beneficiary.'' In contrast, there is no language included in the flat prohibition in section 1848(g)(1)(A)(i) of the Act against nonparticipating physicians, suppliers, and other persons charging more than the limiting charge. For these reasons, we believe that we have no discretion to waive the limiting charge, except when the criteria established by section 4507 of the BBA are met.

Participating physicians, suppliers, and other persons who have agreed to always take assignment on claims for Medicare covered services, and nonparticipating physicians, suppliers, and other persons who take assignment, have also implicitly agreed to submit claims because one cannot take assignment on a claim unless one submits a claim. Moreover, because taking assignment means agreeing to accept Medicare allowed amounts as payment in full for covered services, they have also voluntarily agreed not to collect more than deductibles and coinsurance from all patients they see. For these reasons, signing a participation agreement, or accepting assignment by a nonparticipating physician, precludes private contracting outside of section 4507 of the BBA.

Claims for services that are not reasonable and necessary according to Medicare standards

Comment: Commenters asked that we clarify that there is no limit on the amount physicians and practitioners may charge beneficiaries when services furnished are denied as not reasonable and necessary, and the physician or practitioner has provided the advance beneficiary notice (ABN). Some commenters also asked that we clarify that when an ABN is provided, there is no private contract. They indicated that some physicians and practitioners are refusing to furnish non-covered services to beneficiaries, because they believe that giving an ABN will compel them to opt-out of Medicare.

Response: When a physician or practitioner furnishes a service that does not meet Medicare's criteria for being reasonable and necessary, and the physician or practitioner has furnished the beneficiary with an ABN that advises the beneficiary that for this reason there is a likelihood of denial of the claim by Medicare, there are no limits on what the physician or practitioner may charge the beneficiary. An ABN that states that the physician or practitioner believes that the service will not be covered by Medicare is not a private contract. The act of providing an ABN does not then require that the physician or practitioner opt-out of Medicare so that he or she avoids being at risk of having a penalty assessed for a limiting charge violation. Hence, physicians and practitioners should not hesitate to furnish services to Medicare beneficiaries when the physician or practitioner believes that those services are in accordance with accepted standards of medical care, even when those services do not meet Medicare's particular and often unique coverage requirements.

Beneficiaries in Medicare risk HMOs and Medicare+Choice organizations

Comment: Some commenters wanted us to reaffirm that a physician or practitioner may charge without regard to the limiting charge, when he or she furnishes a service to a beneficiary who is enrolled in a Medicare risk plan and the plan will not pay for that service. In addition, we were requested to address what happens in situations in which the beneficiary appeals the denial of the service and the Medicare risk plan subsequently agrees to pay the claim. Commenters asked that we define what is meant by ''covered services,'' for purposes of physicians and practitioners being able to charge Medicare risk plan or Medicare+Choice (M+C) organization enrollees more than the Medicare fee schedule, without having the physician or practitioner opt-out of Medicare for services not covered by the plan or the M+C organization.

Response: When a Medicare beneficiary enrolls in a Medicare risk plan (either currently under section 1876 of the Act or after January 1, 1999, under the M+C program), that beneficiary has Medicare coverage only to the extent that the services are covered under the risk plan according to the plan's rules for coverage. A risk plan may deny payment for a service if the beneficiary has not abided by the rules for coverage of care under the risk plan. (Examples of non-adherence to the plan's rules could be a beneficiary acquiring care without the required plan prior authorization, or acquiring care from a non-network physician if coverage is limited to network physicians.) In that situation there is no plan coverage of that service and the beneficiary is fully liable for the payment of the service, even when payment would have been made under original Medicare if the beneficiary were not in the risk plan. In these types of situations, the physician or practitioner may charge the beneficiary without regard to the limiting charge for the service furnished, and no claim need be submitted for the non-covered service. A private contract is not needed and the physician or practitioner need not opt-out of Medicare.

We would caution, however, that if the beneficiary seeks plan payment and the plan pays for the service, either initially or on appeal, then the physician or practitioner is entitled to receive no more than the amount he or she would have received under original Medicare. An adjustment would then have to be made to ensure that the beneficiary received a refund for any amount in excess of the Medicare allowed amount (if the physician participates in original Medicare) or the Medicare limiting charge (if the physician does not participate in original Medicare).

Application to Medicaid

Comment: A commenter wanted us to revise the final rule to specify that a physician or practitioner who opts-out of Medicare may not bill Medicaid for services he or she furnishes to individuals who are enrolled in both Medicare and Medicaid.

Response: There is nothing in section 4507 of the BBA that prohibits either dually eligible Medicare and Medicaid beneficiaries, or Medicare providers, from entering into a private contract, or that prohibits these providers from billing Medicaid for Medicaid covered services.

Excluded physicians and practitioners who opt-out

A physician or practitioner may be excluded from Medicare by the Office of Inspector General (OIG) for violations of the law according to sections 1128, 1156, and 1892 of the Act. An excluded physician or practitioner may not furnish, order, prescribe, or certify the need for Medicare-covered items and services (except as permitted in 42 CFR 1001.1901) for the term of the exclusion. A physician or practitioner must request and be granted reinstatement by the OIG before billing Medicare.

Comment: A commenter asked that we not permit excluded physicians and practitioners to opt-out. She believes that we need to clarify the relationship between opting-out and being excluded. She believes that if we permit excluded physicians and practitioners to opt-out, all the rules that apply to excluded physicians and practitioners can and should apply to physicians and practitioners who have opted-out. For example, excluded physicians cannot order covered services. Commenters also wanted us to agree that a private contract entered into by an excluded physician or practitioner would be recognized by us and the Office of the Inspector General as a notice to the beneficiary that the physician or practitioner is excluded, because the private contract must say whether the physician or practitioner is excluded.

Response: Section 1802(b)(2)(B) of the Act says, ''[s]uch contract shall also clearly indicate whether the physician or practitioner is excluded from participation under the Medicare program under section 1128.'' We have interpreted this to mean that, although excluded physicians can enter into private contracts, they must not only indicate their excluded status through the contract, but also still abide by the terms of their sanction under section 1128 of the Act. Practically speaking, this means that excluded physicians or practitioners may file affidavits and enter into private contracts, but that all the provisions of section 1128 of the Act and regulatory requirements pertaining to section 1128 of the Act, such as per-encounter issuances of ABNs, must still apply. Further, although section 1802(b)(2)(B) of the Act specifically mentions exclusions under section 1128 of the Act, the Secretary also has authority to exclude physicians and practitioners under sections 1156 and 1892 of the Act for the reasons specified therein. We believe it was Congress's intent to require clear notice of any exclusion, regardless of the specific statutory basis for it, in the contract with the beneficiary. Therefore, we have added language to §§ 405.415 and 405.425 to require a physician or practitioner provide clear notice of any exclusion, be it under section 1128, 1156, or 1892 or any other provision of the Act. We have also added language to § 405.440 to make clear that excluded physicians and practitioners are bound by the standards in 42 CFR § 1001.1901 for obtaining Medicare payment for emergency or urgent care services.

Grandfathering of physicians and practitioners who already opted-out

Comment: Commenters requested affirmation that the physicians and practitioners who have already opted-out will not have to file either revised affidavits or revised private contracts to meet the new standards contained in these regulations.

Response: We agree. These regulations are effective for private contracts entered into on or after January 1, 1999, and for affidavits submitted to carriers on or after January 1, 1999.

The provisions of section 4507 of the BBA were effective for private contracts entered into on or after January 1, 1998. We have therefore implemented the provisions of section 4507 of the BBA through operational instructions. Specifically, we issued Medicare program memoranda to implement the law in November 1997, January 1998, April 1998, July 1998. Medicare carriers have provided the information in these documents to all physicians and practitioners as they were released throughout the year. If physicians and practitioners submit affidavits in accordance with these program memoranda before January 1, 1999, they have opted-out of Medicare for the 2-year opt-out period, and need not submit revised affidavits to comply with the regulations. Similarly, when they have entered into private contracts with Medicare beneficiaries before January 1, 1999, they need not revise the private contracts or have beneficiaries sign second private contracts.

Comment: Commenters requested that physicians and practitioners who have opted-out before the regulations take effect, be provided with an opportunity to terminate their opt-out within 90 days of the date the new rules are effective, under the terms of early termination of opt-out.

Response: We agree. We have provided a special one time 90-day early termination opportunity for physicians and practitioners who opted-out during 1998, and who are willing to terminate their opt-out by complying with the requirements of §§ 405.445(b) (3) and (4) and 405.445(c).

Charitable care

Comment: Commenters indicated that physicians and practitioners should be permitted to opt-out of Medicare to do charitable care. They believed that because currently physicians and practitioners must collect deductible and coinsurance, they can be found to have made an illegal remuneration if they do not. They believed that the deductible and coinsurance are a financial burden for beneficiaries who do not have Medicaid. In addition, they believed that physicians and practitioners should be able to privately contract on a patient-by-patient basis, when they choose to offer free services to Medicare patients in need of those services.

Response: A physician or practitioner need not opt-out of Medicare to furnish services for which they do not charge, nor need they opt-out when either the deductible or coinsurance or both are waived because of indigence. Under current law, regulations, and instructions, nothing prevents a physician or practitioner from not charging a beneficiary for medical services. Moreover, longstanding Medicare policy permits physicians and practitioners to waive Medicare deductibles and coinsurance, when the physician's or practitioner's analysis of the beneficiary's financial information leads him or her to believe that collecting either the deductible or coinsurance or both would impose a hardship on the beneficiary. This policy has long been stated in Medicare Carrier Manual section 5220, and was stated as a permitted exception to the prohibition on the waiver of the deductible and coinsurance in section 231(h) of Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191).

However, the commenter is correct that the provision of free services can become problematic in some cases, as

for example, when a charge is not made as an inducement for the beneficiary to return for covered services, or as an inducement for the beneficiary to provide referrals. The commenter is also correct that indigence is the only explicitly permitted basis for waiver of either the deductible or coinsurance or both.

Definitions (§ 405.400)

Beneficiary

Comment: Commenters wanted the definition of ''beneficiary'' clarified to indicate that it applies only to individuals who are enrolled in original Medicare and does not apply to individuals who are enrolled in Medicare risk plans, or, after January 1, 1999, the M+C organizations.

Response: We have not made this change. The commenters are under the mistaken impression that a physician or practitioner may opt-out of original Medicare, but continue to be paid by an M+C organization for Medicare-covered services furnished to a beneficiary who is enrolled in an M+C organization. Instead, under the law and as specified in these regulations at § 405.220, a physician or practitioner who opts-out of Medicare may not provide services for which payment is made by Medicare, including where payment is made to the physician or practitioner by an M+C organization for services to a Medicare beneficiary enrolled in such an organization.

Emergency care services

Comment: Some commenters raised the question of whether we would use the ''prudent layperson'' definition of emergency medical condition of § 422.2, instead of the provider agreement definition of the term at § 489.24. The commenter believed that the ''prudent lay person'' definition is preferable.

Response: We agree. In order to give both beneficiaries and physicians and practitioners the greatest protection and flexibility in medical decision-making, we have decided to adopt the more inclusive ''prudent layperson'' standard of § 422.2, which was recently published as part of the M+C regulations at 63 FR 34968.

Legal representative

Comment: Some commenters objected to permitting a beneficiary's ''legal representative'' signing a private contract, because the law makes no provision for this action. They believed the regulations should permit no one but the beneficiary to sign a private contract.

Response: We permit a beneficiary's legal representative to sign a private contract so that beneficiaries who have legal representatives will not be treated differently than beneficiaries who do not have legal representatives. We can foresee a situation in which the legal representative of a beneficiary believes that signing a private contract that allows the physician or practitioner to furnish care would be in the beneficiary's best interest, and, we believe that, if legal representatives have the right to do so under applicable State law, they should not be precluded from doing so by Medicare regulations.

Comment: Some commenters stated that the proposed definition of ''legal representative'' is too restrictive. These commenters believed that we should define a ''legal representative'' to be any person permitted by State law to make health care decisions on behalf of the beneficiary. They believed that we defer to State law under the M+C rules, and that there is no reason to make a different rule for private contracting.

Some commenters requested that the definition of ''legal representative'' be expanded to include any person who would be willing to pay the beneficiary's bill, as, for example, family members. Some commenters stated that we should not define ''legal representative'' or use the term. Rather we should state that the private contract must be recognized under State law as a legally binding contract on the beneficiary, thereby letting the State determine when someone other than the beneficiary may sign it.

Some commenters indicated that the definition is not clear and should be revised. They wanted the revision to reflect differences in State law, or differences in the scope of the court order that appointed the beneficiary's legal guardian, by defining ''legal representative'' as ''the beneficiary's court-appointed surrogate (guardian, conservator or other State law terminology) who has authority to enter into a contract for health care services. Some commenters indicated that the regulation should be revised to clarify that the ''legal representative'' accepts responsibility for making payment from the beneficiary's financial resources or from the beneficiary's estate, but is not responsible for making payments using the legal representative's personal funds. In addition, commenters wanted the regulation to clarify that the legal representative is not personally liable for the beneficiary's bills.

Commenters also indicated that the party who can make health decisions may not be the same party who can make financial decisions. These commenters believed that private contracting involves both health and financial decisions, and, thus, that both parties should have to consult and agree before any one party enters into a private contract on behalf of a beneficiary.

Response: We believe that the question of who should be allowed to enter into a private contract should be determined in accordance with State law. Therefore, we have changed the definition of legal representative as specified in § 405.400 to be: ''one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.''

Comment: One commenter requested that the regulation require that the court order or power of attorney document establishing a ''legal representative'' be attached to the contract.

Response: We leave this matter to the States to regulate in accord with their applicable contract and agency laws.

Physician

Comment: Some commenters wanted optometrists to be able to opt-out.

Response: Section 1802(b)(5)(B) of the Act defines a physician according to the definition given in section 1861(r)(1) of the Act, which defines a physician as a doctor of medicine or osteopathy. For the purposes of opting-out and private contracting, the Congress did not define the term physician to mean the many other types of health care professionals as listed in section 1861(r)(2) through (5) of the Act. Optometrists are included in the definition only at section 1861(r)(4) of the Act.

General Rules (§ 405.405)

Two-year opt-out period

Comment: Many commenters objected to the requirements that when a physician or practitioner opts-out of Medicare, he or she must agree to sign private contracts with all Medicare beneficiaries, for all services furnished to Medicare beneficiaries for 2 years (other than emergency and urgent care services). These commenters believed that the 2-year requirement transforms private contracting from a vehicle for maximizing patient choice and access to services, into a barrier to the acquisition of services by the patient from the physician or practitioner of the patient's choice.

Response: The statute specifies that, in order to privately contract, the physician or practitioner must file an affidavit with Medicare. In the affidavit he or she must agree to enter into private contracts with Medicare beneficiaries (except in the case of those

who require emergency or urgent services) for 2 years.

Effect of opt-out that occurs during a continuum of care

Comment: Commenters asked that we clarify the effect of private contracting when the beneficiary is in a continuum of care that overlaps the opt-out period. For example, what will happen when a beneficiary is in the midst of a course of chemotherapy and the physician chooses to opt-out?

Response: When a Medicare beneficiary is in a continuum of care such as a course of chemotherapy and the physician chooses to opt-out of Medicare, the beneficiary may either privately contract with the physician, or the beneficiary may acquire the remainder of the care from a physician who has not opted-out of Medicare. If a physician or practitioner has opted-out of Medicare by filing an affidavit with the carrier, then he or she must enter into a private contract with every beneficiary to whom he or she furnishes care, except in situations where the beneficiary requires emergency or urgent care.

Conditions for Properly Opting-Out of Medicare (§ 405.410)

Advance notice of opt-out

Comment: A commenter requested that we require that physicians and practitioners give 60 days advance notice of their intention to opt-out. For nonparticipating physicians, this would be 60 days prior to filing the affidavit. For participating physicians, this would be 60 days before the calendar quarter in which their opt-out becomes effective. The notice would be given to beneficiaries treated by the physician or practitioner within 3 years, and to new beneficiaries with pending appointments.

The commenter knew of cases where beneficiaries traveled long distances for medical services without having been informed that the physician or practitioner had opted-out. Then, after arriving for the appointment, the beneficiaries had to leave without receiving the needed medical services, because they could not afford to enter into a private contract. According to the commenter, the beneficiaries in these cases suffered anxiety, distress, expense, and a delay in receiving the needed medical services. Those negative consequences could have been avoided if the beneficiaries had been advised, at the time the appointment was made or earlier, that the physicians had opted-out of Medicare. The commenter believed that the absence of advance notice leaves beneficiaries subject to duress in the physician's or practitioner's office.

Response: We have not imposed an advance notice requirement for physicians and practitioners who opt-out. We do not believe that kind of requirement is warranted. Moreover, the 60-day advance notice the commenter requested may cause physicians and practitioners to refuse to provide services during those 60 days, possibly resulting in the delay of needed medical services.

However, we hope that organizations will encourage member physicians and practitioners who have opted-out to notify the Medicare beneficiaries to whom they provide care as soon as possible after they file the affidavit. We also hope that these physicians or practitioners require that their office staff advise beneficiaries, at the time the beneficiary makes an appointment, that the physician or practitioner has opted-out of Medicare. Advance notice would spare beneficiaries the inconvenience, anxiety, duress, and delay in receiving needed medical services that might otherwise occur if they cannot enter into the private contract.

There are also significant administrative and good will advantages to the physician or practitioner of these notices. Advance notices will prevent the beneficiary from being surprised and possibly upset or angry in the office. Moreover, they will minimize the ill will that may occur if the beneficiary is asked to enter into a private contract at the time of the appointment as a condition of seeing the physician or practitioner, without being given advance notice. In addition, an advance notice will minimize the chance that beneficiaries will leave without having received the needed services, and result in an avoidable loss of income and time for the physician or practitioner.

We also hope that beneficiary organizations will encourage beneficiaries when they make an appointment to seek out information on whether they will need to sign a private contract before seeing a physician or practitioner. Then, the beneficiary could make a thoughtful and careful decision, in an environment less stressful than the physician's or practitioner's office.

Although we hope that the physician and practitioner communities will cooperate to provide an appropriate advance notice, we are concerned about the scenarios presented by the commenter and will continue to consider whether further guidance is needed.

Notice of change in participation status

Comment: A commenter indicated that there should be a mechanism for beneficiaries who have not signed private contracts, to be notified when they receive either emergency or urgent care services from an opt-out physician or practitioner who participated in Medicare before opting-out (and cannot sign a private contract at that time), that the physician or practitioner is now a nonparticipating physician or practitioner. That notification would benefit the beneficiary because the beneficiary's financial liability for those services will rise as a result of the change in the Medicare status of the physician or practitioner.

Response: We believe that this recommendation is an impractical burden to impose on physicians and practitioners, and is of little value to the beneficiary who needs emergency or urgent care services. When a beneficiary needs emergency or urgent care services, he or she probably does not have the alternative to seek care from a participating physician.

Signage

Comment: A commenter asked that we require that physicians and practitioners who opt-out to post a sign in a conspicuous space in his or her office in 5-inch type, stating that the physician or practitioner has opted-out of Medicare. Then beneficiaries will know when they enter the office that they will be required to sign a private contract to acquire non-emergency or urgent care services.

Response: We have not adopted this suggestion. As noted earlier we hope the physician and practitioner communities will cooperate to provide an appropriate advance notice to beneficiaries. We believe that a sign such as the commenter recommends would provide little or no value to the beneficiary who has already come to the physician or practitioner's office, and is about to be asked to enter into a private contract.

Relationship of opt-out physicians and practitioners to beneficiaries who do not enter into private contracts

Comment: A commenter asked that §§ 405.410 and 410.420 be revised to include an affirmative prohibition that physicians or practitioners cannot furnish an item or service to any beneficiary who has not privately contracted. The commenter believed that it should also be a condition to properly opt-out and maintain opt-out so that, if the physician or practitioner does not privately contract, the penalties of § 405.435(b) would be invoked.

Response: We have revised § 405.435 to specify that when a physician or practitioner who has opted-out fails to enter into a private contract (except in emergency or urgent care situations), he or she has failed to maintain opt-out. Therefore, where an opt-out physician or practitioner fails to enter into a private contract (except in emergency or urgent care situations), he or she will be subject to the penalties in that section for failure to maintain opt-out. We believe that this change addresses the commenter's concerns, and that changes to §§ 405.410 and 405.420 are not useful.

Timing of opt-out by participating physicians

Comment: Some commenters believed that participating physicians should be allowed to opt-out at any time after they provide sufficient advance notice. These commenters did not believe that participating physicians should have to await the beginning of a calendar quarter to be able to opt-out. Other commenters believed that physicians should only be permitted to opt-out during the standard participating physician enrollment period. They argued that permitting participating physicians to opt-out on a quarterly basis, and permitting nonparticipating physicians to opt-out at any time, leaves beneficiaries with too little time to find another physician or practitioner if theirs chooses to opt-out.

Response: We have decided to make no changes to the conditions regarding the timing of the opt-out period, either to permit opt-out by participating physicians at will, or to permit opt-out only during the participation enrollment period. Medicare carriers must make systems changes to permit participating physicians to opt-out, and, thereby, become nonparticipating physicians in the middle of the year, in such a way that they do not reduce Medicare payments for services furnished during the part of the year that they had a participation agreement in effect.

Medicare has a longstanding policy of making systems changes no less often than on a quarterly basis. The quarterly opt-out for participating physicians is designed to accommodate that schedule, while simultaneously permitting participating physicians to opt-out without having to await the annual participation enrollment or disenrollment period. The law does not link the opt-out election to the annual participation period and, therefore, we do not preclude participating physicians from opting-out only during that period.

Whether a carrier should send a return receipt to a physician or practitioner that submitted an affidavit

Comment: A commenter wanted carriers to be required to send a return receipt verifying the accuracy and acceptance of the affidavit. The commenter believed that procedure will eliminate problems with lost mail or an incorrect affidavit, and reduce the incidence of physicians and practitioners not properly opting-out and later finding themselves in trouble for having failed to properly opt-out.

Response: Our experience with those physicians and practitioners who have opted-out, indicates that there have been no notable problems with lost mail or incorrect affidavits. Hence, we do not believe that there is sufficient justification at this time for requiring the carrier (and the Medicare program) to incur the costs associated with sending return receipts to the physician or practitioner.

Impact of changes in carrier jurisdiction

Comment: A commenter asked that we address how carrier terminations and replacements will affect the opt-out status of physicians and practitioners. Specifically, the commenter wanted to know if the physician or practitioner needs to again file the affidavit with the carrier that is taking over the jurisdiction.

Response: Physicians and practitioners who have filed affidavits opting-out of Medicare will not need to refile when a carrier is replaced by a new carrier. The information will be transferred from the existing contractor to the new contractor, as part of the systems and records transition process.

Requirement to submit affidavits to all carriers

Comment: Commenters objected to the requirement that the physician or practitioner must submit affidavits to all carriers to which he or she has submitted claims in the past 2 years. They believed that this is a burdensome requirement that will become more so as there are more M+C organizations. Commenters also believed that this requirement is particularly burdensome for physicians and practitioners in States that have a lot of ''snowbirds.'' They asked whether the physician or practitioner must submit an affidavit to each carrier to which they would send claims. A commenter requested that there should either be a standard form that contains all addresses, or the affidavit should be submitted to us for distribution to all carriers.

Response: We do not believe that this requirement is burdensome. The submission of an affidavit is done no more than once every 2 years, and requires simply mailing it to the addresses to which the physician or practitioner ordinarily sends claims. Physicians and practitioners already know to whom they have sent claims within the past 2 years, and this is the reason we proposed this standard.

We want to reinforce the importance of mailing the affidavits to the appropriate carriers. We have received many affidavits that were sent to the Secretary, rather than being sent to the physician's or practitioner's carrier. The result of the misrouting of the affidavits has been significant delays in the processing of these misdirected affidavits by carriers. Physicians and practitioners were instructed where to send the affidavit in the November 1997 ''Dear Doctor'' letter. That letter was sent to all physicians and practitioners who had submitted claims to Medicare within the previous year.

Moreover, the comments reflect several misunderstandings. First, the number of M+C organizations has no relationship to the number of affidavits to be filed, because an M+C organization is not a Medicare carrier. M+C organizations will acquire information on physicians and practitioners who have opted-out through mutually agreed upon arrangements with carriers.

Also, when a physician furnishes care to a Medicare beneficiary who lives much of the time in another State, the physician files the Medicare claim with the carrier that has jurisdiction over the claims for the services furnished in the physician's or practitioner's Medicare locality. For example, when a physician in Jacksonville treats a Medicare beneficiary who resides most of the time in Detroit, the physician files the claim with the carrier who processes claims for services furnished in Jacksonville, not with the carrier who processes claims for services furnished in Detroit. Hence, the physician would file the affidavit with the carrier for Jacksonville, not with the carrier for Detroit.

We recognize that this process could be more streamlined. Therefore, we are considering ways to simplify it for physicians, practitioners, carriers, and M+C organizations, and would welcome suggestions on this subject.

Comment: A commenter asked for specific guidance in the case of physicians and practitioners who have not filed claims with Medicare in the past 2 years.

Response: The physician or practitioner should file the affidavit with the carrier that has jurisdiction over claims for the services furnished in

the Medicare localities in which the physician furnishes services.

Requirements of Private Contracts (§ 405.415)

Need for a model contract

Comment: Some commenters wanted us to develop a model contract. They believed that it would help physicians and practitioners by ensuring that they maintain their opt-out status. They believed that a model contract would increase the probability that beneficiaries will understand the effects of the private contract.

Response: We agree. We plan to create boilerplate language that may be included with any other contractual document the physician or practitioner and beneficiary create. We plan to create boilerplate language as part of the development of manual instructions, after consultation with the physician, practitioner, and beneficiary communities.

Wording of the private contract

Comment: Commenters requested that we require that the wording of the private contract be plain and simple, and not reference law, regulations, or government instructions. They believed such references cause beneficiaries to cease reading documents.

Response: We agree that the wording of private contracts should be plain and simple. At the same time, a private contract is a binding legal document. Its purpose is to waive a beneficiary's right to have his or her government-sponsored insurance coverage pay for certain health services. It is unlikely that a sensible and intelligent contract on this issue could be developed without a reference to law or regulation. Therefore, we are not prohibiting inclusion of references to law and regulations because such references may be necessary. However, contracts could have references to law or regulations and still be in plain and simple language.

Comment: Commenters requested that we require that the private contract specify that the beneficiary does not forego Medicare coverage for the services furnished by other physicians or practitioners who have not opted-out. In addition, commenters requested that the private contract specify that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services.

Response: We believed that these concerns were addressed in § 405.415(g) of the proposed rule. However, because of this comment, we have revised § 405.415(g), adding that the beneficiary must be advised that he or she is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted-out. In addition, this and other terms a private contract should contain may be incorporated in boilerplate language that we plan to create after consulting with the physician, practitioner, and beneficiary communities. That boilerplate language could then be included as part of the private contract document.

Comment: Commenters requested that we require that the private contract contain wording that specifies that the private contract applies to all services by the opt-out physician or practitioner, including emergency and urgent care services, and that, therefore, Medicare will not pay for any services furnished by the opt-out physician or practitioner. Commenters indicated that this wording is needed, because many private contracts specify that the beneficiary will have to pay for certain services, wrongly implying that other services not identified in the contract will be paid by Medicare. If the beneficiary is misled by this wording, it increases the likelihood that he or she will sign the private contract without understanding the effect.

Response: We have revised § 405.415(c) to clarify that the private contract must state that the beneficiary understands that by signing the private contract, the beneficiary or his or her legal representative accepts full responsibility for payment of the physicians's or practitioner's charge for all services furnished by the physician or practitioner. We will consider the exact language to be used in the private contract as part of the development of the boilerplate private contract language.

Beneficiary's copy of the private contract

Comment: Commenters asked how far in advance must the physician or practitioner give the beneficiary a copy of the private contract as required by § 405.415(l).

Response: Under § 405.415(l), we proposed that the beneficiary receive a copy of the contract before receiving any services under the contract, but we did not require that this occur a specific duration of time before services are furnished under the contract. We only proposed that the beneficiary be in possession of the private contract, or a copy of the private contract, by the time services under the private contract are furnished. This is consistent with the policy we have in place under the interim operating instructions issued to carriers in November 1997, January 1998, April 1998, and July 1998.

Duration of retention of the private contract

Comment: Commenters requested that we require the opt-out physician and practitioner to retain the private contract for the duration of the longest statute of limitations in the relevant state jurisdiction, so it would be available to use in potential claims against the physician or practitioner. They believed that this would assist in settling disputes about whether a private contract was required.

Response: We proposed that the private contract be retained for the duration of the opt-out term to which it applies. However, we are aware that, for example, a particular physician's or practitioner's opt-out term may run from January 1, 1999 to December 31, 2001. In this example, a beneficiary could enter into a contract with that practitioner or physician in November 2001, and a dispute over the existence or validity of the contract could arise in January 2002. If the physician or practitioner disposed of the contract on December 31, 2001, the physician or practitioner would not have the contractual evidence in the subsequent dispute. However, because retention of the private contract would be to the practitioner's or physician's benefit, we believe that the contract would become part of the patient's permanent record. In addition, although the physician or practitioner might have disposed of his or her copy of the contract, the beneficiary should still have the copy of the contract the beneficiary was given when the beneficiary entered into the contract.

Private contract type size

Comment: Commenters indicated that they support the absence of specified requirements regarding size of the print in the private contract, but that the regulations should stipulate that the physician or practitioner and the beneficiary should reach mutual agreement on all aspects of the private contract.

Response: Implicit in the fact that both parties enter into a private contract is the notion that both parties have read, fully understand, and agree to the terms and provisions of the private contract.

Requirements of the Opt-Out Affidavis (§ 405.420) Reassignment Implications

Comment: Commenters wanted the proposed regulations to be revised to explicitly authorize continued reassignment of Medicare benefits for

services furnished by opt-out physicians and practitioners to community mental health centers (CMHCs). They believed that opt-out physicians and practitioners should be able to opt-out of Medicare for purposes of their private practices, but be able to remain in Medicare when they furnish services in other settings like CMHCs. That would allow the physician and practitioner to continue to furnish services to low income persons for which the CMHC could bill Medicare.

Response: We disagree. Under the law, when a physician or practitioner opts-out of Medicare, he or she signs an affidavit that promises that he or she will privately contract for all Medicare-covered services he or she furnishes to Medicare beneficiaries. Hence, the opt-out decision applies to all services furnished by the physician or practitioner, including those for which a CMHC bills and is paid by Medicare under a reassignment of benefits to the CMHC, a billing agent arrangement, or through an employment relationship. Except as discussed below, no payment may be made to the physician or practitioner or to the CMHC for the services of a physician or practitioner who has opted-out of Medicare.

The only exception occurs when a clinical social worker (CSW) who is recognized by Medicare as a practitioner provides services as part of a partial hospitalization program for which Medicare is paying the CMHC. In this case, the CMHC (and not the CSW) is the provider of a partial hospitalization service (not a CSW service) and the fact that the CSW opted-out of Medicare does not preclude payment for the partial hospitalization service.

Identifying Information

Comment: Commenters objected to the quantity of information that we proposed requiring in the affidavits. They believed that we have gone beyond what the law requires for the specific identifying information that must be provided. They requested that the proposed regulations be revised to require only a name, address, phone number, and one identifying number such as either the national provider identifier, the uniform provider identification number, or the tax identification number.

Response: We are sympathetic to these commenters concerns, but we believe that we have requested the minimum practical quantity of information be provided in the affidavit that we, and carriers, need to properly and uniquely identify opt-out physicians and practitioners. Given the possibility that a large number of physicians or practitioners could opt-out of Medicare, the potential for having confusion among physician or practitioners with the same name or business address is significant. This is especially true when the additional factors such as the prevalence of the use of billing agents and reassignments are considered.

We need sufficient information to ensure that no entity is billing on behalf of an opt-out physician or practitioner. We also need sufficient information to identify persons who have never been involved in the Medicare program. In addition, and most importantly from the physician's or practitioner's standpoint, we need what some physicians and practitioners may believe to be duplicate information to ensure that we have correctly identified the opt-out physician or practitioner and have not incorrectly assumed that a physician or practitioner has opted-out.

Failure to Properly Opt-Out (§ 405.430)

Difference Between Failing to Properly Opt-Out and Failing to Maintain Opt-Out

Comment: Commenters asked that we clarify the difference between failing to properly opt-out (§ 405.430) and failing to maintain opt-out (§ 405.435).

Response: Failure to properly opt-out means failure to meet the criteria that change a physician's or practitioner's status, from a physician or practitioner who is bound by the Medicare claims filing rules and limits on charges (that is, participating or nonparticipating), to a physician or practitioner who is no longer bound by Medicare claims filing and limits on charges and must privately contract with Medicare beneficiaries (that is, an opt-out physician or practitioner). The effects of failing to properly opt-out as specified in § 405.435(b) are the same conditions that existed before the private contract provisions of section 4507 of the BBA were effective. These conditions continue to exist for all physicians and practitioners who do not properly opt-out by meeting all of the requirements of these rules. A physician or practitioner who has never filed an affidavit is bound by the rules in § 405.430(b) because he or she has not properly opted-out.

Failing to maintain opt-out means failure to continue to comply with the requirements of properly opting-out, but only after having properly opted-out. A physician or practitioner who has opted-out by meeting the requirements of § 405.410, but who fails to continue to meet one of the requirements specified in § 405.435(a), has failed to maintain opt-out and is subject to the effects of § 405.435(b).

Beneficiary rights when a physician or practitioner does not properly opt-out

Comment: Commenters asked that we specify the beneficiary's rights when the physician or practitioner fails to properly opt-out. Specifically, are beneficiaries entitled to refunds for services furnished under private contracts? If the answer is yes, are the refunds based on Medicare rules, and does the pre-opt-out or post opt-out status (participating versus nonparticipating) control the payment?

Response: Beneficiary rights when a physician or practitioner fails to properly opt-out are specified in § 405.430(b). However, we realize that the proposed rule failed to indicate that a participating physician in Part B of Medicare who has not properly opted-out may not charge more than the deductible and coinsurance that applies to the service furnished because, in the absence of the physician properly opting-out of Medicare, the participation agreement to accept assignment on all claims continues to apply. We have made the relevant change to this section.

Repeated attempts to opt-out

Comment: Commenters asked us to clarify what happens when the physician or practitioner fails to properly opt-out. Does a participating physician have to wait until the next calendar quarter to properly opt-out? Commenters wanted the regulations to specify that all attempts to properly opt-out must meet the same criteria as if no opt-out attempt had occurred.

Response: A physician or practitioner who fails to properly opt-out continues to be bound by the Medicare claims filing and charge limit rules identified in § 405.430(b). However, he or she may make an unlimited number of attempts to properly opt-out at any time. We believe that the regulations are clear that the criteria for properly opting-out as specified in § 405.410 must be met for the physician or practitioner to opt-out.

Failure to Maintain Opt-Out (§ 405.435)

Inclusion of failure to enter into a private contract as a failure to maintain opt-out

Comment: Some commenters requested that the regulations specify that the failure of a physician or practitioner who has properly opted-out to privately contract with a beneficiary to furnish services, that are not emergency or urgent care services, is a failure to maintain opt-out. In those

cases, the commenters wanted the penalties for failure to maintain opt-out to apply.

Response: We agree and have revised § 405.435(a). Failure to enter into a private contract with a beneficiary who requires services that are neither emergency nor urgent care services is now a condition that results in the physician or practitioner failing to maintain opt-out as specified in § 405.435(a)(5). Commenters have provided information about situations in which physicians and practitioners who opted-out of Medicare failed to enter into private contracts with beneficiaries who did not need emergency or urgent care services. Those beneficiaries subsequently learned that they would be wholly liable for the physician's or practitioner's charges because they had opted-out of Medicare. We believe that failing to privately contract after promising to do so in the affidavit clearly violates the intent of the law. That intent, we believe, is to ensure that beneficiaries have entered into private contracts before they assume liability for payment of furnished services without regard to charge limits.

Medicare payment when the beneficiary has not entered into a private contract

Comment: Some commenters requested that we require that when the opt-out physician or practitioner fails to enter into a private contract before furnishing services that are not emergency or urgent care services, the beneficiary be reimbursed by Medicare. In addition, the physician or practitioner would have to refund to the beneficiary any amount in excess of the limiting charge. Commenters indicated that this would parallel longstanding policy in which Medicare pays the first claim submitted by an excluded physician or practitioner.

Response: We have revised § 405.435 to add failure to enter into a private contract as a failure to maintain opt-out. Under these provisions, the physician or practitioner would be required to refund amounts in excess of the charge limits under the limited terms described in § 405.435(b). Under those terms, where a carrier notifies a physician or practitioner that he or she appears to have failed to maintain opt-out, the physician or practitioner would have 45 days to respond to the carrier with the good faith efforts that he or she has taken to resolve the problem. In cases in which the physician or practitioner did not sign private contracts, those good faith efforts would have to include refunds to those beneficiaries of amounts in excess of the charge limits (that is, the limiting charge for physicians, and deductible and coinsurance for practitioners). Where a carrier notified a physician or practitioner that there was an apparent failure to maintain opt-out and he or she did not respond within 45 days with an explanation of how the problem was or would be solved, the charge limits would apply after the 45th day, resulting in refund of excess amounts if any are collected for the remainder of the opt-out period. Where the physician or practitioner responded to the carrier notice and resolved the problem, no refunds would be required and the opt-out would continue unaffected.

In addition, we have added § 405.435(c), which specifies that payment may be made to beneficiaries in a similar manner as payment made to beneficiaries who receive services from physicians and practitioners who are excluded from Medicare by the Office of the Inspector General (OIG).

Under a longstanding exclusion provision at 42 CFR 1001.1901(c), payment may be made to a beneficiary who has not been notified of the physician's exclusion, for the first claim submitted by the enrollee. Payment to the beneficiary may also be made for services received by the beneficiary no more than 15 days after the date of the carrier's notice to the beneficiary that the physician has been excluded from Medicare. Therefore, in § 405.435(c), we have included similar provisions with respect to physicians and practitioners who have opted-out of Medicare, but failed to enter into private contracts before furnishing services that are not emergency or urgent care services.

We agree with the commenters that it is not fair to deny beneficiaries reimbursement for otherwise allowable services when they had no reason to believe that Medicare would not pay for the furnished services. We should point out, however, that as a practical matter, payment to the beneficiary will probably be made after denial of the beneficiary's claim and as part of the appeal process. In other words, the beneficiary's claim initially would be denied on the basis that the physician or practitioner opted-out. Should the beneficiary then appeal on the basis that he or she did not enter into a contract with the physician or practitioner, and should the physician or practitioner fail to produce documentation that there was a contract, the beneficiary's appeal would be allowed and the claim would be paid.

Comment: Commenters objected to any recovery of payment from the physician or practitioner when the physician or practitioner failed to maintain opt-out, because he or she failed to enter into a private contract with the beneficiary before furnishing services that were not emergency or urgent care services.

Response: As discussed above, we have revised § 405.435 to define failure of an opt-out physician or practitioner to enter into a private contract as being a failure to maintain opt-out. When a carrier notifies an opt-out physician or practitioner that he or she appears to have failed to maintain opt-out by not entering into a private contract, he or she may continue to opt-out if he or she makes good faith efforts at fixing the problem that led to the failure to maintain opt-out and notifies the carrier of these efforts within 45 days of the carrier notice. When a physician or practitioner appears to have failed to maintain opt-out by not entering into a private contract with a Medicare beneficiary (except in emergency or urgent care cases), these good faith efforts should include refunding amounts collected in excess of applicable charge limits (that is, limiting charge for physicians and deductible and coinsurance for practitioners) to beneficiaries. Where the physician or practitioner makes good faith efforts to correct the problem he or she would not be subject to the consequences of failing to maintain opt-out. However, if he or she does not make good faith efforts to fix the problem that resulted in violating the opt-out, the consequences of § 405.435(b) would apply.

Treatment of incidental failure to maintain opt-out

Comment: Some commenters indicated that the first time the carrier becomes aware that a physician or practitioner failed to enter into a private contract before furnishing services that were not emergency or urgent care services, there should be a presumption that there was an isolated error. They believed in those cases that no adverse consequences should occur to the physician or practitioner. Some commenters stated that there should be a process for dealing with physicians and practitioners who demonstrate a pattern of failing to enter into private contracts with beneficiaries, before furnishing services that are not emergency or urgent care services.

Response: We agree that, as written, an isolated error causes the physician or practitioner to fail to maintain opt-out. We also recognize that isolated errors will occur and should not result in the consequences provided in § 405.435(b). We accommodated this concern in our operating instructions to carriers. Consequently, we have revised the

regulation at § 405.435(b). We have limited the effects of failing to maintain opt-out when the physician or practitioner has failed to maintain opt-out in accordance with the provisions of § 405.435(a), by failing to make a good faith effort to advise carriers regarding how they will correct violations of opt-out within 45 days of the date a carrier brings those violations to their attention. This change comports with the current operating procedures in place when a physician or practitioner submits a claim for Medicare payment in violation of the affidavit, in which he or she promised not to submit claims.

Payment to physicians and practitioners when they fail to maintain opt-out

Comment: Commenters indicated that it is unclear whether the physician or practitioner would be paid anything for the services they furnished if they fail to maintain opt-out. Commenters objected to what they view as provisions that prevent them from collecting more than the deductible and coinsurance if the physician or practitioner fails to maintain opt-out.

Response: Physicians and practitioners who have opted-out and who fail to maintain opt-out are not precluded from collecting payment from the beneficiary. But if they failed to privately contract with a beneficiary (other than in an emergency or urgent care case), they may have to refund amounts in excess of the applicable charge limits to those beneficiaries with whom they failed to privately contract in order to preserve their opt-out status.

Specifically, under § 404.435(b) when a physician or practitioner fails to maintain opt-out, he or she is given 45 days after a notice from the carrier to respond with a description of the good faith efforts that he or she has made to correct the problem that led to the failure to maintain opt-out. If the failure to maintain opt-out was caused by the physician's or practitioner's failure to privately contract with a beneficiary (other than one in need of emergency or urgent care), then the good faith efforts would include refunding to that beneficiary amounts collected in excess of the applicable charge limits (that is, the limiting charge in the case of physicians, and the deductible and coinsurance in the case of practitioners). If the physician or practitioner does not respond with a description of the good faith efforts taken to resolve the problem that led to the failure to maintain opt-out, then the provisions of § 405.435(b) apply after the 45th day after the carrier notice and the physician or practitioner become again required to submit claims and are bound by the applicable charge limits (that is, the limiting charge in the case of physicians, and the deductible and coinsurance in the case of practitioners) for the rest of the opt-out period.

Medicare inspection of private contracts

Comment: Commenters stated that a very high threshold should be met before we are allowed to inspect private contracts. Commenters wanted the regulations to specify that we would be allowed to inspect private contracts only if the request is reasonable and does not interfere with the delivery of services. Commenters wanted the regulations to require that we obtain beneficiary consent before asking to see the private contract. Otherwise, they believed it is a violation of privacy. Some commenters indicated that when it is alleged that a physician or practitioner opted-out but did not enter into private contracts before furnishing services that are not emergency or urgent care services, settlement of the case should be on a case-by-case basis by the appeal process.

Response: We anticipate that we will request to see private contracts rarely, and only in cases where a beneficiary alleges that he or she did not enter into a private contract before the service was furnished. We anticipate we will have the consent of the beneficiary, or his or her legal representative, to acquire a copy of the private contract from the physician or practitioner who alleges that one was entered into, and that the contract will be requested as part of the processing of an appeal of a denial of a claim for services.

Application of effects of failure to maintain opt-out

Comment: Commenters objected to considering the provisions of §§ 405.435(a)(2), (3), and (4) to be a failure to maintain opt-out resulting in the adverse effects of § 405.435(b). Commenters believed that the statute provides for the adverse effects in § 405.435(b) only if the physician or practitioner who has opted-out submits a claim for Medicare payment. In addition, they believed that we have exceeded what the law permits by providing adverse consequences in these other cases:

- The physician or practitioner fails to use private contracts that meet the requirements of § 405.435(a)(2).
- The physician or practitioner fails to comply with the emergency and urgent care rules as specified in § 405.435(a)(3).
- The physician or practitioner fails to keep a copy of a private contract or fails to permit us to review contracts on request as specified in § 405.435(a)(4).

In these cases, commenters believed that nothing supports applying the penalties of § 405.435(b) for failing to maintain opt-out, and they objected that we do not apply the knowing and willful test in these cases.

Response: We believe that under general rulemaking authority, we have the authority to impose the requirements we believe are necessary to implement the law in a manner that conforms with the intended effect. We believe that it would be inconsistent with the intent of the law if we could not ensure that—(1) private contracts adequately protect beneficiaries who enter into them; (2) emergency and urgent care services are provided without the patient being asked to enter into a private contract; and (3) a private contract is available for review when an appeal is based on the allegation that a contract was not entered into.

Comment: Commenters wanted the regulations to specify that when the physician or practitioner who has opted-out fails to maintain opt-out, the physician or practitioner must refund amounts collected in excess of the limiting charge for services he or she furnished before the failure to maintain opt-out occurred.

Response: We have not made this change. When a physician or practitioner has properly opted-out, he or she is not limited in what he or she can collect from the beneficiary for services furnished during the period in which he or she has properly opted-out.

As discussed previously, to avoid the consequences of failing to maintain opt-out, the physician or practitioner must respond within 45 days after the carrier notice with good faith efforts to resolve the problem (including refunding to the beneficiary amounts in excess of the charge limits where the physician or practitioner failed to enter into a private contract with a beneficiary who did not need emergency or urgent care). However, if the physician or practitioner does not respond within 45 days with good faith efforts to maintain opt-out, he or she becomes bound by the consequences of failing to maintain opt-out (including applicable charge limits), but only for services furnished in the remainder of the opt-out period—not for services furnished while he or she was in compliance with the opt-out.

Emergency and Urgent Care Services (§ 405.440)

Disagreements about emergency or urgent care services

Comment: Commenters asked what will happen if the physician or practitioner furnishes services that they believe are emergency or urgent care services, but the carrier disagrees. Will the physician or practitioner be subjected to any penalties for failure to privately contract? Commenters believed that this is particularly problematic in instances of furnishing urgent care services, when the carrier or M+C organization believes those services could wait more than 12 hours, but the physician or practitioner disagrees. There should be some protection for the physician or practitioner who believes that the proper categorization of the needed furnished services was urgent care, even if the physician or practitioner loses on appeal.

Response: We believe that changing the definition of emergency care, from the ''anti-dumping'' definition specified at § 489.24 to the ''prudent layperson'' standard specified at § 422.2, will offer more protection to physicians and practitioners who are presented with a beneficiary who believes he or she is in need of emergency or urgent care services. Therefore, we have revised the text of emergency care services to mean ''services furnished to an individual for treatment of an 'emergency medical condition' as that term is defined in § 422.2 of this chapter.''

Comment: Commenters asked what oversight processes we will use to ensure that physicians and practitioners that opt-out do not abuse their ability to see patients without private contracts. The commenters were concerned that beneficiaries may be left unprotected if Medicare disagrees with the physician's or practitioner's view that the services were emergency medical care or urgent care services. They were also concerned that beneficiaries who believe that they need emergency medical care or urgent care services may be coerced by physicians or practitioners to enter into private contracts. The reason for that coercion would be to protect the physician or practitioner from potential conflict with the carrier, if the physician or practitioner does not believe that the patient needs emergency medical care or urgent care services.

Response: Section 1802(b)(2)(A)(iii) of the Act is clear that a physician or practitioner cannot enter into a private contract with a beneficiary if the private contract is entered into when the beneficiary is facing an emergency or urgent health care situation. We also extend this analysis to mean that, in case of a beneficiary emergency, the beneficiary's legal representative cannot enter into a private contract on the beneficiary's behalf. Because we are adopting the prudent layperson standard the test would be whether the beneficiary is a prudent layperson, and whether a prudent layperson would have thought he or she was facing an emergency or urgent health care situation under the particular circumstances involved.

Renewal and Early Termination of Opt-Out (§ 405.445)

Early termination of opt-out

Comment: Commenters asked that we clarify whether a physician or practitioner who opted-out but then completed an early termination of opt-out, may reapply for a subsequent opt-out period. They also asked that we also identify what notice he or she must give to the beneficiary.

Response: A physician or practitioner who opted-out of Medicare and completed an early termination of opt-out may reapply for a subsequent opt-out period under the same terms, including the same beneficiary notice terms, that would apply if he or she had not opted-out and then terminated opt-out.

We would note, however, that a physician or practitioner can terminate opt-out early only once. Therefore, if a physician or practitioner opts-out, then executes an early termination of opt-out, and then submits a second affidavit opting-out again, he or she will not be permitted early termination of that or any subsequent opt-out. We expect that a single early termination of opt-out will be sufficient to meet the needs of a physician or practitioner who has opted-out and decides that it was a mistake. Moreover, permitting more than one early termination of opt-out would be very difficult for carriers' systems to accommodate and would impose a costly systems burden to them (and to Medicare).

Comment: Commenters asked what participation status applies to a physician or practitioner who completes early termination of opt-out. In addition, they asked what payment status (participating versus nonparticipating) applies to service charges for services furnished during the aborted opt-out period.

Response: When a physician or practitioner terminates opt-out early, he or she resumes the participation status that existed before he or she opted-out. That participation status would apply to the service furnished during the shortened opt-out period.

Medicare+Choice Organizations (§ 405.450)

Acquisition of information on opt-out physicians and practitioners by Medicare+Choice organizations

In § 405.455, we indicate that M+C organizations may not pay for services of physicians or practitioners who opt-out of Medicare under these rules. We also specify that M+C organizations must acquire the information needed to implement this requirement from Medicare carriers that have jurisdiction over the claims in the areas the M+C organization serves.

We recognize that this approach for acquiring this information may not be optimal and we want to streamline it. We welcome suggestions on the specific information M+C organizations need to implement these rules and the most efficient means by which they could receive it.

C. Payment for Outpatient Rehabilitation Services

The term outpatient rehabilitation therapy encompasses outpatient physical therapy (including speech-language pathology) and outpatient occupational therapy.

1. BBA 1997 Provisions Affecting Payment for Outpatient Rehabilitation Services

a. Reasonable Cost-Based Payments. Section 4541(a) of BBA 1997 added new section 1834(k) to the Act. Section 1834(k)(2) establishes a 10-percent reduction in the reasonable cost of therapy services furnished during 1998. The 10-percent reduction does not apply to outpatient therapy services furnished by hospitals. In accordance with this provision, we have revised our policy to make payment for outpatient rehabilitation services furnished during 1998 based upon the lesser of the charges imposed or the reasonable cost determined for such services, reduced by 10 percent. The 10-percent reduction does not apply to outpatient physical therapy or occupational therapy services furnished by a hospital to an outpatient or to a hospital inpatient entitled to benefits under Part A but who has exhausted benefits or is otherwise not in a covered Part A stay.

As stated in our proposed rule, the salary equivalency guidelines will remain in effect until all BBA provisions regarding a prospective payment system for outpatient rehabilitation services are implemented. The prospective payment system, which is effective for services

furnished on or after January 1, 1999, removes the need for salary equivalency guidelines because providers will no longer be paid on a reasonable cost basis for their therapy services. The salary equivalency guidelines were a tool used to determine the reasonable cost of therapy services provided by practitioners other than physicians.

Comment: We received several comments stating that the 10-percent payment reduction may cause certain small providers to cease operations or cease providing services to Medicare beneficiaries. The commenters also stated that the Congress did not adequately consider the impact of the 10-percent reduction on small providers and that the Congress was misled.

Response: The 10-percent payment reduction is required by BBA.

b. Prospective Payment System for Outpatient Rehabilitation Services.

(1) Overview

Section 4541 of BBA adds a new section 1834(k) to the Act that provides for a prospective payment system for outpatient rehabilitation services and all services provided by CORFs. The prospective payment system is effective for services furnished on or after January 1, 1999. Section 1834(k)(1)(B) of the Act provides for payment for those services to be made at 80 percent of the lesser of (1) the actual charge for the services, or (2) the applicable fee schedule. Section 1834(k)(2) defines the applicable fee schedule amount as the amount determined under the physician fee schedule, or, if there is no such fee schedule established for those services, the amount determined under the fee schedule established for comparable services as specified by the Secretary.

The physician fee schedule is currently applied to certain outpatient rehabilitation therapy services. It is now the basis of payment for outpatient rehabilitation services furnished by physical therapists in independent practice (PTIPs) and occupational therapists in independent practice (OTIPs), physicians, and certain nonphysician practitioners or incident to the services of these physicians or nonphysician practitioners. The physician fee schedule has been the method of payment for outpatient rehabilitation therapy services provided by such entities for several years. As discussed in our proposed rule, fee schedule payment will now apply when outpatient physical therapy, occupational therapy, and speech-language pathology services are furnished by rehabilitation agencies, public health agencies, clinics, SNFs, home health agencies for beneficiaries who are not eligible for home health benefits because they are not homebound or to homebound beneficiaries who are not entitled to home health benefits, hospitals (when such services are provided to an outpatient or to a hospital inpatient who is entitled to benefits under Part A but who has exhausted benefits, or is not entitled), and CORFs. The fee schedule also applies to outpatient rehabilitation services furnished under an arrangement with any of the cited entities that are to be paid on the basis of the physician fee schedule. The fee schedule will not apply to outpatient rehabilitation services furnished by critical access hospitals. Under section 1833 of the Act as amended by section 4541 of BBA, these services will be paid on a reasonable cost basis.

Comment: We received one comment in support of delaying the implementation of a prospective payment system for outpatient rehabilitation services until April 2000 because implementation of the hospital outpatient prospective payment system is being delayed. The commenter stated that a delay would provide sufficient time for HCFA to develop a site-of-service differential and, at the same time, would allow for implementation of all revisions to hospital outpatient billing. It was also noted that hospitals are faced with Year 2000 (Y2K) problems as well and that the piecemeal implementation of outpatient regulations adds to the already daunting Y2K task.

Response: We disagree that development of a site-of-service differential for outpatient rehabilitation services is a rational basis for seeking to delay implementation of a prospective payment system for outpatient rehabilitation services because as we noted in our proposed rule, we find no legislative basis for making such a payment differential. On the other hand, we are sensitive to the commenter's concerns about the Y2K system compliancy challenges confronting hospitals and their need to effectively and efficiently renovate their systems. We face similar challenges and have therefore, to delay implementation of certain BBA provisions such as the hospital outpatient PPS to which the commenter refers. However, we will not be delaying implementation of the outpatient rehabilitation PPS. Implementation of hospital outpatient PPS must be delayed by the year 2000 system renovations because it requires massive system changes. Major contractor systems will be affected and the consequence of these required changes to the basic systems will be to change the entire way fiscal intermediaries process and pay hospital outpatient and community mental health claims (These latter claims will be paid under the hospital outpatient PPS).

By contrast, implementation of the fee schedule provision for outpatient rehabilitation services does not require that we develop an entirely new system or even undertake extensive reprogramming of the existing system in order to accommodate the new entities such as CORFs and rehabilitation agencies that will bill under this system. Basically, we can implement the fee schedule provision because it involves extending billing under an existing system (the physician fee schedule) to additional practitioners and services.

However, extension of the two $1,500 outpatient financial limitations or caps on a per-beneficiary basis as proposed in our June 5, 1998 rule requires considerable new programming that we are not able to undertake concurrent with our Y2K efforts. Therefore, we are delaying *full* implementation of the caps, effective January 1, 1999. We will implement them as discussed in our proposal as soon as possible after January 1, 2000.

Effective January 1, 1999, we will begin employing a transitional approach to implementing the caps on a provider/practitioner specific basis. This approach, will require each provider/practitioner not subject to the current limitations to cap their Medicare billings at $1,500 per beneficiary. We describe this partial implementation measure elsewhere in this rule under the section on financial limitations.

(2) Services Furnished by Skilled Nursing Facilities

Section 4432(a) of BBA added a new subsection(e) to section 1888 of the Act to establish a prospective payment systems for SNFs. Under the statute, effective for cost reporting periods beginning on or after July 1, 1998, Medicare pays for covered Part A SNF stays on the basis of prospectively determined payment rates that encompass all costs of ''covered SNF services'' furnished to an SNF resident. The statute defines covered SNF services to include (1) post-hospital extended care services paid for under Part A, and, (2) certain services that may be paid under Part B and that are furnished to SNF residents receiving covered post-hospital extended care services. Section 1888(e)(2) provides for exclusion of specific services from the definition of covered SNF services, but the statute explicitly states that the exclusions do not encompass ''any

physical, occupational or speech-language therapy services regardless of whether or not the services are furnished by, or under the supervision of, a physician or other health care professional.'' Thus, if an SNF resident is in a covered Part A stay, therapy services furnished to the SNF resident are encompassed in the PPS payment and Medicare does not make a separate Part B payment.

Under the new payment system for SNF inpatient services, and consistent with current policy (which applied before enactment of BBA), services furnished to SNF residents that are not covered under Part A may nevertheless be covered under Part B. Section 4432(b) of BBA amended section 1842(b)(6) of the Act to require that payment for most services furnished to an individual who is a resident of an SNF, including outpatient rehabilitation services, be made to the facility (without regard to whether the service was furnished by the facility, by others under arrangement with the facility, or under any other arrangement). When the services are not being furnished directly, the facility then pays the provider of therapy services. The consolidated billing provision was scheduled to be effective for services furnished on or after July 1, 1998. However, due to systems modification delays in implementing SNF consolidated billing, instructions in Program Memorandum (PM) AB–98–18 dated July 1998, as they apply to services and supplies furnished to residents in a Part A stay in an SNF not yet on the PPS and to the Part B stay (Part A benefits exhausted, posthospital or level of care requirements not met), are delayed until further notice. We announced this decision in a subsequent Program Memoranda, that is, PM AB–98–35 dated July 1998.

Section 4432(b)(3) of BBA added a new paragraph (9) to section 1888(e) of the Act to provide that, with respect to a service covered under Part B that is furnished to an SNF resident, the amount of payment for the service is the amount provided under the fee schedule for such item or service. This provision must be read in conjunction with the provisions of section 4541 of BBA. Section 4541 added a new section 1833(a)(8) to specify that the amounts payable for outpatient rehabilitation services furnished by an SNF will be the amounts determined under section 1834(k) of the Act. Section 1834(k) of the Act provides that payment in 1998 is to be based on the lesser of the charges imposed for these services or the adjusted reasonable costs and, in 1999 and thereafter, 80 percent of the lesser of the actual charge for the service or the physician fee schedule. Thus, as discussed in our proposed rule, we have revised our policy so that Part B services furnished to a SNF inpatient (Part A benefits exhausted, posthospital or level of care requirements not met) remain payable on a reasonable cost basis until January 1, 1999. Effective January 1, 1999, the services will be paid in accordance with the physician fee schedule.

The physician fee schedule amount applicable to services furnished in a nonfacility setting will apply to the Part B services to inpatients (Part A benefits exhausted, posthospital or level; of care requirement not met) and other outpatient rehabilitation services furnished by the SNF. The nonfacility amount applies because the consolidated billing provision requires that the SNF be directly paid for the entire therapy service (including facility costs) based on the physician fee schedule. This is in contrast to the amount applicable to physician services, excluding outpatient rehabilitation services, billed for SNF residents. In this case, the physician payment is not intended to cover the facility costs associated with the service and the fee schedule amount applicable to services furnished in a facility applies. Through PM AB–98–63 dated October 1998, we advised our fiscal intermediaries to require SNFs to bill Medicare directly for all outpatient therapy services provided to their SNF residents in a noncovered Part A stay and to the their nonresidents covered under Part B.

(3) Services Furnished by Home Health Agencies

Section 1833(a)(8)(A) applies the physician fee schedule to outpatient rehabilitation services furnished by an HHA to an individual who is not homebound. Most outpatient rehabilitation services furnished by an HHA under section 1861(s)(2)(D) of the Act is to individuals who are not homebound. The likelihood is great that most individuals who are homebound and are receiving physical therapy, speech-language pathology, or occupational therapy are entitled to home health benefits. However, there may be some individuals who are homebound and have not required a qualifying service for home health benefits but who need occupational therapy services. If provided by an HHA, these services could be provided under section 1861(s)(2)(D) of the Act. Although section 4541 of BBA did not expressly address these services, the statute allows them to be remain payable on a reasonable cost basis under section 1861(v)(1) of the Act. All other services furnished by the HHA will be paid under a prospective payment system. (Implementation of an HHA prospective payment system that was scheduled to take effect October 1, 1999 has been delayed due to our Y2K compliancy efforts.) Section 1861(v)(1) provides that the reasonable cost of any service is the cost actually incurred, excluding any costs unnecessary to the efficient delivery of needed health services.

Section 1861(v)(1) also allows, use in determining reasonable cost, to provide for the use of estimates of cost for particular items and services. In enacting section 4541 of BBA, the Congress determined that payment in the amounts dictated by the physician fee schedule represents the appropriate level of payment for outpatient rehabilitation services provided by HHAs to certain non-homebound beneficiaries who do not qualify for the HHA benefit. (Of course, pursuant to section 4541, this payment level applies to all suppliers of rehabilitation services enumerated in the provision.) The Congress has, thus, evinced its view that payment at the fee schedule level adequately compensates HHAs for their expenses for this group of services. We believe that the Congress' determination in this case forms a basis for us to find that this level of payment represents an acceptable estimate of the expenses of providing rehabilitation services to other, homebound beneficiaries receiving services from HHAs, but also not eligible for the HHA benefit. Thus, we are applying the fee schedule payment level as our estimate of the reasonable costs of these services for these beneficiaries receiving outpatient rehabilitation services and not eligible for HHA benefits. Therefore, § 413.125 is modified to provide that effective for services furnished on or after January 1, 1999, the reasonable cost of outpatient rehabilitation services furnished by an HHA to homebound patients who are not entitled to home health benefits may not exceed the amounts payable under the fee schedule.

(4) Services Furnished by Comprehensive Outpatient Rehabilitation Facilities

Section 4541(a)(1) of the BBA adds a new section 1832(a)(2)(D)(9) to the Act to provide that all services furnished by a CORF, not just outpatient rehabilitation services, will be paid the applicable fee schedule amount. In cases in which there is no physician fee schedule amount for the services, section 1834(k) of the Act specifies that