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42 CFR Parts 405, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1999; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

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

[HCFA–1006–P]

RIN 0938–AI52

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1999

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would make several policy changes affecting Medicare Part B payment. The changes that relate to physician services include: resource-based practice expense relative value units, medical direction rules for anesthesia services, and payment for abnormal Pap smears. Also, we would rebase 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 relative value units. The Balanced Budget Act of 1997 (BBA 1997) delayed, for 1 year, implementation of the resource-based practice expense relative value units until January 1, 1999. Also, BBA 1997 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 1997 permits certain physicians and practitioners to opt out of Medicare and furnish covered services to Medicare beneficiaries through private contracts. In addition, since we established the physician fee schedule on January 1, 1992, our experience indicates that some of our Part B payment policies need to be reconsidered. This proposed rule is intended to correct inequities in physician payment and solicits public comments on specific proposed policy changes.

DATES: Comments on the proposed resource-based practice expense policy will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on September 3, 1998. Comments on all other issues will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 4, 1998.

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–P, 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 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 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–P. 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 309–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).

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FOR FURTHER INFORMATION CONTACT: Roberta Epps, (410) 786–4503 (for issues related to outpatient rehabilitation services, nurse practitioners, clinical nurse specialists, and certified nurse-midwives).

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).

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

SUPPLEMENTARY INFORMATION: 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 V.

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In addition, because of the many organizations and terms to which we refer by acronym in this proposed 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
ASA—American Society of Anesthesiologists
AWP—Average Wholesale Price
BBA—Balanced Budget Act of 1997
BLS—Bureau of Labor Statistics
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 [4th Edition, 1997, copyrighted by the American Medical Association]
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
GAAP—Generally accepted accounting principles
GAF—Geographic adjustment factor
GPCI—Geographic practice cost index
HCFA—Health Care Financing Administration
HCPCS—HCFA Common Procedure Coding System
HHS—[Department of] Health and Human Services
HMO—Health maintenance organization
HUD—[Department of] Housing and Urban Development
MEDPAC—Medicare Payment Advisory Commission
MEI—Medicare Economic Index
MGMA—Medical Group Management Association
MSA—Metropolitan Statistical Area
NAIC—National Association of Insurance Commissioners
NPI—National provider identifier
OBRA—Omnibus Budget Reconciliation Act
OTIP—Occupational therapist in independent practice
PC—Professional component
PMSA—Primary Metropolitan Statistical Area
PPI—Producer Price Index
PPS—Prospective payment system
PTIP—Physical therapist in independent practice
RUC—[AMA's Specialty Society] Relative [Value] Update Committee

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 physician 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 physician services; (2) a sustainable growth rate for the rates of increase in Medicare expenditures for physician 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

We published a final rule on November 25, 1991 (56 FR 59502) to implement section 1848 of the Act by establishing a fee schedule for physician services furnished on or after January 1, 1992. In the November 1991 final rule (56 FR 59511), we stated our intention to update RVUs for new and revised codes in the American Medical Association's (AMA's) Physicians' Current Procedural Terminology (CPT) through an ''interim RVU'' process every year. The updates to the RVUs and fee schedule policies follow:

- November 25, 1992, as a final notice with comment period on new and revised RVUs only (57 FR 55914).
- December 2, 1993, as a final rule with comment period (58 FR 63626) to revise the refinement process used to establish physician work RVUs and to revise payment policies for specific physician services and supplies. (We solicited comments on new and revised RVUs only.)
- December 8, 1994, as a final rule with comment period (59 FR 63410) to revise the geographic adjustment factor (GAF) values, fee schedule payment areas, and payment policies for specific physician services. The final rule also discussed the process for periodic review and adjustment of RVUs not less frequently than every 5 years as required by section 1848(c)(2)(B)(i) of the Act.
- December 8, 1995, as a final rule with comment period (60 FR 63124) to revise various policies affecting payment for physician services including Medicare payment for physician services in teaching settings, the RVUs for certain existing procedure codes, and to establish interim RVUs for new and revised procedure codes. The rule also included the final revised 1996 geographic practice cost indices (GPCIs).
- November 22, 1996, as a final rule with comment period (61 FR 59490) to revise the policy for payment for diagnostic services, transportation in connection with furnishing diagnostic tests, changes in geographic payment areas (localities), and changes in the procedure status codes for a variety of services.
- October 31, 1997, as a final rule with comment period (62 FR 59048) to revise the geographic practice cost index (GPCI), physician supervision of diagnostic tests, establishment of independent diagnostic testing facilities, the methodology used to develop reasonable compensation equivalent limits, payment to participating and nonparticipating suppliers, global surgical services, caloric vestibular testing, and clinical consultations. The final rule also implemented certain provisions of the Balanced Budget Act of 1997 (BBA 1997) (Public Law 105–33), enacted on August 5, 1997, and implemented the RVUs for certain existing procedure codes and established interim RVUs for new and revised procedure codes.

This proposed rule would affect 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 1999

A. Resource-Based Practice Expense Relative Value Units

1. Current Practice Expense Relative Value Unit System

The Act details the types of services that are paid under the physician fee schedule. These include physician services, services and supplies incident to a physician service, diagnostic x-ray tests, diagnostic laboratory tests (excluding clinical laboratory tests), and x-ray, radium, and radioactive isotope therapy. BBA 1997 added other services such as certain preventive services. While some of these services do not have work RVUs, all of the services have practice expense and malpractice expense RVUs. (Physician anesthesia services are included under the physician fee schedule but are paid under a different payment methodology that uses a separate CF and allowable base and time units. Physician anesthesia services do not have practice expense and malpractice expense RVUs.) Payments for practice expense RVUs account for approximately 41 percent of total physician fee schedule payments.

In most cases, the current practice expense RVUs are calculated based on a statutory formula. They are derived from the product of ''base allowed charges'' and service-specific practice expense percentages. The base allowed charge is the national allowed charge for the service furnished during 1991. The service-specific practice expense percentage is a weighted average of the practice expense percentages of the specialties performing the service.

For services furnished beginning with calendar year 1994 and whose practice expense RVUs exceed 1994 work RVUs and are performed in the office setting less than 75 percent of the time, practice expense RVUs in each of 1994, 1995, and 1996 were reduced by 25 percent of the amount they exceed the 1994 work RVUs. (Before 1998, practice expense RVUs were not reduced to less than 128 percent of 1994 work RVUs.)

For services furnished beginning with calendar year 1998 whose practice expense RVUs (determined for 1998) exceeded 110 percent of the work RVUs and which 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 18, 1997 proposed rule (62 FR 33158), which was

an increase from its 1997 practice expense RVU. For office visit procedure codes performed beginning calendar year 1998, the practice expense RVUs were increased by a uniform percentage to equal the aggregate decrease in the practice expense RVUs for other services.

2. Criticism of Current Practice Expense Relative Value Unit System

A common criticism of the current practice expense RVU system is that for many services the RVUs, which are based on charges under the reasonable charge system, are not based directly on the resources involved with furnishing the service. Rather, the charge-based nature of the current fee schedule practice expense retains historical charge patterns that existed before the implementation of the physician fee schedule on January 1, 1992. Those charge patterns favor procedures and tests performed in hospitals rather than evaluation and management services and other office-based services.

For example, a primary care physician would have to bill CPT code 99213 (level 3 office visit, established patient) approximately 80 times to collect the same amount of practice expense payments as a cardiac surgeon would for performing one coronary artery bypass graft with three coronary venous grafts (CPT code 33512), although the practice expenses the surgeon typically incurs for the cardiac surgery are primarily related to the pre- and postoperative services furnished in the office, administrative costs, and overhead. The costs for clinical staff, medical supplies, and medical equipment furnished to hospital patients are included in the diagnosis-related group (DRG) payment made to the hospital as required by section 1862(a)(14).

In their 1993 annual report to the Congress, the Physician Payment Review Commission recommended that the Congress revise the practice expense component of the physician fee schedule so that it is resource-based. They further recommended that we collect data regarding the direct cost incurred in delivering each service and that a formula-based approach be used to allocate indirect costs. This recommendation was instrumental in the Congress' legislating the resource-based practice expense component.

3. Resource-Based Practice Expense Legislation

Section 121 of the Social Security Act Amendments of 1994 (Public Law 103–432), enacted on October 31, 1994, requires us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician service. In developing the methodology, we must consider the staff, equipment, and supplies used in providing medical and surgical services in various settings. The legislation required the new payment methodology to be effective for services furnished in 1998.

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

Before publication of the final rule in October 1997, section 4505 of the BBA 1997 delayed initial implementation of resource-based practice expense RVUs until 1999. It also required that we do the following:

- Use, to the maximum extent practicable, generally accepted cost accounting principles that recognize all staff, equipment, supplies, and expenses, not solely those that can be linked to specific procedures.
- Consult with organizations representing physicians regarding methodology and data to be used.
- Develop a refinement method to be used during the transition.
- Consider impact projections that compare new proposed payment amounts to data on actual physician practice expenses.

4. Originally Proposed Methodology for Developing Resource-Based Practice Expense Relative Value Units

To implement the October 1994 legislation, we published a proposed rule on June 18, 1997 (62 FR 33158). In the proposed rule, we established a framework in which practice expenses were divided into direct and indirect costs. Direct costs are those costs that can be directly attributed to providing a service, such as the cost of a nurse's time (salary), medical supplies and equipment, administrative costs of billing, record maintenance, and the scheduling of office patients. Direct costs also include the physician's costs of office staff time for scheduling appointments and billing and collection activities associated with a medical procedure furnished in a hospital. Indirect costs cannot be directly attributed to a specific service, and include costs such as rent, utilities, office equipment and supplies, and accounting and legal fees. The allocation of indirect costs to specific products or services is a classic accounting problem. The indirect costs are difficult to relate directly to a specific service because they are incurred by the practice as a whole.

The June 1997 proposed rule (62 FR 33172) described the following methodology for calculating the proposed direct practice expense RVUs.

- We calculated the total pool of practice expense RVUs for 1995 and divided it into direct and indirect practice expense pools using the American Medical Association's (AMA's) Socioeconomic Monitoring System (SMS) survey data and our 1995 national claims history data. The national distribution of direct and indirect practice expense RVUs was 55 percent direct practice expense RVUs and 45 percent indirect practice expense RVUs.
- The underpinning for the proposed direct components of the practice expense RVUs was the data reported by the Clinical Practice Expert Panels (CPEPs) for clinical and administrative labor, medical supplies, and medical equipment inputs. There were 15 CPEPs, corresponding to the major medical specialties, which were made up of nominees from all major specialty societies. (A description of the CPEPs is contained in the June 1997 proposed rule (62 FR 33161).) (See Addendum A for a detailed description of the CPEP process.)
- These data were edited to apply Medicare payment policy rules to ensure that the reported data were consistent with our national hospital and physician payment policies. The primary adjustment was the removal of direct inputs recorded for clinical labor staff, medical equipment, and medical supplies furnished to hospital patients. Other adjustments were made for the professional component of a service, the technical component of a service, and the combined service, for codes that have an indicator of ZZZ under the physician fee schedule, and for certain allergy and immunotherapy codes performed on a per-test, per-dose, or per-vial basis.
- We believed that the relative relationships of the staff time estimates within the individual CPEPs were generally correct but that the absolute time estimates needed normalization. We placed the codes from the different CPEPs on the same scale using a normalization process that we call ''linking.'' Specifically, linking shifted an entire CPEP's data relative to other CPEPs' data, based on the relationship of the values assigned across panels for codes that had been assigned to multiple CPEPs. We separately linked clinical and administrative labor costs. Statistically, the linking was done using regression methods.

• After the data were edited and linked, our physicians and clinical staff analyzed the direct practice expense RVUs to determine if there were unexplainable variations in the underlying CPEP data. This review resulted in the application of two general reasonableness rules. First, a decision was made to cap the administrative time of several categories of service (services without a global period and procedures subject to global periods with zero follow-up days) at the administrative time assigned to CPT code 99213 (midlevel office visits). Second, we decided to cap the nonphysician clinical staff time at 1.5 times the physician time, in minutes, for performing the procedure. Additional more specific rules were applied to certain supplies and supply costs and for certain codes, such as psychotherapy, physical therapy, chemotherapy, and nerve block codes.

• The aggregate percentage shares across all specialties of labor and medical supplies and equipment from the CPEP data were scaled to the percentage shares of these categories from the AMA's SMS survey data. The CPEP expenses for labor, medical supplies, and medical equipment were adjusted by scaling factors of 1.21, 1.06, and 0.39 respectively.

• The direct practice expense dollar amounts were converted into direct practice expense RVUs. An adjustment factor of 0.65 was used to convert the aggregate direct practice expense dollars to the available Medicare direct practice expense dollars.

• Aggregate indirect practice expense RVUs were allocated to individual codes based on the code-specific sum of the direct practice expense, the malpractice expense, and the physician work RVU.

• The direct and the indirect practice expense RVUs per code were combined to produce a single practice expense RVU per code.

Other practice expense proposals in the June 1997 proposed rule (62 FR 33160) included:

• Replacement of the current site-of-service differential policy that systematically reduces the practice expense RVUs by 50 percent for certain procedures with a policy that would generally identify two different levels (office or nonoffice) of practice expense RVUs for each procedure code depending on the site of service.

• Elimination of the current policy that allows additional practice expense RVUs for supplies that are used incident to a physician service but were not the type of routine supplies included in the current practice expense RVUs for specific services. These supplies were included in the CPEP data for the specific procedure code.

• Reduction of the practice expenses for multiple nonsurgical services performed at the same time as an evaluation and management service.

The June 1997 proposed rule provided for a 60-day comment period ending on August 18, 1997.

5. Balanced Budget Act of 1997 Provisions Pertaining to Resource-Based Practice Expense Relative Value Units

On August 5, 1997, the President signed into law the Balanced Budget Act of 1997 (BBA 1997). Section 4505(a) of BBA 1997 delayed the effective date of the resource-based practice expense RVU system until January 1, 1999. In addition, BBA 1997 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 1997 provided for a 4-year transition period. The practice expense RVUs for the year 1999 will be the product of 75 percent of the previous year's 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(c) of BBA 1997 required the Comptroller General to review and evaluate our proposed rule and report to the Congress by February 1998. The review was required to include an analysis of (1) the adequacy of the data used in preparing the rule, (2) categories of allowable costs, (3) methods for allocating direct and indirect expenses, (4) the potential impact of the rule on beneficiary access to services, and (5) any other matters related to the appropriateness of resource-based methodology for practice expenses. The Comptroller General was also to consult with representatives of physician organizations with respect to matters of both data and methodology.

Section 4505(e) of BBA 1997 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 which 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 1997 proposed rule that was an increase from its 1997 practice expense RVU. The total of the reductions 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 1997 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) requires 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 31, 1998.

BBA 1997 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: (1) 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; (2) consult with organizations representing physicians regarding the methodology and data to be used; and (3) develop a refinement process to be used during each of the 4 years of the transition period.

6. HCFA Response to BBA 1997 Requirements

BBA 1997 required us to develop new resource-based RVUs and to consult with physician organizations regarding methodology and data. To meet the BBA 1997 requirements and to promote input as we developed new RVUs, we have sought and will continue to encourage maximum input from those affected by this initiative. The following is a summary of activities we have undertaken.

• Validation Panel Meetings.

We hosted 17 medical specialty panels that were charged with validating the CPEP direct cost data for the high-volume CPT codes for each specialty. All the major medical specialty societies were represented, including nonphysician organizations.

Each panel, consisting of about 12 to 15 members, was made up of the appropriate specialists, two general surgeons, two primary care physicians, and two Medicare carrier medical directors. The panel members reviewed and, if they believed necessary, revised the clinical and administrative times and the supplies and equipment involved for each code. Consensus within panels was reached on about 200 codes.

• Cross Specialty Panel.

Although the October validation panels were able to reach consensus on many high-volume procedures within specific specialties, we were concerned that there was not a uniform or consistent scale applied to labor inputs across specialties. Therefore, in December, we convened a multiple specialty panel of 37 panelists, including physicians, nonphysicians, and administrators nominated by the specialty societies.

We expected the panel to help us achieve consistency across panels on resource inputs, such as insurance billing and transcription times, and to standardize the clinical staff types for similar classes of services, whether they be registered nurses, medical assistants, licensed practical nurses, or a mix of these staff types. The results of the cross specialty panel were generally unsuccessful. While the panel did provide the arena for panelists to furnish explanations of times for activities that we believed to be excessive, the panelists were generally reluctant to make any major modifications in the times or staff they had assigned to their own services. The panelists could not agree to any rules that would aid us in standardizing the data.

The panelists did recommend that we explore an option that treats billing and insurance activities as indirect costs. Many panelists also suggested that we proceed cautiously and try to minimize the magnitude of redistribution.

• Indirect Cost Symposium.

We convened a meeting on November 21, 1997 on indirect practice expenses to provide a forum for participants to discuss their preferred methodology for allocating indirect costs. We asked those organizations that commented on our proposed indirect cost methodology to make a formal presentation of their views. All major medical specialty groups were invited to attend and join in the discussion.

Some groups endorsed the methodology we proposed in the June 1997 proposed rule (62 FR 33172) with some modifications. One modification recommended was to eliminate malpractice RVUs as a factor in allocating indirect costs. It was noted, even by some advocates for other allocation methods, that our proposed methodology embodied traditional accounting methods for allocating indirect costs.

Only two major alternatives to our proposed methodology were presented. The first, the Activity Based Costing (ABC) method, was described as a cutting edge approach to determining the cost of individual products (CPT codes). Under the ABC method, the total costs of a practice are collected and assigned to discrete processes or activities. These costs are then assigned to products to which they are related.

The ABC method was developed for industries in which direct labor (the traditional cost accounting method for allocating indirect costs) is not the dominant factor in the production of the good or service. This method is in the early developmental stages in medical practice use.

The second alternative methodology presented was the physician work RVU method of allocating indirect practice expenses. This method would allocate indirect costs using only the physician work RVUs. However, there did not appear to be much support for this methodology at the meeting. It would, for example, penalize physician practices that have proportionately higher equipment costs.

• October 31, 1997 Notice with Comment Period

• To inform all interested parties of our plans to issue a new proposed rule and to request additional data from the medical community to assist us in meeting BBA 1997 requirements, on October 31, 1997, we published a notice (62 FR 59267).

In that notice, we requested that physicians, physician organizations, or others provide us with the following information:

• Generally accepted cost accounting principles—We specifically requested information on the following: (1) Aspects of the cost accounting methodology used in the June 1997 proposed rule that were not consistent with the statutory guidance; and (2) complete copies of studies of resource-based practice expense RVUs, including any underlying surveys supporting these studies, performed by physicians or physician groups or their contractors or consultants, including pertinent details about the survey.

• Equipment utilization—We specifically requested complete copies of any studies or other data showing the actual utilization of equipment by physician practices, including pertinent details about the survey, such as response rates, sampling design, methodology, directions, and definitions.

• Other assumptions—We specifically requested information regarding the useful life of equipment, the amount and percentage of direct practice costs versus the amount and percentage of indirect costs by specialty, and practice expense values for sites for which values were not proposed in the June 1997 proposed rule (62 FR 33158).

• Use of physician-employed staff in hospitals and other facility settings—We specifically requested comments and information about the extent to which a physician employee, such as a registered nurse, accompanies the physician to the hospital, ambulatory surgical center, or other facilities to provide services, such as acting as an assistant at surgery or serving as a scrub nurse. We asked for names of specific facilities so that we might contact them in order to more fully understand the nature of the relationships.

• Refinement process—We requested comments on how this refinement process would operate including assigning practice expense RVUs to new codes, who would be involved in the refinement process, and how all of the users of the physician fee schedule would have access to the process.

• Review of New Methodology by KPMG Peat Marwick LLP—Under contract #500–97–0402, we requested that KPMG Peat Marwick LLP review the practice expense per hour methodology. They concluded that the methodology follows reasonable cost accounting principles. They made this determination based on an examination of the available data sources and a consideration of the cost and feasibility of acquiring additional nationally representative data. As a future consideration, they recommended sample validation of our cost allocation bases.

7. Summary of General Input From the Medical Community and Comments From the October 1997 Notice With Comment Period

Some physicians, such as primary care physicians, expressed satisfaction that the proposed methodology was generally sound. In addition, the AMA was supportive of our panel process for direct expenses and offered many helpful comments. However, many surgeons and medical specialties argued that we should discard our current practice expense data, and develop payments that reflect their ''actual costs.''

Both in written comments and in our meetings with the medical community, we received much feedback on our methodology for indirect practice expense. However, there was no consensus regarding methods for allocating indirect costs to individual procedure codes.

In addition, we received 56 specific comments from individuals, major organizations, and physician specialty groups on our October 1997 notice. The comments are summarized by the following categories:

• Generally Accepted Accounting Principles.

Some of the groups expected to experience an increase in payment under the June 1997 proposed rule thought our approach satisfied the current statutory mandate that we utilize generally accepted accounting principles (GAAP). Those physician groups that expected to experience a decrease in payments based on the methodology described in the June 1997 proposed rule said the approach in the proposed rule was inconsistent with GAAP. They argued that GAAP requires us to use actual practice expense data and said the data from the CPEPs and validation panels were based on erroneous assumptions, or were unverified approximations. At least five commenters supported using the activity-based accounting approach.

• Equipment utilization.

Some groups furnished equipment-specific utilization levels for a few services. Generally, the equipment and utilization levels were not based on representative surveys of physicians performing the service. Some suggestions were as follows:

	Percent
Electroencephalography equipment.	26
Electromyography	36.5
Nerve Conduction Velocity	36.5
Cystoscope	5
Loop electrode excision procedure.	1
Colposcope	1.6
YAG laser	12
ARGON laser	5 to 6.4
Fundus camera	31.3
Spirometry and Ancillary Equipment.	10 to 17
Bronchoscopy	5 to 10

• Useful Life.

We did not receive specific comments on suggested useful lives for specific medical equipment, which is an important factor in estimating equipment costs.

• Direct and Indirect Costs.

Some commenters pointed out that not all clinical labor can be classified as direct costs. Tasks such as ordering supplies and attending meetings or continuing education classes should be captured as indirect costs. Some groups, including one primary care group, said that billing costs should be an indirect expense, while others supported maintaining them as direct costs. Many groups supported an allocation process in which indirect costs are assigned based on a specialty's specific indirect cost percentage. Only one group specifically objected to this approach. Some physician groups provided specific direct and indirect cost ratios based on limited surveys of their membership.

• Employed Staff.

According to an American Hospital Association survey, 63 percent of respondents (from 573 hospitals) believed that a physician brought staff to the hospital during the last 6 months of 1996. Of these respondents, 82 percent said this was not a regular practice. Therefore, the American Hospital Association commented it is not a typical practice in the United States for physicians to bring their own staff to a hospital.

Five surgical specialties and subspecialties—neurosurgery, ophthalmology, general thoracic surgery, congenital thoracic surgery, and adult cardiac surgery—indicated that at least 50 percent of practices use employed clinical staff in nonoffice settings. General surgery indicated that 31 percent of general surgery practices pay for clinical staff working in nonoffice settings. The Society of Thoracic Surgeons stated that they do not have data on the number of clinical nurses who work with thoracic surgeons in hospitals. However, they stated that a survey of physician assistants shows that 72 percent of physician assistants employed in cardiovascular surgery were employed by solo or group physician practices.

According to the American Academy of Ophthalmology, 51 percent of ophthalmologists bring equipment, such as keratomes, diamond knives, cataract trays, and muscle trays to furnish services to hospital patients.

• Refinement.

Most commenters support using the AMA's Specialty Society Relative Value Update Committee's (RUC's) process to refine the practice expense RVUs. (Currently the RUC recommends refinement of the physician work RVUs.) Of these commenters, many recommended that the process include nurses and practice managers, that there be established rules and procedures for data collection, survey design, and response rates, and that the process allows participation by subspecialties, such as transplant surgeons and pediatric surgeons. One commenter suggested a process using the AMA, Medical Group Management Association (MGMA), and HCFA. Some commenters suggested using a RUC process only for new codes.

• Transition.

Several commenters stated that the base year for the transition should be the 1997 practice expense RVUs and not the 1998 practice expense RVUs. They suggested that the 1998 adjustment required by BBA 1997 is not intended to be included in the base for purposes of the practice expense transition. Some commenters recommended that we explore using ceilings and floors during the transition period or use caution so as to limit the amount of the redistribution.

• Site-of-Service Differential.

Commenters from the American Academy of Orthopaedic Surgeons stated that we need office practice expense RVUs for musculoskeletal system surgery codes 25000, 25031, 26040, 26060, 26608, 29815 through 29848, and 29870 through 29898. Some commenters believe we should develop practice expense RVUs for all procedures at all sites and permit office endoscopy only under very limited and clearly defined standards.

• Data Quality.

The American College of Surgeons stated that the CPEP data are based on erroneous assumptions, educated guesses, and unverified approximations. They stated that the data from panels are unreliable for the administrative times for chiropractic manipulation, level 3 office visits, inpatient consultations, balloon angioplasty, and clinical times for allergy skin testing.

• Validation.

The AMA stated that we should use AMA and MGMA data on full time equivalent staff for each physician to assess how well various methodological options account for total labor costs. The American College of Physicians suggested we complete an impact analysis that compares proposed practice expense payments to actual practice expenses on a specialty by specialty basis, as well as sponsoring a study requiring on-site visits to practices.

8. Issues Considered in Developing New Practice Expense RVUs

We faced the following major issues as we decided whether and how to modify our original proposal for physician practice expense RVUs. These issues arose from many sources: from concerns about the CPEP data and our

original proposed methodology, from the requirements of BBA 1997, from the findings and recommendations in the General Accounting Office's Report to the Congress on physician practice expense, and from input we received from the medical community.

• Purpose.

Our original practice expense proposal was based on the 1994 legislation, which stated that the new practice expense methodology must consider the staff, equipment, and supplies used in the provision of various medical and surgical services in various settings. We interpreted this to mean that Medicare payments for each service should be based on the relative resources typically and reasonably involved with performing the service. We believed we could best calculate these resources by achieving clinical consensus on the actual inputs it would typically take to perform a given service. However, surgeons and some other specialties contended that the purpose of a resource-based practice expense system should be to reimburse them based on their total current expenditures for practice costs. Because the higher paid specialties have more to spend on their practices as a result of historic charging practices and insurance coverage, there is a concern that adopting such a methodology would not achieve the desired equity. The argument made by some outside groups is that physicians have been increasingly forced to be more efficient and, as a result, differences in practice expenses among specialties reflect ''real'' costs that should then be reflected in the new practice expense RVUs.

With the passage of BBA in August 1997, the statute now 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. * * *'' Therefore, in developing and analyzing any new alternative methods for computing practice expense RVUs, we have evaluated how well each option recognizes all practice expense costs.

• ''Bottom-up'' versus ''Top-down'' Methodology.

In line with our original stated purpose and the 1994 legislation, our practice expense methodology published in the June 1997 proposed rule (62 FR 33172) used a ''bottom-up'' approach, which obtained expert panel estimates of actual inputs—staff times, supplies, and equipment—for each procedure and then used these estimates to build up to the direct practice expense RVUs. Some groups complained that some of the published relative values were too low and favored using studies that actually measured the inputs onsite. Unfortunately, if any reliable data exist at all, they are only for a few scattered specialties, and it certainly is not practical for us to undertake such a task (Medicare pays physicians for over 7,000 services). We understand that even the few specialties that have attempted surveys have had limited success obtaining complete practice expense data from even limited selected practices.

Many of the specialty societies favored a ''top-down'' methodology, which would start our calculations with their total current expenditures and then allocate these costs down to the procedure level by some method. Several groups supported using an Activity Based Costing (ABC) methodology for calculating practice expenses. The proponents of ABC maintain that it produces more accurate costs because it measures the costs of processes (for example, servicing patients, scheduling, and billing) as opposed to traditional costing systems, which measure resources (for example, salaries and rent). However, ABC is only in the experimental stages in medical practice use, and many difficult questions about its utility in medical practices have not been resolved, for example, its assumption that all medical practices operate in the same manner. ABC still requires subjective estimations, or some other algorithm, to allocate costs from ''processes'' to individual CPT codes.

• Available Data Sources.

Much of the debate about what would constitute the most accurate practice expense methodology cannot be resolved in the short run. There is no consensus about the best way to determine the most accurate practice expense methodology. Furthermore, there are only limited data sources available. CPEP data, along with the modifications made by our subsequent panels, are the only source of estimates at the CPT code level of resource inputs needed to provide each service. AMA's SMS survey data are from a national survey of randomly selected self-employed physicians that collects information on practice expense on an aggregate level, and can be used to determine overall differences in expenditures among specialties.

The only other relevant data sources of which we are presently aware are a few other surveys of practice expense, such as those performed by the MGMA, *Medical Economics*, and the American College of Surgeons. Because of selective sampling and low response rates of these three surveys, these data are not representative of the population of physicians and cannot be used to derive code-specific RVUs, though the data might prove useful in validating general impacts.

• Specialty-Specific Differences.

Our June 1997 proposed rule did not explicitly recognize specialty-specific differences. Differences across specialties were only reflected implicitly to the extent that more indirect RVUs would be allocated to those procedures with the greatest physician work and direct costs. Under our June 1997 proposed approach, we allocated indirect relative values based on the typical use of resources, that is, the direct practice expense RVUs, the physician work RVUs, and the malpractice RVUs per code.

The specialty groups, along with the AMA and even some primary care groups, were almost unanimous in their view that we should use an approach that explicitly recognizes specialty-specific differences in the indirect cost of practice. It was pointed out, as an example, that some specialties such as radiology or ophthalmology would have much higher indirect equipment costs than other specialties. The specialty groups believed that not recognizing such specialty differences would be inherently unfair to some specialties. The AMA staff suggested that we use their survey data to calculate the specialty-specific indirect costs.

In developing our options for a new practice expense methodology, we, therefore, needed to decide whether we would maintain specialty-neutral methods, use specialty differentials to help allocate only indirect RVUs, or use specialty-specific data to establish the total redistributive pools for each specialty.

• Administrative Costs.

Another decision we had to make as we developed new practice expense RVUs was how a new proposal would treat administrative costs. The June 1997 proposed rule (62 FR 33167) methodology treated administrative labor cost as a direct expense, and the administrative cost RVUs were derived from the CPEP data. On first reviewing the raw CPEP inputs for administrative staff times, it appeared that there were some problems with the data. First, some of the suggested administrative staff times appeared excessively high, particularly for the billing staff. Second, there was variation in staff times for the same CPT code between the different panels. In the June 1997 proposed rule (62 FR 33166), we dealt with these problems through our linking

methodology and by capping administrative times. Both of these methods were strongly opposed by many specialty groups, largely because our adjustments had dramatic effects on the raw data. For example, the linking coefficient for thoracic surgery reduced their administrative inputs by 76 percent. There were also comments claiming that many administrative duties are of a general nature that cannot be fully captured on a code-specific basis.

As a result of these concerns, many outside groups have suggested that we treat administrative cost as an indirect practice expense. The advantages of adopting this suggestion would be that we could get around the mentioned data discrepancies, avoid the controversial use of linking for administrative labor, and be more certain that we had captured all administrative costs. The main disadvantage would be that it would greatly increase the percentage of RVUs that would have to be allocated by a formula.

• Clinical Costs.

Although the problems were on a lesser scale, we observed many of the same difficulties with the raw CPEP inputs for clinical costs as there were for the administrative costs discussed above. There was some lack of standardization of clinical staff types between the CPEP panels, and some staff times appeared excessive. In the June 1997 proposed rule, these problems were addressed by linking and by capping the clinical times; both of these methods caused considerable controversy in the medical community. We had hoped that the validation and cross-specialty panels would have resolved the inconsistencies across specialties, but they were unable to accomplish this task. It was clear, therefore, that any new proposal would still have to address a method of standardizing the data between the various specialty panels.

• The General Accounting Office (GAO) Report to Congress on Physician Practice Expense.

As already mentioned, BBA 1997 required the GAO to review and evaluate our June 1997 proposed rule on a resource-based methodology for practice expenses. This report was issued in February 1998 and concluded that both our use of expert panels to develop direct cost estimates and our original allocation methodology for indirect costs were acceptable options. However, the GAO raised questions about the validity of some specifics of the linking regression model and about the appropriateness of capping administrative and clinical labor time estimates. In addition, the report suggested that using specialty-specific indirect expense ratios, based on the SMS survey data, would be more clearly consistent with BBA 1997. Also, the report recommended that we consider classifying administrative labor costs as indirect expenses. (See section 18 for a more detailed discussion of the report's recommendations.)

9. Alternative Practice Expense Methodologies Considered

We carefully considered two alternative approaches to developing new practice expense RVUs: the first maintained the ''bottom-up'' methodology of our original proposal, while the second adopted a ''top-down'' methodology.

• ''Bottom-up'' Option.

We regard our original ''bottom-up'' proposal as a viable method of developing practice expense RVUs. It clearly fulfilled the requirement of the Social Security Amendments of 1994, which states that practice expense relative values should be based on the relative practice expense resources involved in furnishing the service. Both the GAO and the Physician Payment Review Commission, as well as many researchers in the field, supported our use of expert panels to estimate direct practice expenses. Therefore, we developed a method that was similar to our original proposal.

Like our proposal in the June 1997 proposed rule, this option based its calculation for all direct inputs on the data reported by the CPEPs. As before, both clinical and administrative labor were linked, and all direct cost estimates were scaled as in the original proposed rule. However, in a significant departure from our original proposal, the caps on clinical and administrative staff times were eliminated. For indirect costs, this option continued not to recognize a specialty-specific method of cost allocation to specific procedures. It did, however, have a different indirect allocation formula from our original proposal; under this option, 50 percent would be allocated on the basis of direct costs and 50 percent on the basis of physician time. Of the latter 50 percent, physician time in the office would get a weight 50 percent higher than physician time out of the office. If there was no physician involvement, as is the case with technical component services, the maximum clinical staff time would be used.

• The ''Top-Down'' Option.

This option is a departure from our original proposal and is an effort to balance the requirements of the 1994 Social Security Amendments with the 1997 BBA requirements. It uses the two significant sources of actual practice expense data we have available: the CPEP data and the AMA's SMS survey data. It allocates current aggregate specialty practice costs to specific procedures and, thus, can be seen as a ''top-down'' approach.

This option is based on an assumption that current aggregate specialty practice costs are a reasonable way to establish initial estimates of relative resource costs of physician services across specialties. The specialty practice cost data are derived from the AMA's SMS survey data on actual practice expenses. The survey data are used to calculate the practice expenses generated for every hour worked by a physician. The average practice expense per hour for the physicians in a given specialty is then multiplied by the total number of physician hours worked by that specialty as reflected in the Medicare claims data. This determines the total pool of practice expense payments for that specialty. We then allocated this pool to the procedures performed by that specialty using the CPEP data (excluding the administrative staff time associated with specific procedures) and the physician work RVUs. We calculated a weighted average of the practice expense payments for procedures performed by more than one specialty.

After much analysis and discussion, we have decided to propose the ''top-down'' methodology. We believe the ''top-down'' methodology is more responsive than the ''bottom-up'' approach to both BBA 1997 requirements and to many of the concerns of the medical community. By using aggregate specialty practice costs as the basis for establishing the practice expense pools, we are recognizing all of a specialty's costs, not just those linked with a specific procedure. By basing the redistributions of the practice expense system on physician-reported actual practice expense data, by using a specialty-specific allocation method, and by treating administrative costs as an indirect expense, we avoid many of the criticisms leveled at our original proposal.

We also believe this option is responsive to the short-term recommendations in the GAO Report to Congress on physician practice expense payments relating to the June 1997 proposed rule's limits on clinical and administrative staff time and possible changes in the linking algorithm. Our recommended methodology would make these recommendations moot by eliminating the limits and linking algorithm that were part of our previous

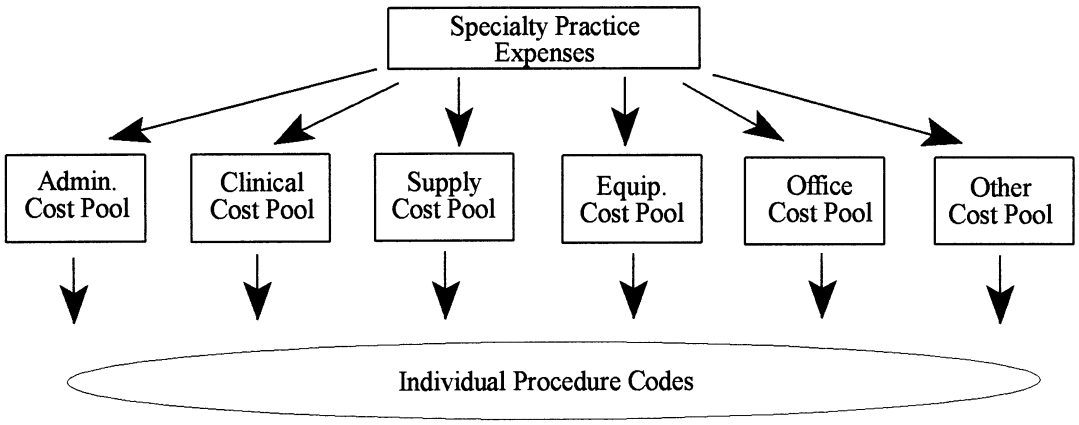
proposal. Finally, based on our experiences with the validation panels we held in October and December 1997, we believe the ''top-down'' approach will be less difficult to refine.

10. Description of the Proposed Methodology for Developing Practice Expense Relative Value Units

(See Addendum B for a detailed technical description of the proposed methodology.)

a. Overview. We used actual practice expense data by specialty to create six cost pools (administrative labor, clinical labor, medical supplies, medical equipment, office supplies, and all other). We then allocated these cost pools to individual procedure codes. An overview of this approach is presented in Exhibit 1.

Exhibit 1. Overall Allocation Approach



b. Data Sources. We used the 1995 through 1997 AMA's SMS survey data to develop the cost pools and the CPEP data to allocate these cost pools to procedure codes.

The AMA originally developed the SMS in 1981. It covers a broad range of economic and practice characteristics. The annual SMS survey is designed to provide representative information on the population of all non-federal physicians who spend the greatest proportion of their time in patient care activities. The survey is sent to both office and hospital-based physicians, but excludes residents. The recipients of the survey are randomly selected from the AMA's physician master file, which contains current and historical information on every physician in the United States, including nonmembers of the AMA.

The SMS survey consists of three distinct sections:

- Screening questions to verify the physician's self-designated practice specialty and eligibility for the survey.
- A main questionnaire to collect information on practice characteristics, hours worked, volume of services, fees for selected procedures, income, and expenses.
- Special topic questions to provide information on key socioeconomic issues.

The SMS survey is a computer-assisted telephone survey that checks the consistency of responses during the survey and automatically skips questions that are not relevant to the physician. To prepare the physician, the AMA mails a practice expense summary in advance. The physician may designate a proxy such as a practice manager or an accountant to answer the practice expense questions. The AMA makes vigorous efforts to achieve a high response rate despite the short field period of surveys. Each interviewer's work is monitored by supervisory staff for both production and quality. AMA staff also monitors interviews to ensure that a high level of quality is maintained throughout the survey.

The CPEP data were collected from panels of physicians, practice administrators, and nonphysicians (for example, registered nurses) who were nominated by physician specialty societies and other groups. There were 15 CPEPs consisting of 180 members from more than 61 specialties and subspecialties. Approximately 50 percent of the panelists were physicians. The CPEPs identified the direct inputs involved in each physician service for procedure codes in an office setting and out-of-office setting. (See Addendum A for a detailed description of the CPEP process.)

c. Practice Expense Cost Pools. We created practice expense cost pools by physician specialty for clinical labor, administrative labor, medical supplies, medical equipment, office supplies, and all other expenses. There are three steps in the creation of the cost pools.

Step 1: Use the AMA's SMS survey data of actual cost data, by physician specialty, for 1995 through 1997 to determine practice expenses per hour by cost category.

Step 2: Determine the total number of physician hours, by specialty, spent treating Medicare patients as reflected in the Medicare claims data.

Step 3: Calculate the practice expense pools by specialty and by cost category using the results from step 1 and step 2.

A short description of each step follows.

Step 1: Determine practice expenses per hour by cost category.

Based on the AMA's SMS survey data for each physician respondent, we calculated practice expenses per hour spent in patient care activities by cost pool. We made the following assumptions in this calculation:

- The physician respondent shares practice expense equally with all other physician owners in the practice.
- The physician respondent works the same number of hours as all other physician owners in the practice.
- For any employee physician in the practice, the hours spent in patient care activities are the average hours spent in patient care activities for employee physicians in the specialty of the physician respondent.

Using the above assumptions, 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: Determine the number of physician hours spent treating Medicare patients.

For each specialty, the total number of physician hours spent treating Medicare patients was calculated from physician time data for each procedure code and the Medicare claims data. The primary sources for the physician time data are surveys submitted to the AMA's RUC and surveys done by Harvard for the initial establishment of the work RVUs.

Step 3: Determine the practice expense pools by specialty and by cost category.

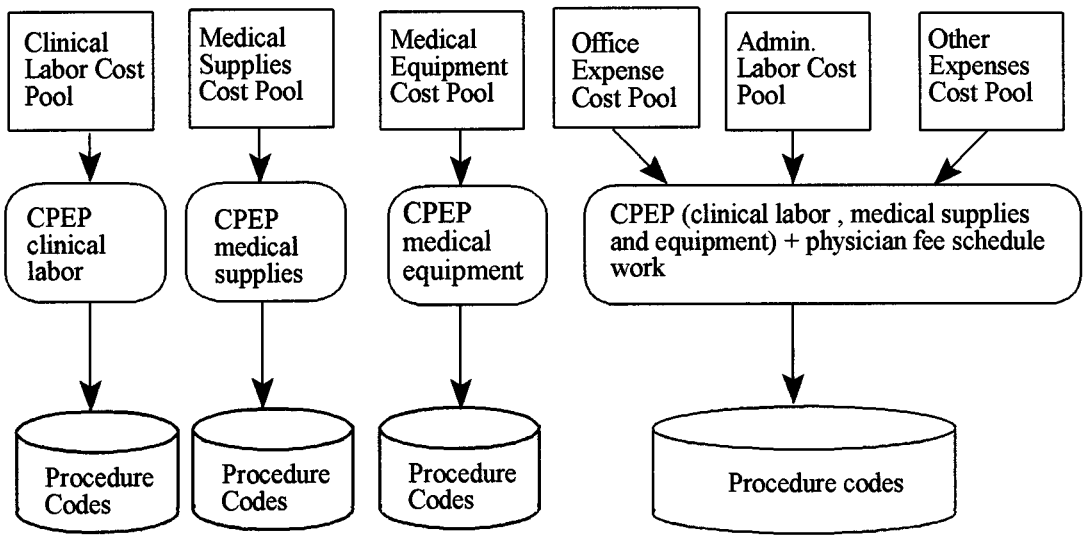
The practice expense cost pools for clinical labor, administrative labor, medical supplies, medical equipment, office expenses, and all other expenses are determined by multiplying the practice expenses per hour for these categories (calculated in step 1) by the total physician hours (calculated in step 2).

d. Cost Allocation Methodology

We allocated by specialty each practice expense cost pool to individual procedure codes either using the CPEP data for clinical labor, medical supplies, and medical equipment, or using a combination of the CPEP data for clinical labor, medical supplies, and medical equipment and the physician fee schedule work RVUs.

Exhibit 2 depicts our cost allocation methodology. For each specialty, the six cost pools and their respective cost allocation bases are used to determine costs for each procedure code.

Exhibit 2. Cost Allocation Methodology



Step 4: Allocate the practice expense pools by specialty to individual procedures.

For each specialty, we separated the six practice expense pools (clinical labor, administrative labor, medical supplies, medical equipment, office expenses, and all other expenses) created in Step 3 into two groups and used a different allocation basis for each group. Group one includes clinical labor, medical supplies, and medical equipment, and group two includes administrative labor, office expenses, and all other expenses.

Group one: clinical labor, medical supplies, and medical equipment.

We used the CPEP data as the allocation basis for the group one pools (clinical labor, medical supplies, and medical equipment). The CPEP data for clinical labor were used to allocate the clinical labor cost pool, the CPEP data for medical supplies were used to allocate the medical supplies cost pool, and the CPEP data for medical equipment were used to allocate the medical equipment cost pool.

Group two: administrative, labor, office expenses, and other expenses.

For the allocation of administrative labor, office expenses, and other expenses, a combination of the group one cost allocations and the physician fee schedule work RVUs was used to allocate the cost pools.

Step 5: Weight average allocations for procedures performed by more than one specialty.

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.

11. Comments of the American Medical Association Regarding the Use of the Socioeconomic Monitoring System Survey Data to Construct Practice Expense Relative Value Units

At our request, the AMA sent two tables summarizing practice expense information by physician specialty. Additionally, the AMA supplied us with SMS background information and comments regarding its use to construct resource-based practice expense RVUs.

The following are the AMA's comments as well as two tables derived from the SMS data:

The SMS survey is an annual nationally representative survey of physicians drawn randomly from the AMA's Physician Masterfile (a listing of all member and nonmember physicians in the United States). The survey was conducted by an external contractor—the Rand Corporation was the survey contractor for the 1995 through 1997 SMS surveys. Unit response rates to SMS have been roughly 60 percent in recent years, which is as high or higher than comparable physician surveys. It is a computer-assisted telephone survey which allows checks to be made for the consistency of responses during the survey and to automatically skip questions that are not relevant to particular physicians. On the practice expense questions, special effort is made to obtain accurate information. A practice expense summary is mailed to all physicians that are to be surveyed to allow them to obtain the information before being contacted. The physician may designate a proxy such as a

practice manager or accountant to answer the practice expense questions if they do not have the information.

However, it is important to stress that the SMS data were never collected for the purpose of developing relative values. We feel that there are several potential problems with using SMS data to construct practice expense RVUs. These concerns were first raised in a letter from the AMA to HCFA in November 1996. In particular, we are concerned that:

—Sample sizes for some specialties will be too small to permit separate calculation of expense data from SMS. Even among the larger specialties, the inherent variability of the expense data will mean that the average expense figures provided will be subject to significant sampling error.

—Response rates for the expense items tend to be low relative to other questions on the survey leading to potential non-response bias.

—SMS is a physician-level survey, and physicians in groups are asked for their share of expenses rather than the practice's expenses. Practice-level data may provide a better basis for constructing practice expense RVUs.

Despite these problems, we recognize your need to use the best available information. The tables that you requested show the means and standard errors of practice expenses per direct patient care hour from the 1995 through 1997 SMS surveys. Since SMS collects practice expense data for the prior year, these tables summarize SMS respondents' hourly expenses for the years 1994 through 1996. Only non-federal, non-resident, patient care physicians are surveyed on SMS. In addition, only physicians who are full or part-owners of their practices are asked the practice expense questions. The following records were excluded prior to tabulating the data as you requested:

—Physicians practicing fewer than 26 weeks the prior year (including cases where weeks worked the previous year were missing);

—Cases with a missing response to the question on typical hours in direct patient care per week (3 cases where the response to this question was 168 hours were also excluded);

—Cases where any of the individual expense items (total non-physician personnel expense; clerical non-physician personnel expense; office expenses; medical supplies expenses; medical equipment expenses; and other or miscellaneous practice expenses) were missing; and

—Cases where total expenses (excluding professional liability insurance premiums and employee physician payroll expense) were zero.

Expenses per hour were calculated as you requested (and as described in the notes to the tables). All results were weighted for unit non-response. It will not be possible to replicate these figures exactly from the AMA's Physician Marketplace Statistics or Socioeconomic Characteristics of Medical Practice publications due, in part, to the exclusions mentioned above.

TABLE 1.—MEAN PRACTICE EXPENSES PER HOUR SPENT IN PATIENT CARE ACTIVITIES, HOURS AND EXPENSES ADJUSTED FOR PRACTICE SIZE

[In dollars]

Specialty	Number of cases	Non-phys payroll per hour	Clerical payroll per hour*	Office expense per hour	Supplies expense per hour	Equipment expense per hour	Other expense per hour	Total expense per hour**
ALL PHYSICIANS	3910	27.0	15.0	19.1	7.2	3.2	11.0	67.5
GENERAL/FAMILY PRACTICE	409	30.2	15.1	18.2	8.1	3.6	8.6	68.6
GENERAL INTERNAL MEDICINE	430	22.4	13.3	17.0	6.4	2.1	6.2	54.2
CARDIOVASCULAR DISEASE	94	30.2	14.9	19.9	5.8	6.4	20.7	82.9
GASTROENTEROLOGY	84	23.2	15.4	17.9	2.7	1.8	11.0	56.6
ALLERGY/IMMUNOLOGY	31	66.2	27.0	33.3	17.5	3.3	16.4	136.6
PULMONARY DISEASE	49	20.0	12.2	15.0	2.8	1.6	6.4	45.8
ONCOLOGY	27	44.7	22.7	25.7	87.2	5.5	10.3	173.4
GENERAL SURGERY	257	22.5	15.7	17.2	3.1	2.0	9.4	54.1
OTOLARYNGOLOGY	103	44.8	27.3	33.4	7.7	5.8	18.3	110.1
ORTHOPEDIC SURGERY	203	42.9	26.0	30.8	10.3	3.6	18.1	105.6
OPHTHALMOLOGY	210	52.9	27.8	35.9	11.3	9.0	22.7	131.8
UROLOGICAL SURGERY	118	29.6	18.6	22.8	24.5	6.0	11.6	94.6
PLASTIC SURGERY	85	28.6	18.3	30.2	16.3	4.6	23.3	103.0
NEUROLOGICAL SURGERY	42	33.5	24.3	31.7	1.8	1.1	15.7	83.9
CARD/THOR/VASC SURGERY	44	30.1	16.2	18.3	1.4	3.1	11.0	63.8
PEDIATRICS	249	26.1	13.3	20.0	10.8	1.6	8.4	66.9
OBSTETRICS/GYNECOLOGY	266	32.3	16.9	21.2	7.3	3.4	11.7	75.9
RADIOLOGY	214	19.0	9.6	12.5	4.8	8.3	13.6	58.2
PSYCHIATRY	351	7.3	5.3	10.1	0.4	0.3	7.5	25.6
ANESTHESIOLOGY	232	14.4	3.7	5.9	0.3	0.4	5.7	26.7
PATHOLOGY	82	16.7	8.4	6.7	4.0	1.6	17.7	46.7
DERMATOLOGY	96	49.5	26.7	33.1	12.5	4.8	15.2	115.0
EMERGENCY MEDICINE	61	5.3	1.9	1.6	0.5	0.1	5.5	13.0
NEUROLOGY	61	26.2	21.6	15.8	5.0	4.2	7.7	58.8
PHYS MED/RHEUMATOLOGY	75	38.6	23.2	28.5	4.9	3.9	12.0	88.0
OTHER SPECIALTY	37	21.1	12.4	19.7	3.6	1.3	9.7	55.4

Source: American Medical Association, 1995–1997 Socioeconomic Monitoring System (SMS) surveys.

* Clerical payroll is included in total non-physician payroll.

** Total expenses exclude professional liability insurance premiums and employee physician payroll.

Notes:

(1) Only self-employed non-federal non-resident patient care physicians who responded to all relevant expense questions are included. Self-employed physician respondents with no practice expenses for the year are excluded.

(2) Physicians whose typical number of hours worked in patient care activities per week is missing, less than 20, or equal to 168 (3 cases) are excluded. Physicians whose number of weeks worked the previous year is missing or less than 26 are excluded.

(3) For each respondent, total practice expense and expense components per hour are calculated as (4)/(5) below.

(4) Expenses adjusted for practice size = self-employed respondent expenses* # physician owners.

(5) Hours adjusted for practice size = (respondent hours* # physician owners) + (employee physician hours (see (6) below)* # employee physicians).

6) The typical number of hours worked in patient care activities for the employee physician(s) of a self-employed physician's practice is not known. Mean hours worked in patient care activities for employee physicians of each specialty are used as an estimate of employee physician hours.

TABLE 2.—STANDARD ERRORS OF MEAN PRACTICE EXPENSES PER HOUR SPENT IN PATIENT CARE ACTIVITIES, HOURS AND EXPENSES ADJUSTED FOR PRACTICE SIZE

[In dollars]

Specialty	Number of cases	Non-phys payroll per hour	Clerical payroll per hour	Office expense per hour	Supplies expense per hour	Equipment expense per hour	Other expense per hour	Total expenses per hour**
ALL PHYSICIANS	3910	0.5	0.3	0.4	0.3	0.2	0.3	1.1
GENERAL/FAMILY PRACTICE	409	1.3	0.6	1.2	0.5	0.7	0.6	3.0
GENERAL INTERNAL MEDICINE	430	1.2	0.6	1.0	0.6	0.3	0.6	2.6
CARDIOVASCULAR DISEASE	94	2.9	1.4	1.9	0.8	1.3	5.2	8.0
GASTROENTEROLOGY	84	1.6	1.1	1.9	0.3	0.3	2.2	4.1
ALLERGY/IMMUNOLOGY	31	7.9	3.8	3.8	4.2	1.5	2.9	11.2
PULMONARY DISEASE	49	1.6	1.4	2.2	0.6	0.5	0.9	3.5
ONCOLOGY	27	7.5	3.8	5.7	16.4	1.4	3.8	23.2
GENERAL SURGERY	257	1.4	0.9	0.9	0.3	0.3	0.8	2.5
OTOLARYNGOLOGY	103	3.0	2.3	3.5	0.9	1.1	2.1	6.8
ORTHOPEDIC SURGERY	203	1.7	1.2	2.1	0.8	0.4	2.0	4.7
OPHTHALMOLOGY	210	2.9	1.4	2.6	1.3	1.1	2.1	6.3
UROLOGICAL SURGERY	118	1.4	1.0	2.1	1.8	1.0	1.4	4.4
PLASTIC SURGERY	85	2.3	1.4	3.5	2.8	1.0	3.4	8.1
NEUROLOGICAL SURGERY	42	4.0	2.5	5.7	0.7	0.4	2.1	9.4
CARD/THOR/VASC SURGERY	44	4.2	2.0	2.9	0.3	1.7	2.2	8.0
PEDIATRICS	249	1.6	0.7	1.7	1.0	0.3	1.2	3.8
OBSTETRICS/GYNECOLOGY	266	1.7	0.9	1.3	0.7	0.3	1.0	3.3
RADIOLOGY	214	2.0	0.9	2.0	0.8	1.9	1.3	5.7
PSYCHIATRY	351	0.7	0.5	0.6	0.2	0.1	0.6	1.5
ANESTHESIOLOGY	232	1.8	0.6	0.8	0.1	0.1	0.7	2.4
PATHOLOGY	82	2.7	1.8	1.7	0.8	0.5	2.9	6.4
DERMATOLOGY	96	4.8	2.0	5.2	2.0	1.2	1.8	10.4
EMERGENCY MEDICINE	61	1.4	0.6	0.5	0.3	0.1	0.9	2.1
NEUROLOGY	61	3.1	3.1	1.4	1.5	1.1	2.2	6.4
PHYS MED/RHEUMATOLOGY	75	5.1	2.5	6.1	0.7	1.4	2.9	12.1
OTHER SPECIALTY	37	4.4	2.4	5.1	1.1	0.6	2.1	9.5

Source: American Medical Association, 1995–1997 Socioeconomic Monitoring System (SMS) surveys.

* Clerical payroll is included in total non-physician payroll.

** Total expenses exclude professional liability insurance premiums and employee physician payroll.

Notes:

(1) Only self-employed non-federal non-resident patient care physicians who responded to all relevant expense questions are included. Self-employed physician respondents with no practice expenses for the year are excluded.

(2) Physicians whose typical number of hours worked in patient care activities per week is missing, less than 20, or equal to 168 (3 cases) are excluded. Physicians whose number of weeks worked the previous year is missing or less than 26 are excluded.

(3) For each respondent, total practice expense and expense components per hour are calculated as (4)/(5) below.

(4) Expenses adjusted for practice size = self-employed respondent expenses * # physician owners.

(5) Hours adjusted for practice size = (respondent hours * # physician owners) + (employee physician hours (see (6) below) * # employee physicians).

(6) The typical number of hours worked in patient care activities for the employee physician(s) of a self-employed physician's practice is not known. Mean hours worked in patient care activities for employee physicians of each specialty are used as an estimate of employee physician hours.

12. Other Methodological Issues

a. Professional and Technical Component Services. Using the methodology described above, the professional and technical components of the resource-based practice expense relative value units do not necessarily sum to the global resource-based practice expense relative value units since specialties with different practice expenses per hour provide the components of these services in different proportions. For example, emergency medicine physicians have proportionately more professional component chest x-ray billings than global billings relative to radiologists. We used the following methodologies so that the professional and technical component resource-based practice expense relative value units for a service sum to the global resource-based relative value units.

For codes with professional and technical components excluding HCPCS codes 70010 through 79440, G0030 through G0047, G0050, G0062, G0063, G0106, G0120, G0122, G0125, and G0126, we used the following methodology:

After we determined the practice expense RVUs using the practice expense per hour methodology, we budget neutrally distributed the total (global, professional, and technical) practice expense payments for each code between the global, professional, and technical components as follows:

Step 1: Calculate a weighted average resource-based practice expense RVU across the facility and nonfacility settings using the allowed utilization from the Medicare claims data.

Step 2: Using the RVUs calculated in Step 1 for the global, professional, and

technical components of each code and the Medicare utilization data, calculate the total new resource-based practice expense payments for each code.

Step 3: Set the global resource-based practice expense RVUs for each code equal to the sum of the resource-based practice expense RVUs for the professional and technical components calculated in Step 2.

Step 4: Using the global RVUs calculated in Step 3, the professional and technical component RVUs calculated in Step 1, and the Medicare utilization data, calculate practice expense payments for each code.

Step 5: Multiply the global relative value units calculated in Step 3 and the professional and technical component RVUs calculated in Step 1 by the ratio of the practice expense payments for each code calculated in Step 2 to the practice expense payments for each code calculated in Step 4.

For HCPCS codes 70010 through 79440, G0030 through G0047, G0050, G0062, G0063, G0106, G0120, G0122, G0125, and G0126, we used the following methodology:

We used the current 1998 practice expense RVUs for this set of codes, which are based primarily on the original radiology fee schedule, to determine the relatives between the new resource-based practice expense relative value units as follows:

Step 1: Using the current 1998 practice expense RVUs, calculate the current aggregate practice expense payments for this set of codes.

Step 2: Using the resource-based practice expense RVUs determined from the methodology described above, calculate the aggregate practice expense payments for this set of codes.

Step 3: Uniformly multiply the current practice expense RVUs by the ratio of the aggregate resource-based practice expense payments calculated in Step 2 to the aggregate practice expense payments calculated in Step 1.

For HCPCS codes Q0092, R0070, and R0075, we used the following methodology:

The practice expense RVUs for HCPCS code Q0092 was determined by applying the ratio described in Step 3 above to the existing practice expense RVUs. The practice expense RVUs for HCPCS codes R0070 and R0075 were determined by applying the ratio described above to practice expense RVUs for these codes calculated from the average allowed charge in the Medicare claims data.

b. Practice Expenses per Hour Adjustments and Specialty Crosswalks. We have one general comment on our use of the SMS practice expense per hour data. Some practices employ midlevel providers such as nurse practitioners and optometrists. The practice expenses per hour from the SMS survey are calculated in terms of hours spent in patient care activities by physicians in a practice. These practice expenses per hour are greater than practice expenses per hour spent in patient care activities by the physicians and midlevel providers in a practice. As a result, the practice expense per hour methodology is potentially biased in favor of specialties who use more, relative to other specialties, midlevel providers as physician extenders to create billable services under the Medicare fee schedule. Although we made no adjustment to the practice expenses per hour for this due to a lack of data, we believe the issue should be examined as part of the refinement of the resource-based practice expense RVUs.

Below are the adjustments we made to the practice expense per hour data and the crosswalks we used to assign the specialties reflected in our claims data to those found in the practice expense tables from the SMS survey 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'' since we make separate payment for the drugs furnished by these specialties.

With regard to oncology, while Medicare does not have an expansive outpatient drug benefit, it does cover outpatient drugs that are furnished by a physician, oral cancer drugs, and certain other specific drugs. In addition to paying for the costs of these drugs (outside the physician fee schedule), Medicare also makes a separate payment to physicians for the ''administration'' of cancer drugs (under the physician fee schedule). This separate payment for chemotherapy administration recognizes the expenses involved with ordering, storing and handling, and performing other tasks associated with administering such drugs. These expenses are practice expenses and are treated as part of resource-based practice expenses; they are not part of the costs of the drug and are not included in Medicare payments for chemotherapy drugs.

We believe that physicians' expenses for the administration of cancer drugs, as well as the costs of the drugs themselves, are included in their responses to the AMA survey. Therefore, to avoid a duplicate payment (that is, paying for the drug separately and also including the costs of the drug in practice expenses), we need to separate the costs of the drug from the practice expenses for the administration of the chemotherapy drugs.

We are proposing to use the ''All Physician'' practice expenses per hour for medical materials and supplies to reflect, in a relative sense, all the practice expenses for administration of chemotherapy. The difference between the practice expense per hour for medical material and supplies for oncologists and for all physicians would be the costs of the drugs themselves. We invite comments about our approach or alternative ways to separate the costs of the drugs from the costs of their administration.

- 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. (Since speech and language pathologists are not identified as Medicare specialties in our claims data, we could not explicitly use their salary equivalency guideline data.) The data used to calculate the salary equivalency practice expenses per hour for these categories of expenses includes an allowance for 250 square feet of space per therapist, and the utilities and other overhead to run the practice, including administrative costs. We set the remaining practice expense per hour categories equal to the ''All Physicians'' practice expenses per hour from the SMS survey data. We used the clinical payroll expenses for ''All Physicians'' instead of the salary equivalency data for physical therapy assistants and aides since we are concerned that there may be an overlap between the cost of therapy assistants and aides reflected in the practice expenses and the amount of work allocated to services provided by occupational and physical therapists.

- The following are the crosswalks we used to assign the specialties reflected in our claims data to those found in the practice expense tables from the SMS survey data. Note that we refer to the difference between the nonphysician payroll expenses per hour and the clerical payroll expenses per hour as the clinical payroll expenses per hour.

TABLE 3.—PRACTICE EXPENSE PER HOUR CROSSWALKS

HCFA specialty code and description	AMA specialty	Clinical labor PE/Hr	Medical supplies PE/Hr	Medical equipment PE/Hr	Cler., office, and other PE/Hr
01—General Practice	General/Family Practice	$15.10	$8.10	$3.60	$41.90
02—General Surgery	General Surgery	6.80	3.10	2.00	42.30
03—Allergy/Immunology	Allergy And Immunology*	39.20	7.20	3.30	76.70
04—Otology, Laryn., Rhino	Otolaryngology	17.50	7.70	5.80	79.00
05—Anesthesiology	Anesthesiology	10.70	0.30	0.40	15.30
06—Cardiology	Cardiovascular Disease	15.30	5.80	6.40	55.50
07—Dermatology	Dermatology	22.80	12.50	4.80	75.00
08—Family Practice	General/Family Practice	15.10	8.10	3.60	41.90
10—Gastroenterology	Gastroenterology	7.80	2.70	1.80	44.30
11—Internal Medicine	General Internal Medicine	9.10	6.40	2.10	36.50
12—Manip. Therapy	All Physicians	12.00	7.20	3.20	45.10
13—Neurology	Neurology	4.60	5.00	4.20	45.10
14—Neurosurgery	Neurological Surgery	9.20	1.80	1.10	71.70
16—OB–GYN	Obstetrics/Gynecology	15.40	7.30	3.40	49.80
18—Ophthalmology	Ophthalmology	25.10	11.30	9.00	86.40
19—Oral Surgery	All Physicians	12.00	7.20	3.20	45.10
20—Orthopedic Surgery	Orthopedic Surgery	16.90	10.30	3.60	74.90
22—Pathology	Pathology	8.30	4.00	1.60	32.80
24—Plastic Surgery	Plastic Surgery	10.30	16.30	4.60	71.80
25—Physical Medicine	Physical Medicine/Rheumatology	15.40	4.90	3.90	63.70
26—Psychiatry	Psychiatry	2.00	0.40	0.30	22.90
28—Colorectal Surgery	General Surgery	6.80	3.10	2.00	42.30
29—Pulmonary Disease	Pulmonary Disease	7.80	2.80	1.60	33.60
30—Radiology	Radiology	9.40	4.80	8.30	35.70
33—Thoracic Surgery	Cardiac/Thoracic/Vascular Surgery	13.90	1.40	3.10	45.50
34—Urology	Urological Surgery	11.00	24.50	6.00	53.00
35—Chiropractor, Licensed	General Internal Medicine	9.10	6.40	2.10	36.50
36—Nuclear Medicine	Radiology	9.40	4.80	8.30	35.70
37—Pediatrics	Pediatrics	12.80	10.80	1.60	41.70
38—Geriatrics	General Internal Medicine	9.10	6.40	2.10	36.50
39—Nephrology	General Internal Medicine	9.10	6.40	2.10	36.50
40—Hand Surgery	Orthopedic Surgery	16.90	10.30	3.60	74.90
41—Optometrist	All Physicians	12.00	7.20	3.20	45.10
43—CRNA/AA	Anesthesiology	10.70	0.30	0.40	15.30
44—Infectious Disease	General Internal Medicine	9.10	6.40	2.10	36.50
46—Endocrinology	General Internal Medicine	9.10	6.40	2.10	36.50
48—Podiatry	General Surgery	6.80	3.10	2.00	42.30
50—Nurse Practitioners	General Internal Medicine	9.10	6.40	2.10	36.50
62—Psychologist (Billing Independently)	Psychiatry	2.00	0.40	0.30	22.90
65—Physical Therapist (Indep. Practice)	All Physicians*	12.00	7.20	3.20	10.90
66—Rheumatology	Physical Medicine/Rheumatology	15.40	4.90	3.90	63.70
67—Occupational Therapist	All Physicians*	12.00	7.20	3.20	10.90
68—Clinical Psychologist	Psychiatry	2.00	0.40	0.30	22.90
69—Independent Laboratory	All Physicians	12.00	7.20	3.20	45.10
70—Clinic Or Other Group	All Physicians	12.00	7.20	3.20	45.10
76—Periperal Vascular Disease	All Physicians	12.00	7.20	3.20	45.10
77—Vascular Surgery	Cardiac/Thoracic/Vascular Surgery	13.90	1.40	3.10	45.50
78—Cardiac Surgery	Cardiac/Thoracic/Vascular Surgery	13.90	1.40	3.10	45.50
79—Addiction Medicine	Psychiatry	2.00	0.40	0.30	22.90
80—Clinical Social Worker	Psychiatry	2.00	0.40	0.30	22.90
81—Critical Care (Intensivists)	All Physicians	12.00	7.20	3.20	45.10
82—Hematology	General Internal Medicine	9.10	6.40	2.10	36.50
83—Hematology/Oncology	Oncology*	22.00	7.20	5.50	58.70
84—Preventive Medicine	General Internal Medicine	9.10	6.40	2.10	36.50
85—Maxillofacial Surgery	All Physicians	12.00	7.20	3.20	45.10
86—Neuropsychiatry	Psychiatry	2.00	0.40	0.30	22.90
89—Clinical Nurse Practitioner	General Internal Medicine	9.10	6.40	2.10	36.50
90—Medical Oncology	Oncology	22.00	7.20	5.50	58.70
91—Surgical Oncology	All Physicians	12.00	7.20	3.20	45.10
92—Radiation Oncology	Radiology	9.40	4.80	8.30	35.70
93—Emergency Medicine	Emergency Medicine	3.40	0.50	0.10	9.00
94—Interventional Radiology	Radiology	9.40	4.80	8.30	35.70
95—Indep. Physiological Lab	All Physicians	12.00	7.20	3.20	45.10
97—Physician Assistants	General/Family Practice	15.10	8.10	3.60	41.90
98—Gynecology/Oncology	Obstetrics/Gynecology	15.40	7.30	3.40	49.80

*Practice expense per hour were adjusted as follows:
(1) Allergy & Immunology and Oncology use supplies for All Physicians.
(2) Physical Therapy and Occupational Therapy use salary equivalency data for clerical, office and other practice expenses per hour.

• Due to uncertainty concerning the appropriate crosswalk and time data for the nonphysician specialty ''Audiologist'' and the fact that the relatively few codes performed by audiologists are also performed by other specialties, we did not crosswalk this specialty. Until we can obtain more data, we derived the resource-based practice expense RVUs for codes performed by audiologists from the practice expenses per hour of the other specialties which perform these codes.

• Because we have no reason to assume that the distribution of radiologists by equipment ownership reflected in the SMS survey data differs from the distribution found in our claims data, we did not attempt to differentiate the practice expenses per hour for radiologists by equipment ownership. The use of the average practice expenses per hour should create the appropriate practice expense pool for radiology. We invite comments on this issue. We realize that practice expenses vary by equipment ownership; however, the appropriate recognition of this is through the differential allocation of the practice expense pool to the professional, technical, and global services performed by radiologists.

c. Time Associated with the Work Relative Value Units. As a general comment on the time data, we are concerned that any imprecision in the time estimates for high volume services which have relatively little time associated with them may potentially bias the practice expense methodology in favor of the specialties which perform these services. For example, if a high volume procedure which typically takes four minutes to perform has a surveyed time of 5 minutes, this procedure's contribution to the practice expense pool for that specialty is inflated by 25 percent. In contrast, if a procedure which typically takes 100 minutes to perform has a surveyed time of 101 minutes, its contribution is only inflated by 1 percent. We believe this issue should be examined as part of the refinement of the resource-based practice expense RVUs.

• The time data from the Harvard study performed for the initial establishment of the work relative value units were collected over a number of years using primarily surveys of practicing physicians. The time data submitted to the RUC for the refinement of the work relative value units were also collected over a number of years using primarily physician surveys. The time data resulting from the refinement of the work relative value units have been systematically greater than the time data obtained by the Harvard study for the same services. On average, this difference is approximately 25 percent. We increased the Harvard time data in order to ensure consistency between these data sources.

• We calculated the total physician time for CPT codes 70010 through 79440 using the work RVUs and the work per unit time for CPT 99213, except for codes in the range of CPT codes 78000 through 78891 for which we had Harvard survey data and codes for which we had data from surveys done for the AMA RUC.

• Based on the judgment of our clinical staff, we calculated the total physician time for CPT codes 90918 through 90921 using the work RVUs and the work per unit time for CPT code 99213.

• Based on the judgment of our clinical staff, we set the total time associated with the work RVUs for CPT 97001 through 97770 as follows:

HCPCS	Time (min)
97001	30
97002	20
97003	45
97004	30
97010	5
97012	15
97014	13
97016	18
97018	13
97020	14
97022	15
97024	15
97026	10
97028	9
97032	18
97033	14
97034	16
97035	12
97036	15
97039	10
97110	15
97112	15
97113	15
97116	15
97122	15
97124	15
97139	15
97150	15
97250	15
97260	15
97261	15
97265	15
97504	15
97520	15
97530	15
97535	15
97537	15
97542	15
97703	15
97750	15
97770	15

• A high percentage of codes performed by the nonphysician specialties of Independent Physiological Lab, Clinical Psychologist, and Psychologist (Independent Billing) do not have work RVUs and, therefore, time data. Because the practice expenses per hour for these specialties were crosswalked from SMS specialties, when calculating their practice expense pools we used the maximum clinical staff time from the CPEP data for the codes that lack work RVUs.

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

13. Other Practice Expense Policies

a. Site-of-Service Payment Differential. Under the physician fee schedule, if a physician service of the type routinely furnished in physician offices is furnished in facility settings, our current policy is that the fee schedule amount for the service is determined by reducing the practice expense RVUs for the service by 50 percent. Certain services are excluded from the regulation including rural health clinic services, surgical services not on the ambulatory surgical center covered list that are furnished in an ambulatory surgical center, anesthesia services, and diagnostic and therapeutic radiology services (see § 414.32 (Determining payments for certain physician services furnished in facility settings)).

The site-of-service payment differential is a long established policy to avoid duplicate payments for practice costs while, at the same time, recognizing that some office practice cost is incurred when physicians perform procedures outside the office setting. The site-of-service policy applies to both inpatient and outpatient hospital settings.

Since the implementation of the physician fee schedule, we have compiled a list of services furnished outside physician offices that are subject to the site-of-service payment differential. The current list includes approximately 700 services.

As part of the resource-based practice expense initiative, we are proposing to replace the current policy that systematically reduces the practice expense RVU by 50 percent for certain procedures 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. In general, we would furnish two levels of practice expense RVUs per code; one when the procedure is performed in the office or other site (or nonfacility) if no additional facility fee is paid and

another when the procedure is performed out of the office (for example, in a hospital or an ambulatory surgical center in which the costs of resources, such as labor, medical supplies, and medical equipment are paid outside the physician fee schedule and only to the hospital or ambulatory surgical center).

Some services, by the nature of their codes, are performed only in certain settings and would 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. Examples of these codes are the following:

- Inpatient hospital care for new or established patients (CPT codes 99221 through 99223).
- Subsequent hospital care (CPT codes 99231 through 99239).
- Emergency department services for new or established patients (CPT codes 99281 through 99285).
- Critical care services (CPT codes 99291 through 99297).
- Nursing facility services (CPT codes 99301 through 99303).
- Subsequent nursing facility care (CPT codes 99311 through 99313).
- Domiciliary, rest home (CPT codes 99321 through 99333).
- Home services (CPT codes 99341 through 99350.

We note that office or outpatient evaluation and management services (CPT codes 99201 through 99215) are used to report services furnished in the physician office or in a hospital outpatient department; therefore, these procedure codes will have different levels of practice expense RVUs. 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 would 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 office and for services furnished to a patient in the patient's home, or facility or institution other than a hospital, skilled nursing facility, or ambulatory surgical center. For these services, the physician typically bears the cost of resources, such as labor, medical supplies, and medical equipment associated with the physician service.

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

b. Additional Relative Value Units for Additional Office-Based Expenses for Certain Procedure Codes. Usually office medical supplies or surgical services in the physician 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 that allowed a practice expense RVU of 1.0 to pay for the supplies that are used incident to a physician service but generally are not the type of routine supplies included in the practice expense RVUs for specific services. For example, if the physician performed a cystourethroscopy with a biopsy (CPT code 52204) in the office and billed for a surgical tray (HCFA Common Procedure Coding System (HCPCS) code A4550) in addition to the procedure, the physician would receive approximately $34.86 (an RVU of .95) for the surgical tray in addition to the payment for the cystourethroscopy with biopsy. The November 1991 final rule (56 FR 59811) listed 44 procedure codes that qualified for additional RVUs if furnished in the physician office. This list was expanded in the December 1993 final rule (58 FR 63854) to include several cystoscopy codes. Included in this list of procedures for which an additional amount for supplies may be paid if performed in a physician office are closing a tear duct (CPT code 68671) and billing for a permanent lacrimal duct implant (HCPCS A4263) and inserting an access port (CPT code 36533) and billing for an implantable vascular access portal/catheter (A4300). These supplies were given the same RVU as HCPCS code A4550.

We are proposing 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 related procedure code. Therefore, we are proposing to discontinue separate payment for supply codes A4263, A4300 and A4550.

c. 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 proposing to follow the same process and make an adjustment to the anesthesia CF to move anesthesia services under the resource-based practice expense system. The adjustment to the anesthesia CF is 3.5 percent.

14. Refinement

Section 4505(d)(1)(C) of the BBA requires the Secretary to develop a refinement process to be used during each of the 4 years of the transition period. In this section, we will describe those aspects of this proposed rule that we believe are subject to refinement as well as our proposed process for refinement during the coming year. In light of the complexity of the issues associated with establishing the initial proposed practice expense RVUs, we believe it is premature to propose, in this proposed rule, the refinement process for subsequent years of the transition period. We also believe it would be premature to finalize the practice expense RVUs before the fall of 1999. Therefore, we will keep the practice expense RVUs as interim RVUs until at least the fall of 1999. We also are open to extending the period during which the practice expense RVUs are interim beyond 1999 if we believe that more time is needed to identify and correct errors.

We are particularly interested in receiving comments on our proposed refinement process for this year, and we are soliciting recommendations for the process in subsequent years. Based on our analysis of comments we receive, we hope to describe our plans for the entire refinement process in the final rule.

a. Issues Involved in Refinement. We believe the refinement process for practice expense RVUs will enable us to:

- Review and refine practice expense/hour data.
- Obtain and review practice expense/hour data for specialties or practitioners not included in the SMS survey.
- Address anomalies, if any, in the code-specific Harvard/RUC physician time data.
- 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.
- Refine, as needed, our process of developing practice expense RVUs for codes that were not addressed by the

CPEP process, for example, codes that were new in 1996, 1997, and 1998.

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

Our plans for each of these six points are as follows:

• Refinement of the practice expense/hour data. The practice expense/hour data are based on the SMS survey. (These data can be found in Table 1). Although the SMS survey was not designed to support the development of practice expense RVUs, we believe it is the best available source of data on actual practice costs that allows us to recognize all staff, equipment, supplies, and expenses, not just those that can be tied to specific procedures. In fact, we believe one advantage of the SMS data is that they were collected before this proposed rule.

The SMS survey data used in this proposed rule do not include the practice expense information on all specialties recognized by Medicare. However, for certain larger specialties, for example, family practice and general surgery, the sample of physicians surveyed is of sufficient size to serve as the basis of the practice expense/hour calculation in the short term. For those larger specialties, we are unlikely to make any changes in the practice expense/hour calculation in the final rule to be published this fall. In the long term, specifically, 1999 and beyond, we are prepared to refine the practice expense/hour data of the larger specialties if we receive compelling evidence that the SMS data are incorrect. Any arguments that the practice expense/hour for a given specialty should be changed would be strengthened by the submission of survey data comparable to the SMS that include data for a range of specialties expected to gain and lose Medicare revenue.

We are concerned that the validity of future SMS surveys could be affected if we decided to explicitly link the data collected to future revisions of the Medicare fee schedule. Also, SMS is a physician level survey, and physicians in groups are asked for their share of expenses rather than the practices' expenses. Practice level data may provide a better basis for constructing practice expense RVUs. We invite comments on potential revisions to the SMS survey or alternative sources of data that could be used for long term refinement. Finally, because the calculation of the practice expense/hour is so critical to our methodology, we also invite comment on the need to confirm, through audit or other means, the survey data that would be used for long term refinement.

• Refinement of the crosswalk for the practice expense/hour data. The SMS data we used for this proposed rule do not include data for all specialties that are recognized by Medicare, and they do not include data on nonphysician practitioners who are paid under the physician fee schedule. To develop this proposal, it was necessary to crosswalk certain specialties and nonphysician practitioners to the practice expense/hour data we developed for the specialties included in the SMS. We invite comments on the appropriateness of our crosswalks. Any arguments that the practice expense/hour data should be changed would be strengthened by the submission of survey data comparable to the SMS data.

• Refinement of the physician time data. The number of practice expense RVUs assigned to the services performed by a given specialty is determined by the practice expense/hour data from the SMS and the physician time data for each of the codes. The physician time data are based on the Harvard resource-based RVS study and RUC survey data that were developed as part of the refinement of the work RVUs. We are confident that these data are accurate although there may be some codes for which the final work RVUs we have assigned may be inconsistent with the time data. We will accept comments on the code-specific physician time data but must point out that any proposed revisions to the time data have implications for the work RVUs assigned to those codes. We do not intend to revisit work RVU issues that have been already addressed as part of the 5-year review. (Total physician time data can be found in the ''Total Physician Time'' file located on the HCFA Homepage. Specific instructions for accessing this and other Internet files referred to in this proposed rule can be found at the end of this refinement section.)

• Refinement of the CPEP data. The identification and correction of errors, 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 has its principal effect on the relative relationship of the practice expense RVUs assigned to services performed by a given specialty.

It is important to understand that the allocation of practice expense RVUs at the code level is based on CPEP data that have not been revised or edited in any fashion. We have not made any revisions or edits for two main reasons. First, we received many comments in response to last year's proposed rule that objected to the data reasonableness edits and caps that were part of our proposal. Second, we received many comments in response to June 1997 proposed rule that objected to our decision to exclude from the CPEP data the direct inputs for medical equipment, medical supplies, and clinical staff recorded for hospital patients. In addition, we found this decision to be quite controversial in subsequent meetings with representatives of various specialty societies. Under our proposed methodology that begins with the total practice expense costs, the question as to the appropriateness of including the direct inputs for medical equipment, medical supplies, and clinical staff in the inputs for hospital patients is much less important because the inclusion of the data impacts the distribution of practice expense RVUs across the entire fee schedule only to the extent codes are performed by more than one specialty.

For example, if a given specialty performs cardiovascular procedures, including time for nursing staff in the hospital for these procedures allocates more of the fixed practice expense pool of dollars for that specialty to these procedures, leaving fewer dollars for the other codes performed by that specialty. We believe the most appropriate method for determining the relative relationship of the RVUs assigned to cardiovascular procedures in this proposed rule is to rely on the CPEP that developed the inputs for those procedures. Therefore, the direct inputs for medical equipment, medical supplies, and clinical staff recorded for hospital patients have not been removed from the CPEP data.

In deciding not to modify the CPEP data, we recognize the possibility that the RVUs assigned to some codes will appear to be incorrect or anomalous. Any apparent errors will be identified and corrected in response to the comments we receive on this proposed rule and through our refinement process. We received comments in response to last year's proposed rule that pointed out apparent errors in the RVUs, and many of the CPEP inputs were revised during the validation panels we conducted in October 1997. We have not incorporated any of those revisions to the data primarily because our methodology for developing RVUs has been revised, and we were not convinced that all the revisions that occurred during the validation panels were correct. To the extent that commenters believe that previously submitted comments are still valid or that data revisions that occurred during the validation panels are still

appropriate, we request that they again be brought to our attention in response to this proposed rule.

While we will accept comments on any code-specific data, we recommend that commenters focus their attention during this comment period on high-volume services with large aggregate expenditures under Medicare. We will review the comments with the assistance of our carrier medical directors. Time constraints preclude convening multiple specialty panels to assist us in our review of the comments. However, as noted above, the practice expense RVUs would be interim values for at least 1999, including those we change as a result of our review of the comments.

Because all of the practice expense RVUs will be interim during 1999, commenters will have another opportunity to identify errors in the code-specific CPEP data during the comment period of the final rule with comment period to be published in the fall of 1998. We believe that the codes identified as 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. In other words, although we may keep all the practice expense RVUs interim beyond 1999 as we refine other aspects of the physician fee schedule, it is not our intention to continually review the inputs for all the codes on the fee schedule on an annual basis.

We do believe it is important to have the advice of practicing physicians on the appropriateness of recommended changes to the CPEP inputs. We have two principal options for obtaining that advice. The first option would be for us to convene multiple specialty panels to review the recommended changes. The second option would be to ask the RUC, or a new organization like the RUC that includes broad representation across all specialties and includes nonphysician practitioners, to do this. We believe that under either option, the panel or panels should include individuals other than physicians, for example, practice managers or nurses, who could bring additional experience and expertise to the discussion. 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 invite comments on these options and would welcome any other recommendations.

- Refinement of the crosswalk for 1996, 1997, and 1998 codes. Because the CPEP process was based on 1995 CPT codes, it was necessary for us to develop practice expense RVUs for new codes that were developed for the 1996, 1997, and 1998 CPT books. The process we used was based on comparing the new codes to other comparable codes for which we had actual CPEP data. Files containing information about the crosswalks used for codes that were new in 1996, 1997, and 1998 are available on the HCFA homepage under the heading ''CPEP Data Crosswalked to 1998 CPT Codes.'' Since this crosswalk was based on our judgment rather than actual data, we invite comments on the appropriateness of our crosswalks. Also, we will accept new code specific-data on clinical staff types and times, quantity and cost of medical supplies, and quantity and cost of medical equipment. Any comments we receive on these codes will be reviewed as part of the process of review described above.
- Development of practice expense RVUs for codes that will be new in 1999 and beyond. There will be new codes included in CPT 1999 for which we will not have practice expense data in time for publication in the 1998 final rule. We plan to develop interim practice expense RVUs for these codes by preparing a crosswalk of CPEP data from existing codes. The crosswalk we use will be available with the final rule, and the practice expense values for the codes will be subject to comment. However, the interim values will serve as the basis of payment during 1999.

We do not believe that preparing a crosswalk of new codes is the most appropriate method of developing practice expense RVUs for new codes. However, for 1999, time constraints do not permit any other approach. Beyond 1999, we would like to develop a process whereby we receive recommended practice expense RVUs or recommended inputs for clinical staff types and times, quantity and cost of medical supplies, and quantity and cost of medical equipment.

For the assignment of work RVUs to new and revised codes, we first look to the RUC for recommended RVUs. Under that process, codes that will be new or revised in the next year's CPT are referred from the CPT editorial panel to the RUC. Specialty societies are informed of these codes and furnished an opportunity to survey a sample of physicians in their specialty for the development of recommended RVUs. The entire RUC then reviews the survey results and forwards the recommended work RVUs to us.

We then review the RUC's recommended work RVUs with the assistance of our Medicare carrier medical directors and publish our decisions as interim RVUs in the final rule for the upcoming year. For example, work RVUs for codes that were new or revised in CPT 1998 were published as interim RVUs in the October 1997 final rule.

Publishing RVUs as interim allows the public the opportunity to furnish comments on the appropriateness of our interim work RVUs. During the following year, we review any comments we have received with the assistance of multiple-specialty panels we have convened. We consider our analysis of any comments on the interim work RVUs and the advice we receive from the multiple specialty panels in the assignment of the final work RVUs that are announced in the final rule for the next year's physician fee schedule.

For practice expense RVUs, we believe there are two principal options. First, we could continue to crosswalk new codes to existing codes, publish the results of that crosswalk as interim practice expense RVUs in the final rule, 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. This approach would allow us to publish interim RVUs based on the advice of practicing physicians. As with the work RVUs, any comments we received on the interim RVUs could then be reviewed with the assistance of HCFA multiple specialty panels. We invite comments on these options and would welcome any other recommendations.

b. Example of the Process for Reviewing and Commenting on Practice Expense Relative Value Units. To facilitate the development of responses to this proposed rule, to illustrate the issues involved in refining the RVUs for practice expense, and to furnish further guidance on the use of the data files that are available on the Internet, we are furnishing the following analysis of an apparent anomaly in a family of codes. This analysis is intended to serve as an example of the process for reviewing and commenting on the practice expense RVUs. We have not concluded that revisions to the RVUs proposed for this family of codes are warranted. In the event that no comments are received on the RVUs for these codes, it is unlikely that we will make any revisions.

In the ophthalmology section of the CPT, there are four codes for the reporting of eye exams. The codes, brief descriptors, and the proposed practice expense RVUs follow:

Code	Descriptor	Practice expense RVUs
92002	Eye exam, new patient, intermediate	0.96
92004	Eye exam, new patient, comprehensive	1.58
92012	Eye exam, established patient, intermediate	1.26
92014	Eye exam, established patient, comprehensive	1.25

We believe there is a rank order anomaly in this family. We expected that the practice expense RVUs for new patients would be higher than the practice expense RVUs for established patients and that the practice expense RVUs for comprehensive visits would be higher than practice expense RVUs for intermediate visits. For example, we expected that CPT code 92014 would have higher practice expenses than CPT code 92012, which is not the case.

To analyze this apparent anomaly, we first reviewed the data on which specialties furnish the services. These data are located on the HCFA Homepage under the file name ''Procedure Code Utilization by Specialty.'' This analysis is important because one potential cause of an anomaly is that codes in a given family of codes are performed by physicians in different specialties whose practice expenses per hour are different. In this case, the dominant specialty performing the codes is ophthalmology. Optometrists also perform these services but with less frequency than ophthalmologists. In Table 2, the sum of the practice expenses per hour for ophthalmology is $131.80, and the sum of the practice expenses per hour for optometry is $67.50. Although the practice expense per hour differs for ophthalmology and optometry because ophthalmology is by far the dominant specialty, this anomaly cannot be attributed to differences in practice expense per hour.

We next reviewed the code-specific data for in-office services on clinical labor, equipment, and supplies that are included in the file ''CPEP Data Converted Into 1998 Dollar Amounts,'' located on the HCFA Homepage. This file is based on the raw CPEP data that have been converted to monetary amounts. It is considerably easier to review than the raw CPEP data because it includes fewer data points per code. (The file containing raw CPEP data, ''Raw CPEP Data'', can also be found in the HCFA Homepage. Both of these files also contain CPEP data for supplies and equipment.)

Code	Descriptor	Clin	Eqp	Sup	Total services	% Ophthalmology	% Optometry
92002	Eye exam, new patient, intermediate.	15.44	11.76	3.41	354,000	48	50
92004	Eye exam, new patient, comprehensive.	16.87	12.85	3.41	1,866,000	72	27
92012	Eye exam, est. patient, intermediate.	11.15	8.49	27.60	6,022,000	85	13
92014	Eye exam, est. patient, comprehensive.	14.01	10.67	3.41	6,980,000	79	20

These data show that the relative relationship within the family of codes appears to be appropriate for clinical staff and equipment. However, for supplies there is a large discrepancy in that the supply costs for code 92012 are eight times greater than the supply costs for the other three codes. To determine whether the supply costs for code 92012 are too high or the supply costs for the other three codes are too low, it is necessary to review the actual supply inputs assigned to the codes by the CPEP. These data may be found as a subdirectory of the file, ''CPEP Data Converted to 1998 Dollars.'' We reviewed the inputs but have made no judgments about them. We believe the inputs should be reviewed by the specialties providing the service.

As can be seen in the table, 85 percent of the code 92012 services are furnished by ophthalmologists, and 13 percent are furnished by optometrists. The table also shows that this is a high volume family of codes and that errors in the CPEP data could cause distortions in the relative relationships of the RVUs assigned to services furnished by ophthalmologists and optometrists. Under our proposed methodology for developing RVUs, any revisions to the CPEP data will primarily impact only those specialties that furnish the service. Thus, if we determine that the supply inputs for code 92012 include items that are not typically furnished and are recommended for removal, that will ''free up'' RVUs that can be redistributed across the other services furnished by the two specialties.

Conversely, if it is determined that the supply inputs for the other three codes are missing items that are typically furnished and are recommended for inclusion, that will require RVUs to be taken from the other services furnished by the two specialties, not from other services on the physician fee schedule. We view this as a significant advantage of our proposed methodology in that the highly contentious atmosphere of refinement under our earlier methodology is greatly reduced because, except when multiple specialties perform the same service, agreement or disagreement with the CPEP inputs of one specialty does not directly impact the RVUs assigned to services furnished by other specialties.

c. Information on Accessing Data Files on HCFA's Homepage. The aforementioned files can be obtained on the HCFA Homepage at ''www.hcfa.gov.'' Following is the step by step process by which the data files can be accessed.

Step 1: After accessing the HCFA Homepage go to Stats and Data.

Step 2: Go to 1999 Resource-Based Practice Expense.

Step 3: Under Resource-Based Practice Expense, you will have the option of accessing one of six files related to resource-based practice expense:

Raw CPEP Data

This file includes the original CPEP data. There are four subgroups within this file:

Clinical Work
Medical Supplies
Procedure Specific Medical Equipment

Overhead Medical Equipment

1998 Code Crosswalks

Since the CPEP data were based upon 1995 data, we performed crosswalks for codes which were new codes in 1996, 1997, and 1998. This file shows the crosswalks that were used for all codes that were new after 1995. In addition, this file also contains those codes gap-filled based on analogous procedures due to an absence of data from the CPEP process.

CPEP Data Crosswalked to 1998 Codes

This file crosswalks all CPEP data to 1998 codes.

CPEP Data Converted to 1998 Codes Converted Into Dollars

This file converts the CPEP data, crosswalked to 1998 codes, into dollars.

Procedure Code Utilization by Specialty

This file shows the Medicare allowed services for each procedure code performed by each specialty.

Time Associated With the Work Relative Value Units

This file contains the time associated with the work RVUs for each procedure.

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

In the June 1997 proposed rule (62 FR 33171), we had recommended reducing the practice expense RVUs for multiple nonsurgical services performed at the same time as an evaluation and management service. We had proposed this as a way to reflect the lower practice costs that would result when more than one service is performed during a single patient encounter. Many commenters, as well as the Medicare Payment Advisory Commission (MEDPAC), recommended that we not implement a multiple procedure reduction, at least until this issue has been further studied.

We have decided not to propose this reduction at this time but will consider it in the future. We invite comments on this specific issue. The current multiple surgical procedure reduction policy with regard to physician work is not affected by the practice expense proposal.

16. Transition

Under the transition enacted under BBA 1997, practice expense RVUs in 1999 are to be based 75 percent on the old method and 25 percent on the resource-based method. In 2000, the shares are 50 percent old method and 50 percent resource-based. In 2001, the shares are 25 percent old method and 75 percent resource-based. Beginning in 2002, practice expense RVUs are entirely resource-based.

In our October 1997 final rule (62 FR 59052), we indicated that the old method to be used in the formula constitutes the 1998 practice expense RVUs actually used for payment. We received a comment that suggested that we consider an alternative interpretation of the law for purposes of the transition starting point that would eliminate the 1998 changes in practice expenses enacted by BBA 1997. This comment was based on the theory that the 1998 changes were for 1 year only and not intended to be included in the base practice expense used for the transition. This alternative would result in higher payments for certain specialty procedures and lower payments for medical visits during 1999, 2000, and 2001. Beginning in 2002, the starting point for the transition does not matter as practice expenses are entirely resource-based.

We have considered this suggestion. We do not believe that we can, as suggested by the commenter, utilize 1997 practice expense RVUs actually used for payment because we do not believe that we could treat the reductions enacted in BBA 1997 for 1998 differently from the similar reductions enacted in OBRA 1993 on practice expenses for 1994, 1995, and 1996. That is, the effects of both amendments should be included in the base or excluded. We believe that the appropriate option, other than using 1998 practice expense RVUs, is to exclude the effects of both the OBRA 1993 and BBA 1997 provisions and revert to practice expense RVUs as they existed before any amendments. We do not believe that this is the better alternative. In addition to creating practical problems of requiring imputation of practice expense RVUs for the many new codes that have been established between 1991 and 1998, it would seem contrary to the statute's plain intent of moving toward a resource-based payment system. This alternative could also potentially result in a ''yo-yoing'' of practice expense RVUs between 1998 and future years. Practice expense RVUs for certain procedures explicitly increased by the Congress in 1998 could be reduced in 1999 only to be increased again when the practice expense is fully resource-based. If we were to use 1997 RVUs as the base for the transitions, payments for office visit procedure codes, for example, would likely decrease noticeably during 1999, reversing the clear policy the Congress enacted in BBA 1997 by raising them. To adopt such a construction of the law would not gradually ''transition'' payments to the new resource-based system, but instead would represent an abrupt change in direction, a result at odds with the purpose of having a transition period and with transitions previously established for payment changes in Medicare. We find nothing in the legislative history to suggest that the Congress intended such an atypical transition. Therefore, we propose to use the 1998 practice expense RVUs for purposes of the blend during the transition years of 1999, 2000, and 2001.

17. Proposed Regulation Revisions

We are proposing to revise § 414.22 (Relative value units (RVUs)), paragraph (b), (Practice expense RVUs), to state that for services beginning January 1, 1999, the practice expense RVUs would be based on a blend of 75 percent of the 1998 code-specific practice expense RVUs and 25 percent of the relative practice expense resources involved in furnishing the service. For services beginning January 1, 2000, the practice expense RVUs would be based on a blend of 50 percent of the 1998 code-specific practice expense 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 would be based on a blend of 25 percent of the 1998 code-specific 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 would be based on 100 percent of the relative practice expense resources involved in furnishing the service.

There would 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 would be two different levels of practice expense RVUs per code. The lower practice expense RVUs would apply to services furnished to hospital or ambulatory surgical center patients. The higher practice expense RVUs would apply to services furnished in a physician office or services other than visits but performed in a patient's home and services furnished to patients in a nursing facility, skilled nursing

facility, or an institution other than a hospital or ambulatory surgical center.

18. Response to GAO Recommendations

As previously discussed, the GAO report to Congress on practice expense made five recommendations for further action; two of these are short term recommendations that are addressed by this proposed rule and three are longer term recommendations that will be addressed during the refinement process. The GAO recommendations are as follows:

• Short Term Recommendations.

+ Use sensitivity analyses to test the effects of the limits we placed on the panels' estimates of clinical and administrative labor and our assumptions about equipment utilization.

We believe that our proposed methodology answers the concerns that prompted this recommendation. Our current proposal has eliminated the limits previously placed on the CPEP panels' estimates of clinical and administrative staff times. In addition, because the proposed methodology is based on specialty-specific RVU pools, changes in assumptions about equipment utilization rates would impact redistributions between specialties only to the extent that codes are performed by more than one specialty.

+ Evaluate the classification of the administrative labor associated with billing and other administrative expenses as indirect expenses, alternative methods for assigning indirect expenses, and alternative specifications of the regression model used to link the panels' estimates.

We again believe that our proposed methodology is responsive to this recommendation. Under our proposal, administrative expenses are treated as indirect costs, and we have developed a method of assigning indirect expenses that we believe most closely reflects the various specialties' actual costs. The third part of the recommendation is now moot as the current proposed methodology no longer utilizes the linking algorithm.

• Longer Term Recommendations.

+ Determine whether changes in hospital staffing patterns and physicians' use of their clinical staff in hospital settings warrant adjustments between Medicare reimbursements to hospitals and physicians. Similarly, we should determine whether physicians have shifted tasks to nonphysician clinical staff in a way that warrants reexamining the physician work RVUs.

+ Work with physician groups and the AMA to develop a process for collecting data from physician practices as a cross-check on the calculated practice expense RVUs and periodically refine and update the RVUs.

+ Monitor indicators of beneficiary access to care, focusing on those services with the greatest cumulative reductions in physician fee schedule allowances, and consider any access problems when making refinements to the practice expense RVUs.

We agree with all of these recommendations. One of the major tasks of any proposed refinement process will be determining when any additional data are need, whether it be on physician practice patterns or actual practice expenses. We welcome comments and suggestions on how best to carry out these recommendations to aid us in developing a strategy for data gathering in our final rule. We plan to monitor access to care.

B. Medical Direction for Anesthesia Services

The conditions for payment of medical direction were discussed in the March 2, 1983 final rule (48 FR 8902) that implemented section 108 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, effective October 1, 1983.

TEFRA added section 1887 to the Act and required that we distinguish between services furnished by physicians to patients that are now payable under the physician fee schedule and services furnished by physicians to hospitals that are reimbursed to the hospital on a prospective payment basis for inpatients or on a reasonable cost basis for outpatients.

Section 1887 of the Act did not, however, include a reference to ''medical direction.'' This is a term we adopted from the medical profession that refers to the necessary level of direct involvement of the anesthesiologist in each of two to four concurrent anesthesia procedures so that the service meets the definition of physician services as required by section 1887 of the Act.

Our definition of medical direction closely followed the standards of anesthesia care team practice promulgated by the American Society of Anesthesiologists (ASA).

The conditions for payment of medical direction are included in § 415.110 (Conditions for payment: Medically directed anesthesia services). For each patient, the physician must furnish seven kinds of services, and the physician may not perform any other services while he or she is directing the concurrent procedures unless they meet the exception as noted. The medical direction activities in § 415.110(a) (Services furnished directly or concurrently) are as follows:

• Performs a pre-anesthesia examination and evaluation.

• Prescribes the anesthesia plan.

• Personally participates in the most demanding procedures in the anesthesia plan, including induction and emergence.

• 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.

• Monitors the course of anesthesia at frequent intervals.

• Remains physically present and available for immediate diagnosis and treatment of emergencies.

• Provides indicated post-anesthesia care.

The regulations currently refer 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 proposing to delete the reference in the regulations to services furnished directly.

The December 1995 final rule (60 FR 63152) included the policy to allow 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.

We are 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 Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) added section 1848(a)(4)(Special Rule For Medical Direction) to the Act. This section of the

Act specified the calculation of the payment allowances for medical direction services on or after January 1, 1994. Thus, the specific payment policy is specified in the law. The law provides that the medical direction of the performance of an anesthesia service 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 the current requirements are outdated and too restrictive. The current requirements are oriented to the administration of a general anesthetic, which was the predominate 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, which are becoming more common and for which 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 have reached consensus on a revised recommended set of medical direction requirements. We have reviewed their recommendations and are proposing to revise our regulations in § 415.110 (Conditions for payment: Anesthesia services) to reflect current anesthesia practice arrangements. Namely, we would:

- 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.
- Require that the physician monitor the course of anesthesia at intervals medically indicated by the nature of the procedure and the patient's condition.

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

With the exception of hospital inpatients, we currently do not allow separate payment for the physician's interpretation of an abnormal Papanicolaou (Pap) smear.

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 the physician 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 service.

The clinical laboratory fee schedule allowances were initially derived from the 1984 prevailing charges made by independent laboratories for the Pap smear test. Historically, independent laboratories did not bill separately for the physician interpretation of the abnormal Pap smear; thus, no separate allowance was established. Therefore, the initial clinical laboratory fee schedule allowances reflect payment for both the test and any associated interpretation.

The 1998 clinical fee schedule national allowance for the Pap smear test is $7.15. The 1998 physician fee schedule national allowance for the physician interpretation of the abnormal Pap smear for a hospital inpatient is $28.62.

The College of American Pathologists requested we recognize separate payment for the physician interpretation of the abnormal Pap smear in all settings. We believe this proposal would establish an understandable and uniform definition of physician services across sites. Therefore, we are proposing to recognize, under the physician fee schedule, separate payment for the physician interpretation of an abnormal Pap smear in all settings.

The Pap smear test may be furnished by a hospital or an independent laboratory. The independent laboratory could bill for the complete service: the technical component (the performance of the test) and the professional component (the interpretation of the test) furnished by the independent laboratory's pathologist. 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.

D. Rebasing and Revising the Medicare Economic Index

1. Background

a. History. In the 1972 Amendments to the Act (Public Law 92–603) enacted on October 30, 1972, the Congress mandated the use of an economic index in determining payment for physician services under Medicare Part B. Although the 1972 Amendments did not specify the particular type of index to be used, we established the Medicare Economic Index (MEI). The MEI follows the recommendations outlined by the Senate Finance Committee in its report accompanying the legislation in that it attempts to present an equitable measure for changes in the costs of physician time and operating expenses.

The current MEI represents a weighted sum of annual price changes for various inputs needed to produce physician services. Since its inception, the MEI has consisted of two principal components or expense categories—physician net income and physician practice expenses. Physician net income is further delineated into wages and salaries and benefits. The physician practice expense portion is delineated into six major categories: (1) Nonphysician employee compensation, which includes the wages and salaries and benefits of nonphysician employees in physician offices; (2) office expenses; (3) medical materials and supplies; (4) professional liability insurance; (5) medical equipment; and (6) other professional expenses. These broad expense categories are still the major expense shares in the proposed MEI and are discussed in greater detail in the following sections.

b. Use of Current Data. The MEI was last rebased and revised in the November 25, 1992 final rule (57 FR 55896). The current base year for the MEI is 1989. We believe that it is desirable to rebase and revise the index periodically so that the expense shares and proxies will reflect current conditions. For this reason, we are proposing to rebase the MEI to reflect 1996 physician expenses and review the proxies we currently use to ensure using 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 productivity and economy-wide productivity in the physician update framework.

The proposed MEI expense categories were derived primarily from the 1997 AMA SMS, which measured physician earnings and practice expenses for 1996.

The AMA data were used to set expenditure weights for physician earnings and the six major physician practice expense categories. To further disaggregate into subcategories reflecting more specific physician expenses, we used data from the 1992 Asset and Expenditure Survey, the 1996 Bureau of the Census Current Population Survey, the 1997 Bureau of Labor Statistics Employment Cost Index, and the *Medical Economics* Continuing Survey data for 1996.

2. Rebasing and Revising Expense Categories

Developing a rebased and revised MEI requires selecting a base year and determining the number and composition of expense categories. As mentioned earlier, we are proposing to rebase the MEI to 1996. 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 proposing to use; and (2) the 1996 data were representative of the changing distribution of physician earnings and practice expenses over time.

We determined the number and composition of expense categories based on the criteria used to develop the current MEI expenditure weights and our other input price index expenditure weights (for more information on these criteria see the November 25, 1992, proposed rule (57 FR 55900)). Using these criteria of mutually exclusiveness and exhaustiveness, we developed the rebased and revised MEI presented in Table 4.

TABLE 4.—REVISED MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	Weights 1989 (1)	Weights 1996 (1 2)	Proposed price proxies
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	
Non-Physician 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.

Footnotes:
(1) Due to rounding, weights may not sum to 100.000%.
(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 non-farm business sector.
(4) Includes employee physician payroll.
(5) Includes paid leave.

To determine the expenditure weights, we used currently available and statistically 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 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. The use of each of these data sources is described in detail below.

a. American Medical Association Socioeconomic Monitoring System Survey. Like the current MEI, the proposed MEI will use AMA data on mean physician net income (physician earnings) and professional expenses for self-employed physicians for the major expenditure categories. The seven major expenditure categories taken from the AMA data, as shown in Table 1, are physician earnings, nonphysician employee compensation, office expenses, medical materials and supplies, professional liability insurance, medical equipment, and other professional expenses. The weights represent each expenditure category's proportion of total expenses in 1996. While many of the category weights have changed since 1989, the effect on the percent change in the MEI has been minimal, as explained later.

The physician earnings expenditure category in the rebased MEI is defined differently from the one in the current MEI as it includes employee physician compensation. Until recently, employee physician compensation was not available through the AMA survey and was not included in any AMA expenditure categories. AMA reported these data separately in 1996. We believe it is appropriate, for our purposes, to include employee physician compensation in the MEI category of physician earnings. The physician income (earnings) and overhead expenses generated by employee physicians are currently included in the AMA expenditure

categories. We propose including employee physician payroll in physician earnings to be consistent with the current methodologies used in payment under the physician fee schedule. Under the physician fee schedule, the work RVU is paid based on the service provided and not on who provides the service. Since employee physicians do the same services as self-employed physicians, employee physician time would be included in the work RVU. By including employee physician compensation in the physician earnings category for the MEI, we have achieved two goals: (1) Appropriately categorizing these expenses to be consistent with the physician fee schedule; and (2) adjusting these expenses by the appropriate price proxies for a physician's own time. A detailed discussion of the price proxies is presented below.

b. Employment Cost Index Survey. The Employment Cost Index (ECI) survey has shares of total compensation for wages and salaries and benefits by private industry health services occupational category that can be used to allocate the wage and fringe benefit shares for nonphysician employees. The data on these shares are produced for March of every year. We determined that March 1997 would be most representative of the shares in 1996 because the March 1996 data would miss any changes that occurred during the last three quarters of that year. The shares are determined from employer costs per hour worked. Paid leave is defined as a benefit under this survey. Unfortunately, this survey does not have data for offices of physicians. However, data are available on wage and fringe benefit shares for total health services that include hospitals, nursing homes, offices of physicians, and offices of dentists. While not a direct measure of employee wage and fringe benefit shares in offices of physicians, the shares for health services from the ECI survey do provide a normative estimate of the split between wages and fringes.

In the ECI survey for total health services, the wage and fringe benefit split of compensation was 73.9 percent and 26.1 percent, respectively. For comparison purposes, when we included paid leave as part of wages, these shares were very similar to nonphysician employee wage and fringe benefit share data from two physician group practice studies. Based on this analysis, we are proposing to use the wage and fringe benefit shares for total health services from the ECI survey, with paid leave as a benefit, in the rebased and revised MEI for nonphysician employee compensation. The wage and fringe benefit shares for physicians and nonphysician compensation in the current MEI were developed from a special study conducted by our Office of the Actuary. These current and revised shares are presented in Table 1.

c. Asset and Expenditure Survey. We are proposing to use the 1992 Bureau of the Census Asset and Expenditure survey to derive an estimate of the wage and fringe benefit share for physicians under the MEI. The wage and fringe benefit share for all persons employed in physician offices is available from the 1992 Asset and Expenditure survey. This share includes both physicians and nonphysician employees in the physician office. By aging this share to 1996 using the ECI for wages and fringe benefits for total health services and moving paid leave from wages to fringe benefits based on analysis of ECI data on health services, we were able to develop a wage and fringe benefit share for physician offices for 1996. The wage share for physician offices was 79.4 percent, and the fringe benefit share 20.6 percent. Using this wage and fringe benefit share, the wage and fringe benefit share for nonphysician employees developed from the ECI survey, and the share for physician and nonphysician compensation developed from the AMA survey, we were able to impute a wage and fringe benefit share for physicians. The wage share was 81.2 percent, and the benefit share 18.8 percent for physicians. We compared these shares to physician group data on physician wage and fringe benefit shares and found them to be very consistent. Therefore, we are proposing to use these wage and fringe benefit shares for physicians in the rebased and revised MEI, as shown in Table 1.

d. Current Population Survey. We are proposing to use the 1996 Current Population Survey (CPS) from the Bureau of the Census to determine the distribution of nonphysician employee wages in the rebased and revised MEI. The 1989 CPS was used to determine the distribution for the current MEI. The new distribution is presented in Table 5. Craft and kindred workers are no longer included in the distribution because their share is not significant.

TABLE 5.—PERCENT DISTRIBUTION OF NON-PHYSICIAN 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.

e. Medical Economics Continuing Survey. Consistent with the current MEI, we are proposing to use the *Medical Economics* Continuing Survey to determine the weight for automobile (professional car) expenses. We used the 1996 Continuing Survey published in the October 27, 1997, *Medical Economics* (Finger, 1997) to determine a weight of 1.3 percent in the proposed MEI for automobile expenses, which is nearly identical to the 1.4 percent share in the current MEI.

3. Selection of Price Proxies

a. Background. After the 1996 cost weights for the revised MEI were developed, we reviewed the current set of price proxies to determine whether they were still the most appropriate to monitor the rate of price change for each expenditure category. As was the case in 1992 (57 FR 55901), most of the indicators we considered are based on BLS data and are grouped into one of the following five categories:

- Producer Price Indices (PPIs). PPIs measure price changes for goods sold in other than retail markets. They are the preferred proxies for physician purchases at the wholesale level. These fixed-weight indexes are a measure of price change at the producer or at the intermediate stage of production.
- Consumer Price Indices (CPIs). CPIs measure change in the prices of final goods and services bought by consumers. Similar to the PPIs, they are fixed-weight. CPIs may not represent the price changes faced by producers. For this reason, CPIs were used absent an appropriate PPI or if the expenditure was similar to that of retail consumers in general, rather than to a purchase at the wholesale level.
- Average Hourly Earnings (AHEs). AHEs permit the measurement of changes in hourly earnings for production and nonsupervisory workers for specific industries as well as the nonfarm business economy. AHEs are calculated by dividing gross payrolls for wages and salaries by total hours. The

series reflects shifts in employment mix and, thus, is representative of actual changes in hourly earnings for industries or for the nonfarm business economy.

- ECIs for wages and salaries. These ECIs measure the rate of change in employee wage rates per hour worked. These fixed-weight indices are not affected by shifts in industry or occupation employment levels.
- ECIs for employee benefits. These ECIs measure the rate of change in employer costs of employee benefits such as the employer's share of Social Security taxes, pension and other retirement plans, insurance benefits (life, health, disability, and accident), and paid leave. Like ECIs for wages and salaries, they are not affected by changes in industry output or occupational shifts.

As with choosing the expenditure categories, choosing appropriate wage and price proxies for each expense category necessarily involves making tradeoffs and using judgment. The strengths and weaknesses of each proxy variable need to be evaluated using several criteria that can potentially conflict.

The first criterion is relevance. The price variable should appropriately represent price changes for specific goods or services within the expense category. Relevance may encompass judgments about relative efficiency of the market generating the price and wage increases and may include normative factors relating to fairness.

The second criterion is reliability or low sampling variability. If the proxy wage-price variable has a high sampling variability or inexplicable erratic patterns over time, its value is greatly diminished since it is unlikely to reflect accurately price changes in its associated expenditure category. Low sampling variability can conflict with relevance since the more specifically a price variable is defined in terms of service, commodity, or geographic area the higher the sampling variability in some cases.

Timeliness of actual published data is the third criterion. For this reason, monthly and quarterly data take priority over annual data.

The fourth criterion is the length of time the time-series data has been in use. A well-established time series is needed to assess the reasonableness of the series and to provide a solid base from which to forecast future price changes in the series. Forecasting the MEI is required to make Federal budget and Trustee's report estimates.

The BLS price proxy categories previously described meet the criteria of relevance, reliability, timeliness, and time-series length. The price-wage proxies for the rebased and revised MEI (shown in Table 1) are the same as those chosen for the current MEI.

b. Expense Categories. (1) Physician Time

Because the revenue associated with physician time is the single largest cost component in the MEI (54.5 percent), the selection of the price proxy for wages and salaries cost category is a major determinant of the rate of change in the MEI. For that reason, we are furnishing an extensive discussion of the selection of the price proxy for the wages and salaries component as we did in the November 1992 final rule (57 FR 55903). We have found no compelling reason to change the wage proxy for this expense category and offer the same rationale that we used in the November 1992 final rule.

The legislative history of the MEI reveals Congressional concern that increases in physician charges are a cause, rather than a result, of inflation. The following language from the Senate Finance Committee report accompanying the 1972 Social Security Amendments makes that point clearly:

> The committee * * * believes that it is necessary to move in the direction of an approach to reasonable charge reimbursement that ties recognition of fee increases to appropriate economic indexes so that the program will not merely recognize whatever increases in charges are established in a locality but would limit recognition of charge increases to rates that economic data indicate would be *fair to all concerned* (emphasis added) and follow rather than lead inflationary trends. * * * Initially, the Secretary would be expected to base the proposed economic indexes on presently available information on changes in expenses of practice and general earnings levels. * * * S. Rep. No. 1230, 92d Cong., 2d Sess. 190–191 (1972).

There is obvious circularity if increases in prevailing charges are linked to increases in physician charges, which are then tied to increases in physician income. The committee's expectation that the rate of price inflation assigned to the physician time portion of the MEI be permitted to increase by an amount consistent with increases in general earnings levels seems to reflect the Congress' preference for an equitable external price proxy; that is, a compensation proxy based on compensation outside or external to the physician services industry. We examined the following three principal alternatives for the wages and salary component of the physician time cost category:

- The use of AHEs for production and nonsupervisory workers in the private nonfarm economy.

This option suggests a standard of payment that implies that price increases for the physician labor component should be the same as for workers in the overall economy, that is, general earnings. This option presumes that the price increase for the physician time category (excluding fringe benefits) should reflect the changing mix of industry output and employment. This alternative appears to reflect most closely the Senate Finance Committee's reference to general earnings levels. Since earnings are per hour, a constant quantity of labor input per unit of time is reflected. In addition, the use of the AHEs data is consistent with the BLS labor productivity measures. The revised MEI as well as the current MEI incorporates an adjustment for economy-wide labor productivity to preclude a double-counting of productivity. Economy-wide wage increases reflect economy-wide productivity increases. In addition, physician practice productivity increases associated with the fee-for-service Medicare payment system automatically result in revenue increases for the individual physician practices. Economy-wide productivity increases are adjusted out of the compensation portion of the MEI so that individual physician practices get all of their own productivity increases, but not economy-wide productivity increases as well. The adjustment will continue to be for the 10-year moving average change in productivity.

- The use of ECIs for wages and salaries of the total private nonfarm economy.

This option suggests a standard of payment that implies that price increases for the physician labor component should be the same as that for workers in a hypothetical, overall economy in which there are no shifts in the employment patterns of workers. The overall ECI weighs nine broad occupational categories and permits measurement of the change in the hourly straight time wage rate for private industry workers (Nathan, 1987 and Schwenk, 1985). ECIs are unaffected by changes in occupational employment shifts or industry output shifts. Therefore, this alternative would not recognize changes in the composition of the work force over time as intended by the Senate Finance Committee.

- The use of an ECI for wages and salaries for private professional and technical workers.

This proxy implies that price changes in the physician time component, excluding fringe benefits, should correspond to those for private sector professional and technical workers. The professional and technical workers category is one of the nine categories that comprise the overall ECI. Physicians are a tiny subset of this occupational group. The supply, demand, and opportunity cost characteristics of this broad category, however, may be different from the supply, demand, and opportunity cost characteristics of an efficient market for physician services. Most professional and technical workers are in labor markets where firms compete for employees. Most office-based physicians are self-employed. Some occupations within the professional and technical group are in short supply leading to upward pressure on compensation levels. Use of this price series would take the MEI away from the general earnings specified in the enacting legislation.

Each of the above options implies a different standard of equity. In Table 6, we compare the annual rates of change in the MEI using three different price variables for physician earnings suggested as options.

TABLE 6.—COMPARISON OF ANNUAL PERCENT CHANGES IN THE MEI WITH ALTERNATIVE PHYSICIAN WAGE PRICE PROXIES

Year ending June 30	Revised MEI with alternative proxies for physicians' own time		
	AHE: total private nonfarm	ECI: wages/salaries for total private	ECI: wages/salaries for professional and technical
1992	2.8	3.1	3.4
1993	2.2	2.3	2.7
1994	2.1	2.3	2.3
1995	2.0	2.1	2.0
1996	1.9	1.9	1.8
1997	2.3	2.2	2.0
Average: 1992–1997	2.2	2.3	2.4

The proposed MEI uses AHEs for the private nonfarm economy as the proxy of choice for the physician wages and salaries component of the input price index and is the same price measure used in the 1989-based MEI. In our judgment, this alternative remains the one that most closely comports with Congressional intent as expressed in the Senate Finance Committee's 1972 report referenced above. AHEs change in accordance with market forces associated with changes in the type and mix of workers. This is not the case with ECIs, since ECIs reflect a fixed composition of the work force at a given time. Therefore, the rate of change in an ECI may differ substantially from an actual AHE measure.

The current MEI uses the ECI for fringe benefits for total private industry as the price proxy for fringe benefits. We propose using the same proxy for the 1996-based MEI. This means that both the wage and fringe benefit proxies for physician time are derived from the nonfarm private sector and are both computed on a per-hour basis.

(2) Nonphysician Employee Compensation. As in the 1989-based MEI, we are proposing to use the 1996 Current Population Survey data on earnings and employment by occupation to develop labor cost shares for the nonphysician occupational groups shown in Table 5. BLS maintains an ECI for each of these occupational groups and we are proposing to use these as price proxies for nonphysician employee wages in the same manner they are used in the current MEI. We multiplied each of the occupational cost shares by the changes in the occupational ECI for that category. These values were summed to yield an overall rate of price change.

The skill mix shift in physician offices has been substantial in the last few years as work formerly done in the hospital increasingly is done in ambulatory settings. These skill mix shifts appropriately are held constant in this Laspeyres index of nonphysician employees' wages and salaries. Skill mix shifts that reflect rising intensity of outputs in physician offices are automatically paid for by higher charge structures for the more complex mix of service inputs. Physicians performing more complex services may hire more skilled employees, and, thus, may tend to charge more for their services.

The current MEI uses the ECI for fringe benefits for white collar employees in the private sector. Most nonphysician employees in physician offices are white collar employees. We are proposing to use the ECI for benefits for white collar employees in the rebased and revised MEI. Note that we will continue to adjust the nonphysician employee compensation portion of the MEI by the 10-year moving average change in economy-wide productivity since physician practice productivity is being recognized.

(3) Office Expense. Office expenses include rent or mortgage for office space, furnishings, insurance, utilities, and telephone. We are proposing the continued use of the CPI–U for housing because it is a comprehensive measure of the cost of housing including rent, owner's equivalent rent, insurance, maintenance and repair services, fuels, utilities, telephones, furnishings, and housekeeping services. This proxy covers about 80 percent of the population.

(4) Medical Materials and Supplies. This cost category includes drugs, outside laboratory work, x-ray films, and other related services. There is no price proxy that includes this mix of materials and supplies. In the absence of one index, in the 1989-based MEI we equally weighted the following three price proxies associated with the medical materials and supplies listed above:

- The PPI for ethical drugs.
- The PPI for surgical appliances and supplies.
- The CPI–U for medical equipment and supplies.

We propose using the same blended proxy for the 1996-based MEI.

(5) Professional Liability Insurance. This cost category includes costs for professional medical liability or malpractice insurance premiums including costs associated with self-insurance. Changes in the cost of medical liability insurance premiums currently are measured based on our survey of the rate of change in average liability premiums for $100,000/$300,000 coverage (that is, $100,000 for per-case limitation and $300,000 for total coverage or the minimum furnished) among major insurers. We measured change with historical data each January 1 and interpolated quarterly changes for March, June, and September.

We improved the professional medical liability index in two major ways. First, we used actual rates for $1 million/$3 million premiums in the index for the most current historical period and estimated them for earlier years. Starting with 1996 levels and 1997 percentage changes, rates for $1 million/$3 million premiums will be computed; in future periods we will use premiums for $1 million/$3 million of coverage.

Second, the revised index uses data on a quarterly basis that is calculated into a four-quarter moving average percent change like all our other price proxies. We achieve this by tracking the premium changes that occur during each quarter. We gathered historical premium data back to 1992 and established average premium levels based on the mix of physicians by specialty in 1996. We calculated four-

quarter moving averages and percent changes from 1992 through 1997 to more accurately forecast changes in premium levels for future budget and Trustees' report estimates. The previous method obtained the premium change only for January 1 of each year.

We are proposing the changes described above because we believe they will improve the quality of measuring change in physician professional medical liability premiums. Far more physicians have $1 million/$3 million coverage rather than $100,000/$300,000 coverage. Taking quarterly measurements and computing a four-quarter moving average percent change is the same methodology used for all the other price proxies. The resulting series better captures the changes through the year.

(6) Medical Equipment. Medical equipment includes depreciation, leases, and rent on medical equipment. We propose to use the PPI for medical instruments and equipment as the price proxy for this category, consistent with the price proxy used in the 1989-based MEI.

(7) Other Professional Expenses. This category has two subcomponents: professional car and ''other.'' The professional car category includes depreciation and upkeep for the practice-related use of a professional car. We are proposing the continued use of the CPI–U for private transportation for this cost category, consistent with the price proxy used in the 1989-based MEI. This excludes airline fares, inter-city bus and train transportation, and intra-city bus and train transportation.

This category also includes the residual subcategory of other expenses. This residual category includes professional expenses such as accounting services, legal services, office management services, continuing education, professional association memberships, journals, and other professional expenses. In the absence of one price proxy or even a group of price proxies that might reflect this heterogeneous mix of goods and services, we use the CPI-U for all items less food and energy, consistent with the price proxy used in the 1989-based MEI.

4. Summary of Changes

Updating the MEI to the 1996 base year resulted in small changes in expense category weights. Physician earnings increased slightly from 54.2 percent of the index in 1989 to 54.5 percent in 1996. Physician practice expenses dropped slightly due to declines in the expense shares for medical materials and supplies, professional liability insurance, and medical equipment. These declines were mostly offset by increases in the expense shares for nonphysician employee compensation, office expenses, and other professional expenses.

TABLE 7.—ANNUAL PERCENT CHANGE IN THE CURRENT AND REVISED MEDICARE ECONOMIC INDEX

Years ending June 30	Current MEI 89-base % change	Revised MEI 96-base % change	Difference
1985	3.3	3.2	−0.1
1986	3.3	3.0	−0.3
1987	3.0	2.7	−0.3
1988	3.6	3.4	−0.2
1989	3.4	3.5	0.1
1990	3.0	3.4	0.4
1991	3.2	3.4	0.2
1992	2.8	2.8	0.0
1993	2.1	2.2	0.1
1994	2.1	2.1	0.0
1995	2.0	2.0	0.0
1996	2.1	1.9	−0.2
1997	2.2	2.3	0.1
Average 1985—1997	2.8	2.8	0.0

The rebased and revised MEI is very similar to the current MEI. Using the new expense category weights and new proxy for professional medical liability premiums, the difference in the annual percent change in the index is within two-tenths of one percent in most years from 1985 through 1997. The average annual percent change from 1985 to 1997 was identical. Thus, this revision and rebasing, while making the expense shares more timely, has little impact on the percent changes in the MEI as a whole.

III. Implementation of the Balanced Budget Act of 1997 (BBA 1997)

In addition to the resource-based practice expense relative value units, BBA 1997 provides for revisions to the payment policy for drugs and biologicals, a provision allowing private contracting with Medicare beneficiaries, payment for outpatient rehabilitation services based on the physician fee schedule, and revisions to our policy for nonphysician practitioners.

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 drugs and biologicals. Examples of drugs that are paid on this basis are drugs furnished incident to a physician 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 1997 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 proposed rule, we are revising the current regulations at § 405.517 to conform to this statutory change. This regulation would remove 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 proposing to revise 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, we are proposing that the AWP for multiple-source drugs would equal the lower of the median price of the generic AWPs or the lowest brand name AWP.

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. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. This section, which was effective on January 1, 1998, and was implemented through operating instructions, counters the effect of certain provisions of Medicare law that, absent section 4507 of BBA 1997, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits.

Specifically, section 1848(g) of the Act restricts the amounts that can be collected from beneficiaries by nonparticipating physicians who do not take assignment on the Medicare claim (physicians who take assignment

voluntarily agree to accept the Medicare payment amount as payment in full and collect only deductible and coinsurance amounts from the beneficiary). Moreover, section 1842(b)(18) requires certain practitioners to take assignment when they furnish covered services to Medicare beneficiaries and restricts what they can collect from beneficiaries to deductible and coinsurance amounts. The statute not only imposes these rules (without an exception before passage of section 4507 of BBA 1997), but it also provides strong sanctions for violation of them. Hence, Medicare law absent section 4507 effectively precludes a physician or practitioner from privately contracting with a Medicare beneficiary for the delivery of Medicare-covered items and services, except in compliance with these rules (for example, to pay more than the limits set by law). Section 4507 of BBA 1997 permits such private contracting, provided the requirements of BBA 1997 are met.

The private contracting provision was effective for private contracts entered into, on, or after January 1, 1998. We implemented it through a series of operating instructions for Medicare carriers and information that carriers were instructed to provide to physicians and practitioners. Specifically, in November 1998, we issued Program Memorandum No. B–97–9 (change request number 294) that transmitted the Medicare fee schedule for physician services and contained the fact sheet that carriers were instructed to send to physicians and practitioners with the 1998 fee schedule information. This document, which is commonly called the ''Dear Doctor letter,'' advised physicians and practitioners of the fee schedule amounts for 1998, the changes to regulations, and also the important changes that BBA 1997 made to coverage and payment for physician services, including the private contracting changes.

Due to the private contracting provisions, we extended the participating enrollment period to February 2, 1998, to give physicians sufficient time to consider the changes made by BBA 1997 before making a participation decision. In January 1998, we issued Program Memorandum No. B 97–17 (change request number 193), that was devoted in its entirety to private contracting and not only laid out the processes that would apply but also answered the most frequently asked questions about private contracting. Carriers were instructed to share this information with physicians and practitioners through carrier bulletins.

Lastly, in April 1998, we issued Program Memorandum No. B 98–12 (change request number 468), which amended the process to be followed when the carriers receive a claim from a physician or practitioner who has opted-out of Medicare under the private contracting provision and thus should not bill Medicare.

We are using this proposed rule to place in regulations the requirements that section 4507 of BBA 1997 added to sections 1802(b) and 1862(a)(19) of the Act. In addition to placing the statutory requirements in regulations, this proposed rule also proposes ancillary policies that we believe are necessary to clarify what it means when a physician or practitioner exercises his or her ability to ''opt out'' of Medicare.

There has been a lot of confusion and misinformation about when private contracts are needed. Before we discuss our proposed rules governing private contracting, we want to address some of the most common questions about Medicare claims submission rules and private contracting.

• Do the private contracting rules apply to Part A?

No. The Medicare claims submission and private contracting rules apply only when a physician or practitioner furnishes Medicare-covered services to a beneficiary who is enrolled in Medicare Part B. They do not apply to individuals who have only Medicare Part A or to individuals who are age 65 or over but who do not have Medicare. Therefore, if the patient is not enrolled in Medicare Part B, a private contract is not needed for the physician or practitioner to continue to bill the patient and to charge without regard to the Medicare mandatory claims submission and limiting charge rules.

The private contracting provision of the statute defines ''beneficiary'' (for purposes of that section only) as a person who is eligible for Part A or who is enrolled in Part B. However, the private contracting provisions of the law set aside the mandatory claims and limiting charge rules that apply only to Part B. Therefore, notwithstanding the statutory definition of the term ''beneficiary'' to mean, in part, an individual who is eligible for Part A, as a practical matter section 4507 applies only to services furnished to an individual who is enrolled in Part B.

• Must a physician or practitioner who provides services that are not covered by Medicare sign a private contract with the beneficiary and opt-out of Medicare to be paid for noncovered services?

No. Since Medicare rules do not apply to services that Medicare does not cover, a section 4507 private contract is not needed to bill for them, and neither the Medicare claims submission nor the Medicare limiting charges rules apply to these services. A private contract is needed only for Medicare-covered services and then only if the physician or practitioner is opting-out or has opted-out.

A physician or practitioner may furnish a service that Medicare covers under some or many circumstances but that would likely be deemed as not reasonable and necessary by Medicare in a particular case (for example, multiple nursing home visits, some concurrent care services). In that particular case, the physician or practitioner should give the beneficiary an advance beneficiary notice (ABN) that states the service may not be covered by Medicare and that the beneficiary will be liable to pay for the service if it is denied. If the claim is denied by Medicare, a private contract is not necessary to permit the physician or practitioner to bill the beneficiary for the service.

• What are the rules governing claims submission to Medicare?

There are situations where a physician or practitioner who has not opted-out of Medicare is not authorized to submit a claim for a covered item or service provided to a Medicare beneficiary. A beneficiary, for reasons of his or her own, may decline to authorize the physician or practitioner to submit a claim or to furnish confidential medical information that is needed to submit a proper claim to Medicare. For example, the beneficiary may not want information about the beneficiary's mental illness or HIV/AIDS status to be disclosed to anyone. If the beneficiary does not sign the claim or otherwise authorize the claim submission, the physician or practitioner should not submit the claim to Medicare. However, the limiting charge would apply to the service. Moreover, if the beneficiary or his or her legal representative later decides to authorize the submission of a claim for the service and asks the physician or practitioner to submit the claim, the physician or practitioner must do so.

Where the beneficiary authorizes the claim submission, physicians and practitioners must submit claims for services furnished to an individual enrolled in Medicare Part B unless they have opted-out of Medicare under the private contracting provisions of the law.

Physicians and practitioners who furnish services to a Medicare beneficiary need not submit claims to Medicare in the following cases:

- The beneficiary is not enrolled in Medicare Part B; Medicare limiting charge does not apply.
- The beneficiary refuses to authorize the physician or practitioner to submit a claim for a covered service to Medicare; Medicare limiting charge does apply.
- The service is categorically noncovered (for example, hearing aids and meals on wheels for diabetics); Medicare limiting charge does not apply.
- The service is not covered because the beneficiary is enrolled in a Medicare risk HMO and the HMO will not pay for the service because the physician or practitioner is outside of the HMO's network; Medicare limiting charge does not apply.

Provisions of the proposed rule relating to private contracting.

Definitions

In § 405.400, we define certain terms. We are proposing to define ''beneficiary'' to mean an individual who is enrolled in Part B of Medicare. As we discussed above, the statute's definition of the term has created considerable confusion about whether physicians must opt-out of Medicare to charge individuals who are over age 65 and eligible for Part A of Medicare but who are not enrolled in Part B of Medicare. We believe it is necessary to define the term ''beneficiary'' as being limited to an individual who is enrolled in Part B of Medicare in order to avoid continued confusion on this issue. We believe that having a definition that differs from the statute's definition is justified because the context in which the definition is used is that of Part B claims submission rules, Part B limiting charges, and coverage of Part B services. None of these policies is applicable to individuals who are not enrolled in Part B of Medicare.

We propose to define ''emergency care services'' as being services furnished to an individual who has an ''emergency medical condition'' as that term is defined in § 489.24. Reliance on the longstanding definition of emergency medical condition is, we believe, an appropriate and useful way to define emergency care services.

We are proposing to define ''legal representative'' to mean an individual who has been appointed as the Medicare beneficiary's legal guardian under State law, or who has been granted a power of attorney from the beneficiary, which power of attorney is sufficient to permit the individual to enter into private contracts on the Medicare beneficiary's behalf. This is necessary to clarify that, if a beneficiary has a legal representative, that party can act on the beneficiary's behalf when signing a private contract. We recognize that this is a strict standard and we invite comments on it. However, our concern is that we ensure that only parties who were authorized to make legal and financial commitments on behalf of the beneficiary be permitted to sign private contracts on a beneficiary's behalf since signing such a contract may incur a significant debt for a beneficiary.

We are defining the term ''opt-out'' to mean the status of meeting the conditions specified in § 405.410. When the physician or practitioner meets these conditions, he or she ceases to be bound by Medicare's mandatory claims submission rule and, in the case of a physician, the limiting charge rule or, in the case of a practitioner, the mandatory assignment rule.

We are defining ''participating physician'' to mean a physician as defined in this section who has signed an agreement to participate in Part B.

We are defining ''physician'' to mean a doctor of medicine or a doctor of osteopathy (who is legally authorized to practice as such in the State in which he or she practices). This is the statutory definition of the term for purposes of this section as specified in section 1802(b)(5)(B) of the Act.

We are defining ''practitioner'' to mean any of the following to the extent that the individual is legally authorized to practice as such by the State where he or she furnishes services: a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, and clinical social worker. These practitioners are those included in the statutory definition of practitioner for this purpose in section 1802(b)(5)(C) of the Act, that incorporates by reference those practitioner types listed in section 1842(b)(18)(C) of the Act.

We are defining ''private contract'' to mean a document that meets the criteria in § 405.415.

We propose to define ''properly opt-out'' to mean to fully complete the requirements in § 405.410, each of which must be met for the physician or practitioner to opt-out of Medicare and furnish items or services under a private contract.

We propose to define ''properly terminate opt-out'' to mean to fully complete the requirements in § 405.445, each of which must be met for the physician or practitioner who has opted-out of Medicare to terminate his or her opt-out.

We are proposing to define ''urgent care services'' as services that are provided to an individual who requires services to be furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

We also adopted the concept of ''emergency medical condition'' as defined in § 489.24 to help define urgent care services because the former term has a longstanding history of use in Medicare with respect to when a hospital must furnish emergency care to an individual who appears at its door (specifically, the ''anti-dumping'' rules). We have no standardized definition of ''urgent care services.'' We have been unable to find a definition of an ''urgent care service'' in standard usage. However, we think that an urgent care service would appropriately be any service that needs to be furnished without significant delay so as to avoid the onset of an emergency medical condition. Therefore, we are proposing that an ''urgent care service'' is one that needs to be furnished within 12 hours of the determination of need in order to avoid the individual's condition from becoming an emergency medical condition. The chief distinction between urgent care services and emergency care services is that urgent care services do not have to be furnished ''immediately'' as do ''emergency care services.''

General Rules

In § 405.405, we specify the general rules that apply to private contracting. Specifically, in § 405.405(a), we state that a physician or practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare when the requirements of these rules are met. This is required by section 1802(b)(1)of the Act.

In § 405.405(b), we specify that a physician or practitioner who enters into at least one private contract with a Medicare beneficiary under this provision, and who submits one or more affidavits in accordance with these rules, opts out of Medicare for a 2-year period. This is required by section 1802(b)(3)(B)(ii) of the Act. We also specify that the physician's or practitioner's opt-out may be renewed for subsequent 2-year periods. Since the statute specifies that the physician or practitioner who meets the criteria for private contracting cannot be paid by Medicare for a 2-year period and does not address continuance of this period, we have chosen to make the opt-out period 2 years but to permit subsequent opt-out periods. There is no limit on the number of subsequent periods for which a physician or practitioner may opt-out.

In § 405.405(c), we specify that both the private contracts described in paragraph (a) and the physician's or practitioner's opt-out described in paragraph (b) are null and void if the physician or practitioner fails to complete opt-out in accordance with these rules or fails to remain in compliance with the conditions for opting-out. We specify the results of failure to properly opt-out or to maintain the conditions for opting-out in § 405.430 and § 405.435. Sections 1802(b)(2) and (b)(3)(A) of the Act, the criteria that governs the private contract and the affidavit, must be met by physicians and practitioners that want to opt-out and to privately contract with Medicare beneficiaries.

In § 405.405(d), we specify that services furnished under private contracts meeting the requirements of this Subpart are not covered services under Medicare and that no Medicare payment will be made for such services either directly or indirectly. This implements section 1862(a)(19) of the Act, which causes services furnished under private contracts by physicians and practitioners who opt-out to be excluded from coverage under Medicare.

Conditions for Opting-Out of Medicare

In § 405.410, we specify the conditions that must be met for a physician or practitioner to opt-out of Medicare and to furnish services under private contracts with Medicare beneficiaries. Specifically, in § 405.410(a), we specify that each private contract between a physician or a practitioner and a Medicare beneficiary must meet the specifications of § 405.415. In § 405.410(b), we specify that the physician or practitioner who wants to privately contract with Medicare beneficiaries must submit to Medicare one or more affidavits that meet the specifications of § 405.420. The physician or practitioner must submit an affidavit to each Medicare carrier to which the physician or practitioner submits claims for Medicare payment.

In § 405.410(c), we specify that a nonparticipating physician or a practitioner may opt-out of Medicare at any time. We also specify that the 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 is signed, as long as the affidavit is timely filed (that is, within 10 days after the first private contract is entered into). In addition, we specify that if any required affidavit is not timely filed, the 2-year opt-out period begins when the last of the affidavits is filed. In this event, the private contracts signed by the parties before the last required affidavit is properly filed become effective upon the filing of the last required affidavit, and the furnishing of any items or services to Medicare beneficiaries under contracts before the last required affidavit is properly filed are subject to standard Medicare rules. Section 1802(b)(3)(B)(ii) provides that the opt-out period begins when the affidavit is signed, and section 1802(b)(3)(B)(iii) of the Act specifies that the affidavit must be filed within 10 days of the date the first private contract is signed.

In § 405.410(d), we specify that a participating physician may opt-out of Medicare at the beginning of any calendar quarter, provided the affidavit described in § 405.420 is submitted to Medicare at least 30 days before the beginning of such quarter. Private contracts signed by the parties before the beginning of the calendar quarter become effective at the beginning of such calendar quarter, and the furnishing of any items or services to Medicare beneficiaries under these contracts before the beginning of that calendar quarter is subject to standard Medicare rules.

It is necessary to treat participating physicians differently from nonparticipating physicians because each participating physician has entered into a contract with Medicare to be paid at the full fee schedule for the services they furnish to Medicare beneficiaries (rather than at 95 percent of the payment amount for nonparticipating physicians). When a participating physician opts-out of Medicare, he or she, in effect, terminates his or her participation agreement with Medicare since he or she no longer agrees to accept assignment on all services furnished to Medicare beneficiaries. When a participating physician opts-out of Medicare, the carrier (that is, each applicable carrier) must make systems changes to ensure the system pays the physician at the higher participating-physician rate for the period before the effective date of the opt-out, pays the physician as a nonparticipating-physician for emergency and urgent care services effective the date of the opt-out, and does not pay at all for all other items and services effective the date of the opt-out. Therefore, carriers need at least 30 days advance notice when a participating physician opts-out to ensure that the systems changes are made correctly. Moreover, carriers generally make systems changes no less frequently than at the beginning of each calendar quarter. Therefore, participating physicians must provide 30 days notice that they intend to opt-out at the beginning of the next calendar quarter for the changes to be made properly. We do not anticipate that this requirement will cause significant hardship on participating physicians who choose to opt-out or on beneficiaries who choose to privately contract with them.

Requirements of Private Contracts

In § 405.415, we are specifying criteria for a physician or practitioner to opt-out of Medicare. To opt-out of Medicare, the physician or practitioner must meet all of the criteria in this section.

In § 405.415, we specify the requirements for a private contract. In § 405.415(a) we specify that it must be in writing, in accordance with section 1802(b)(2)(A)(i) of the Act. In addition, we are proposing requiring that the contract be printed in sufficiently large type to ensure that beneficiaries are able to read the contract.

In § 405.415(b), we specify that, as required by 1802(b)(2)(B) of the Act, it must state whether the physician or practitioner has been excluded from Medicare under section 1128 of the Act.

In § 405.415(c), we specify that, as required by 1802(b)(2)(B)(ii) of the Act, it must state that the beneficiary or legal representative accepts full responsibility for payment of the physician's or practitioner's charge for the services furnished.

In § 405.415(d), as required by section 1802(b)(2)(B)(iii) of the Act, it must state that the beneficiary or legal representative understands that there are no limits on what the physician or practitioner may charge for items or services furnished by the physician or practitioner.

In § 405.415(e), we specify that, as required by 1802(b)(2)(B)(i) of the Act, it must state that the beneficiary or legal representative agrees not to submit a claim to Medicare nor to ask the physician or practitioner to submit a claim to Medicare.

In § 405.415(f), we specify that, as required by section 1802(b)(2)(B)(ii) of the Act, it must state that the beneficiary or legal representative understands that no Medicare payment will be made for any services furnished by the physician or practitioner, although such Medicare-covered services would likely be covered and paid by Medicare if they were provided by a physician or practitioner who had not opted-out of Medicare.

In § 405.415(g), we specify that, in accordance with section 1802(b)(2)(B)(v) of the Act, it must state that the beneficiary or legal representative enters into this contract with the knowledge that he or she has the right to obtain Medicare-covered items and services

from physicians and practitioners who have not opted-out of Medicare.

In § 405.415(h), we propose that the private contract contain the beginning effective date and expiration date of the opt-out period. The private contract must expire on the expiration date of the opt-out period since, after the expiration of the opt-out period, the physician or practitioner is no longer authorized to privately contract unless he or she enters into a new opt-out period.

In § 405.415(i), we specify, in accord with section 1802(b)(2)(B)(iv) of the Act, that the private contract must state that the beneficiary understands that Medigap plans do not, and that other supplemental insurance plans may elect not to, make payments for such items and services because payment is not made by Medicare.

In § 405.415(j), we specify that the contract must be signed by the beneficiary or by the beneficiary's legal representative and by the physician or practitioner. Section 1802(b)(2)(A)(i) of the Act expressly requires that the contract must be signed by the beneficiary. Although there is no parallel express requirement for the physician or practitioner, we believe that such a requirement is implicit in the statute, and we are, therefore, proposing that the physician or practitioner also sign the contract.

In § 405.415(k), in accordance with 1802(b)(2)(A)(iii), we specify that the contract must not have been entered into during a time when the beneficiary requires emergency care services or urgent care services.

405.415(l), we propose that the beneficiary or legal representative must receive a copy of the contract before items or services are furnished under the contract. This is standard practice when parties sign binding contracts, and we believe it is important in this case so that the beneficiary or family members have the contract available if questions about charges for the services furnished arise.

In § 405.415(m), we propose that the physician or practitioner must retain a copy of each private contract for the duration of the opt-out period to which the contract applies. Physicians and practitioners may want to retain the private contracts for a longer period of time in case a beneficiary disputes whether a valid contract was signed.

In § 405.415(n), we propose that the physician or practitioner must permit us to inspect each such contract upon request. We propose these requirements to ensure that the contracts will be available if there are allegations that the physician or practitioner has failed properly opt-out or maintain opt-out or if there is need to review them to process an appeal under § 405.450.

In § 405.415(o), we propose that a private contract must be entered into for each opt-out period.

We have been requested to create a standard form for the private contract. We have decided that such a form is not necessary. While the minimal content of the contract is controlled by Federal law and regulation, the contracts are otherwise private agreements. Moreover, such contracts will not generally be provided to nor inspected by the Government.

Requirements for Opt-Out Affidavits

In § 405.420, we specify the required elements of the affidavit that the physician or practitioner must file with Medicare to opt-out. In § 405.420(a), as required by section 1802(b)(3)(B)(i) of the Act, we specify that the affidavit must be in writing and be signed by the physician or practitioner.

In § 405.420(b), we specify that the affidavit must contain the physician or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number if one has been assigned, uniform provider identification number (UPIN) if one has been assigned, or, if neither a NPI, billing number nor a UPIN has been assigned, the physician or practitioner's tax identification number (TIN). This information is necessary to enable the Medicare carrier to positively and uniquely identify the opt-out physician or practitioner, as required by section 1802(b)(3)(B)(i), and to ensure that no Medicare payment is made to the physician or practitioner or to any party for the services of the physician or practitioner (except for emergency and urgent care services), as required by section 1802(b)(1)(B)of the Act. Medicare carriers will provide the identifying information to Medicare+Choice (M+C) plans to ensure that they do not pay opt-out physicians or practitioners or enable them to be paid by Medicare funds for services they furnish to Medicare beneficiaries.

The TIN is necessary for physicians and practitioners that do not have a NPI, billing number, or UPIN so that the carrier can establish a means of tracking them without forcing them to complete the full Medicare enrollment process in order to opt-out of Medicare.

Recent data indicate that approximately 4 percent of physicians in the nation do not provide services to Medicare beneficiaries. We believe that some of these physicians (and some practitioners who are currently not enrolled in Medicare) are likely to choose to privately contract with Medicare beneficiaries under section 1802(b) of the Act, since doing so will open a market to them. It is also likely that many of these physicians and practitioners do not have Medicare billing numbers or UPINs because they have not been providing care to Medicare beneficiaries. Now, however, if such physicians and practitioners wish to privately contract with Medicare beneficiaries under section 1802 of the Act, they will need to be enumerated, for purposes of monitoring compliance with the law and particularly in case they furnish emergency or urgent care services for which they must bill and be paid by Medicare, notwithstanding that they have opted-out. Since we expect the provision of emergency or urgent care services by opt-out physicians to be very infrequent, and since we intend to monitor for potential abuse, we believe that the burden associated with collecting this information is very slight, is far outweighed by the benefit to beneficiaries of having these physicians available to provide emergency or urgent care services if they need such care, and is necessary to monitor compliance.

In § 405.420(c), we specify, pursuant to sections 1802(b)(3)(A), 1802(b)(3)(B), and 1802(b)(3)(C) of the Act, that the affidavit must state that the physician or practitioner will provide items and services to Medicare beneficiaries only through private contracts that meet the criteria of § 405.415.

In § 405.420(d), we specify that, in accordance with section 1802(b)(3)(B)(ii) of the Act, the affidavit must state that the physician or practitioner will not submit a claim to Medicare for any item or service furnished to a Medicare beneficiary, nor will the physician or practitioner permit any entity acting on his or her behalf to submit a claim to Medicare for any item or service furnished to a Medicare beneficiary. The extension of the requirement to include any ''entity'' reflects our belief that very few physicians and practitioners themselves submit claims for services. Rather, we believe that most physicians and practitioners use a billing service or reassign benefits to organizations that bill and are paid for the physician's or practitioner's services.

In § 405.420(e), we specify that, in accordance with section 1802(b)(3)(B)(ii) of the Act, the affidavit must state that the physician or practitioner understands that he or she may receive no direct or indirect payment from Medicare for services to Medicare beneficiaries who have signed

private contracts, whether as an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a M+C plan. As with the prohibition on billing, this provision reflects the reality that most physician and practitioner services are billed by and paid to organizations to whom the physician or practitioner reassigns benefits.

When a physician or practitioner opts-out of Medicare, no payment may be made for the services of the physician or practitioner, regardless of whether another entity bills and is paid for those services. In our experience, physicians and practitioners frequently fail to understand that organizations to which they have reassigned benefits are not, under Medicare law, considered to be the entity that furnishes the service. Therefore, where a physician reassigns benefits to an organization and subsequently decides to opt-out of Medicare, he or she no longer has any Medicare benefits to reassign and that organization can no longer bill and be paid by Medicare for the services of the physician or practitioner. This has been a source of confusion for physicians and practitioners since the implementation of the private contracting provisions on January 1, 1998, and has resulted in some physicians being terminated by organizations that can no longer bill and be paid by Medicare for their services. Hence, we believe that this important information should be placed in a document that the physician or practitioner must sign before opting-out.

Moreover, we believe that it is important the physicians and practitioners understand that opting-out of Medicare means that they cannot be paid by a Medicare risk or cost contractor or, after June 1, 1998, a M+C organization (for example, an HMO, provider service organizations, M+C fee for service plans, etc.), since payment by these organizations for services to Medicare beneficiaries would constitute payment by Medicare and would be a violation of the private contracting rules.

In § 405.420(f), as required by section 1802(b)(3)(B)(ii) of the Act, the affidavit must state that the physician or practitioner acknowledges that the services provided by the physician or practitioner who opts-out of Medicare are not covered by Medicare and that no Medicare payment may be made to any entity for those services, directly or on a capitated basis. This is important to note since, when Medicare does not cover a service, it neither pays for the item or service as primary payer nor makes secondary payment when other insurers are primary. (Also, many other insurers will not make any payment because the service is not covered by Medicare.)

In § 405.420(g), we specify that the affidavit must bind the physician or practitioner to the terms of both the affidavit and the private contracts for the 2-year opt-out period. Section 1802(b)(3)(B)(ii) of the Act requires that the physician or practitioner may opt-out for a period of not less than 2 years. Accordingly, we have defined the opt-out period to be 2 years and have tied the duration of the private contract to the opt-out period.

In § 405.420(h), we propose that the affidavit must acknowledge that the physician or practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished by the physician or practitioner to Medicare beneficiaries, regardless of any payment arrangement in which the physician or practitioner participates. It is not unusual for physicians and practitioners to have multiple sources of income and to reassign benefits to multiple entities (for example, multiple HMOs, preferred provider organizations, private practice, and part time employment by a facility). When a physician or practitioner opts-out, we want to ensure that he or she understands that he or she opts-out for all Medicare-covered items and services, regardless of where or on whose behalf they are provided. For example, a physician who is employed by a facility and who also has a private practice cannot opt-out of Medicare with respect to only the private practice and not opt-out for services he furnishes on behalf of a facility or other organization for which such services are billed to a carrier and paid under Part B. If the physician opts-out, no Medicare payment can be made either to the private practice or to the facility or other organization for the services of the physician. However, if the physician is paid by the facility for administrative functions which are not billable to individual beneficiaries as physician services, such as direction of a department of a hospital or administrative oversight of a teaching program, the payment by the facility to the physician is not affected.

In § 405.420(i), we propose that the affidavit must acknowledge that the physician or practitioner who has previously signed a Part B participation agreement understands that he or she terminates that agreement as of the effective date of the affidavit. We believe that this is necessary to ensure that the physician or practitioner understands that he or she is no longer a Medicare-participating physician or practitioner. This is important with regard to post opt-out billing for emergency and urgent care services. The physician or practitioner who provides such care (for which Medicare will pay) will be paid as a nonparticipating physician if he or she submits those claims for payment, notwithstanding that he or she had a Part B participation agreement before he or she opted-out.

In § 405.420(j), we specify that the affidavit must acknowledge that the physician or practitioner understands that a beneficiary who has not signed a private contract and who requires emergency or urgent care services may not be asked to sign a private contract with respect to receiving those services. If a physician or practitioner who opts out of Medicare provides emergency or urgent care services to a beneficiary who has not previously signed a private contract, the physician or practitioner must submit a claim to Medicare for those services and may not charge the beneficiary more than the limiting charge for those services.

In § 405.420(k), we propose that the affidavit must be filed with each Medicare carrier to which the physician or practitioner has submitted claims in the previous 2 years. This is necessary to ensure that each Medicare claims payment system that needs to know of the opt-out is advised promptly so that no Medicare payment is made for the services of the opt-out physician or practitioner. This is based on sections 1802(b)(1)(B) and 1802(b)(3)(B)(iii) of the Act.

In § 405.420(l), we specify that in the case of a nonparticipating physician or a practitioner, all required affidavits must be filed within 10 days after the physician or practitioner signs his or her first private contract with a Medicare beneficiary. In the case of a participating physician, we specify that all required affidavits must be filed in accordance with § 405.410(d), which requires that the affidavits be filed no later than 30 days before the beginning of a calender quarter and must be effective on the first day of the calender quarter. Section 1802(b)(3)(B)(iii) of the Act requires that the physician or practitioner file the affidavit within 10 days after the physician or practitioner signs his or her first private contract with a Medicare beneficiary. As discussed previously in this preamble, participating physicians are permitted to opt-out only on a quarterly basis because of the systems changes that must be made to reverse the effect of the participation agreements they previously entered into.

Various members of the public have requested we create a standard affidavit for submission to the Medicare carrier. We do not see a reason to do this. The criteria of a legally sufficient affidavit will be clearly specified in regulations, and we are confident that physicians and practitioners and their counsel can produce an affidavit without needing a Government form to sign.

Effect of Opting-Out of Medicare

In section § 405.425, we specify the effects of opting-out of Medicare. Specifically, we state that, a physician's or practitioner's opt-out of Medicare, for the 2-year period for which the opt-out is effective, has the following effects:

• In § 405.425(a), we state that (except as provided in § 405.440), in accordance with section 1802(b)(1)(B) of the Act, no payment may be made directly by Medicare or by any M+C plan to the physician or practitioner or to any entity to which the physician or practitioner reassigns his or her right to receive payment for services.

• In § 405.425(b), we state that, in accord with section 1802(b)(3)(B)(ii) of the Act, the physician or practitioner may not furnish any item or service that would otherwise be covered by Medicare (except for emergency or urgent care services) to any Medicare beneficiary except through a private contract that meets the requirements of these rules.

• In § 405.425(c), we state that the physician or practitioner is not subject to the requirement to submit a claim for items or services furnished to a Medicare beneficiary (as specified in § 424.5(a)(6)), except as provided in § 405.440 with respect to emergency and urgent care services.

• In § 405.425(d), in accordance with section 1802(b)(3)(B)(ii) of the Act, we state that the physician or practitioner is prohibited from submitting a claim to Medicare for items or services furnished to a Medicare beneficiary, except as provided in § 405.440 in the case of emergency or urgent care services.

• In § 405.425(e), we state that, in accordance with 1802(b)(4) of the Act, the physician who has properly opted-out is not subject to the limiting charge provisions of § 414.48.

• In § 405.425(f), we state that a physician or practitioner who has properly opted-out is not subject to the prohibition-on-reassignment provisions of § 414.80. These are the rules that restrict when physicians and practitioners can reassign Medicare benefits to organizations with which they have financial arrangements.

• In § 405.425(g), we propose that in the case of a practitioner, he or she is not prohibited from billing or collecting amounts from beneficiaries in excess of those provided in section 1842(b)(18)(B) of the Act. This is not specifically provided for by section 4507 of BBA 1997; however, we believe that this provision is consistent with sections 1802(b)(1) and (2)(B) of the Act, that, when read together, permit practitioners to collect more than the deductible and coinsurance to which they are limited under section 1842(b)(18)(B) of the Act when they provide covered services to Medicare beneficiaries under standard Medicare rules. Section 1842(b)(18)(B) of the Act specifies that practitioners must take assignment on all claims and may not collect more than Medicare deductibles and coinsurance from Medicare beneficiaries. We believe that the private contracting provisions exempt practitioners from these restrictions.

• In § 405.425(h), we propose that the death of a beneficiary who (or whose legal representative) has entered into a private contract does not invoke § 424.62 or § 424.64 with respect to the physician or practitioner with whom the beneficiary (or legal representative) has privately contracted. These sections of the regulations permit claims to be filed and payment to be made for services furnished to a beneficiary who has died. We propose to include this section to ensure that it is clear that the terms of a private contract are not superseded by the provisions of § 424.62 or § 424.64.

• In § 405.425(i), we specify that the opt-out physician or practitioner may make referrals and may order or certify the need for Medicare-covered items and services provided the physician or practitioner is not paid directly or indirectly by Medicare for those services. A physician or practitioner who has properly opted-out may continue to act as a physician or practitioner for purposes of ordering Medicare-covered services (for example, laboratory tests), making necessary certifications (for example, home health plan of care), attestations (for example, hospital inpatient), etc., as long as he or she is not being paid directly or indirectly by Medicare for these services.

Failure to Properly Opt-Out

In § 405.430(a), we specify that a physician or practitioner fails to properly opt-out if any private contract between the physician or practitioner and a Medicare beneficiary does not meet the standards of § 405.415 or if the physician or practitioner fails to submit affidavit(s) in accordance with § 405.420. Sections 1802(b)(2) and 1802(b)(3) of the Act specify the criteria that private contracts and affidavits must meet in order for the physician or practitioner to successfully opt-out of Medicare.

In section § 405.430(b), we specify that if a physician or practitioner fails to properly opt-out as specified in § 405.430(a), the following result:

• All of the private contracts between the physician or practitioner and Medicare beneficiaries are deemed null and void.

• The physician's or practitioner's attempt to opt-out of Medicare is nullified.

• The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries. Section 1802(b)(4) of the Act, which would excuse the physician and practitioner from the mandatory claims submission requirements of section 1848(g)(4) of the Act, is not effective when the opt-out rules are not met.

• The physician is subject to the limiting charge provisions of § 414.48. Sections 1802(b)(1) and 1802(b)(2)(B)(iii), which excuse the physician from the limiting charge rules, do not apply and he or she continues to be subject to the limiting charge rules of section 1848(g) of the Act.

• The physician or practitioner may not reassign any claim except as provided in § 424.80. Medicare payment may be made only to the beneficiary, to the physician or practitioner under an assignment of benefits or to another party for the services of a physician or practitioner only when the requirements of the reassignment of benefits provision of § 424.80 are met.

• The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts. Section 1842(b)(18)(B) of the Act explicitly prohibits practitioners from collecting more than the deductible or coinsurance from the beneficiary. While this requirement would not apply if the requirements to properly opt-out had been satisfied, it does apply when the criteria to properly opt-out have not been met.

• The physician or practitioner may attempt to properly opt-out at any time. The statute does not preclude a physician or practitioner who has not complied totally with the statute's criteria for opting-out of Medicare from subsequently meeting the criteria and thus at that time properly opting-out.

Failure to Maintain Opt-out

In § 405.435(a), we specify four circumstances, under any one of which

the physician or practitioner would be considered to have failed to maintain opt-out, that is, failed to remain in compliance with the requirements of these rules. Specifically, in § 405.435(a)(1), we state that a physician or practitioner would be considered to have failed to maintain the opt-out if he or she knowingly and willfully submits a claim for Medicare payment (except a claim for emergency care services or urgent care services) or receives Medicare payment directly or indirectly for services furnished to a Medicare beneficiary (except when the services are emergency care services or urgent care services). This implements section 1802(b)(3)(C) of the Act.

In § 405.435(a)(2), we state that the physician or practitioner would be considered to have violated the terms of the opt-out if he or she enters into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare when the contracts fail to meet the requirements of § 405.415. This implements section 1802(b)(2) of the Act that requires that the physician or practitioner must enter into private contracts that meet certain criteria for the opt-out to be valid. This provision is also consistent with the enforcement provisions of section 1802(b)(3)(C) of the Act.

In addition, in § 405.435(a)(3), we specify that the physician or practitioner would be considered to have failed to maintain the opt-out if he or she fails to comply with the provisions of § 405.440 regarding billing for emergency care services or urgent care services. In part, this provision implements section 1802(b)(2)(A)(iii) of the Act that prohibits a physician or practitioner from requesting that a beneficiary enter into a private contract when he or she is in need of emergency or urgent care services and is otherwise necessary to ensure access by Medicare beneficiaries to emergency and urgent care services.

In § 405.435(a)(4), we propose that the physician or practitioner would be considered to have failed to maintain opt-out if he or she fails to retain a copy of each private contract that he or she entered into for the duration of the opt-out period for which such contracts are applicable or fails to permit us to inspect such contracts upon request. The issue of retaining copies of private contracts is discussed in § 405.415, requirements of the private contract.

We intend to continue the administrative process currently in place for dealing with the submission of claims by physicians and practitioners who have opted-out of Medicare. Specifically, we have instructed carriers to pend claims they receive from physicians and practitioners who have filed an affidavit opting-out of Medicare and to send the physician or practitioner a letter asking him or her if the submission of the claim was intentional or accidental, and if the latter by what date the physician or practitioner can remedy the problem. We recognize that most physicians and practitioners may be somewhat distant from the billing of their claims and that the use of automation and billing services increases the chance that one or more claims may be accidentally submitted to Medicare for an opt-out physician or practitioner. We also recognize that if the problem is systematic, it may take some time to correct. Hence, under the current process, we give physicians and practitioners 45 days from the date of the postmark on the carrier's letter to respond to the carrier and to advise them of when they believe the problem can be fixed. Carrier notices to beneficiaries will advise them that no payment can be made for the services of the opt-out physician, and that there are no limits on what the physician or practitioner can charge the beneficiary, unless the physician or practitioner does not respond timely to the carrier's letter, does not timely correct the billing problem, or states that the submission of the claim was intentional. We do not believe that any of these scenarios will happen often since physicians and practitioner who opt-out of Medicare clearly have an incentive to ensure that they abide by the terms of the opt-out and that neither they nor any party on their behalf submit claims to Medicare.

In section § 405.435(b), we specify that the effects of a physician or practitioner failing to maintain opt-out as specified in paragraph (a) are as follows:

- All of the private contracts between the physician or practitioner and Medicare beneficiaries are deemed null and void.
- The physician's or practitioner's opt-out of Medicare is nullified.
- The physician or practitioner again becomes subject to the mandatory claims submission rule. Therefore, the physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.
- The physician or practitioner will not receive Medicare payment on such claims for the remainder of the opt-out period. This is required by section 1802(b)(3)(C)(ii) of the Act.
- The physician is subject to the limiting charge provisions of § 414.48. This is required by section 1848(g) of the Act pursuant to section 1802(b)(3)(C)(i) of the Act.
- The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts. This is required by section 1842(b)(18)(B) of the Act pursuant to section 1802(b)(3)(C)(i) of the Act.
- The physician or practitioner may not opt-out until the now-nullified 2-year opt-out period expires. This is necessary to give meaning to the enforcement provisions specified in section 1802(b)(3)(C) of the Act.

Emergency and Urgent Care Services

In § 405.440, we specify the rules that apply to furnishing and billing for emergency and urgent care services. Specifically, in § 405.440(a), we specify that a private contract is not necessary for a physician or practitioner to furnish emergency care services or urgent care services to a Medicare beneficiary. Accordingly, a physician or practitioner will not be determined to have failed to maintain opt-out if he or she furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not entered into a private contract, provided the physician or practitioner complies with the Medicare billing requirements with respect to emergency care services or urgent care services.

In § 405.440(b), we specify that when a physician or practitioner furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not entered into a private contract, the physician or practitioner must submit a claim to Medicare in accordance with 42 CFR Part 424 and Medicare instructions issued pursuant to such regulations, including instructions on coding emergency or urgent care services. Also, we propose that the physician may collect no more than the Medicare limiting charge and that the practitioner may collect no more than the applicable deductible and coinsurance amounts. We specify these requirements because the physician or practitioner cannot ask a beneficiary to enter into a private contract when a beneficiary is in need of emergency or urgent care services. Therefore, when the beneficiary has not previously signed a private contract, the beneficiary has not agreed to give up Medicare coverage for the services of the physician or practitioner and the services are not excluded from coverage under Medicare, nor is the physician or

practitioner excluded from the mandatory claims submission and charge rules that would not apply had he or she been able to sign a private contract with the beneficiary.

In § 405.440(c), we specify that emergency care services or urgent care services furnished to a Medicare beneficiary with whom the physician or practitioner has previously entered into a private contract (that is, entered into before the onset of the emergency medical condition or urgent medical condition) are furnished under the terms of the private contract. Although section 1802(b)(2)(A)(iii) of the Act precludes the physician or practitioner from entering into a private contract with a beneficiary when the beneficiary needs emergency or urgent care services, the private contracting rules apply to a beneficiary who has previously entered into a private contract (at a time when the beneficiary was not in need of emergency or urgent care services).

In § 405.440(d), we specify that Medicare may make payment for the emergency care services or urgent care services furnished by a physician or practitioner who has properly opted-out, provided that no private contract has been entered into by the beneficiary to whom emergency care services or urgent care services were furnished. Although the statute does not explicitly address whether payment may be made in these cases, we believe that it is both permissible and desirable to do so since this provision will facilitate access to needed care in the circumstance when the beneficiary or their legal representative has not signed a private contract and the physician or practitioner who has opted-out cannot lawfully request that the beneficiary or their legal representative now do so.

Renewal and Early Termination of Opt-out

In § 405.445, we specify the terms of renewal and early termination of the opt-out. In § 405.445(a), we specify that a physician or practitioner may renew his or her opt-out by filing an affidavit with each carrier to which an affidavit was submitted for the first opt-out period (as specified in § 405.420) and to each carrier to which a claim was submitted under § 405.440 during the previous opt-out period, provided such affidavits are filed within 30 days after the current opt-out period expires. While section 1802(b)(3)(B)(ii) of the Act provides that the physician or practitioner opts-out for a period of 2 years, it does not address renewal of opt-out. Our proposal is to establish reasonable standards and procedures for the physician or practitioner to again opt-out of Medicare for subsequent opt-out periods.

In § 405.445(b), we propose that the physician or practitioner may terminate the opt-out for any reason within the 90 days following the effective date of the first affidavit filed with Medicare if he or she agrees to do the following:

- Notify all Medicare carriers with which he or she filed an affidavit to properly opt-out of the termination of the opt-out, no later than 90 days after the effective date of the opt-out period.
- Refund to beneficiaries all payment collected in excess of the Medicare limiting charge, in the case of physicians, or in excess of the deductible and coinsurance, in the case of practitioners.
- Notify all beneficiaries with whom the physician or practitioner signed private contracts of the physician's or practitioner's decision to terminate opt-out and of the beneficiaries' right to have the physician or practitioner file claims on their behalf, without charge, with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out.

In § 405.445(c), we propose that when the physician or practitioner properly terminates opt-out in accordance with paragraph (b), he or she will be reinstated in Medicare as if there had been no opt-out and the provisions of ' 405.425 will not apply for the 2 years following the signing of the affidavit unless the physician or practitioner subsequently properly opts-out again.

We recognize that there may be cases when the physician or practitioner may not have understood the opt-out rules and may want to return to Medicare. We believe that it is advantageous to all parties to permit a first-time opt-out physician or practitioner to properly terminate opt-out. However, we are requiring that to properly terminate opt-out, the termination must be accomplished within 90 days following the effective date of the first opt-out, and we are permitting only one termination of opt-out by the physician or practitioner. We believe that it would be a mistake to permit repeated terminations of opt-out, since it could be abused to manipulate payment, could create a significant expense for Medicare systems, and would be confusing to beneficiaries.

Appeals

In § 405.450, we propose procedures for appeals by physicians or practitioners and beneficiaries who believe that they have been adversely affected by these rules.

In § 405.450(a), we address appeals of determinations by Medicare that a physician or practitioner has failed to properly opt-out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, or failed to properly terminate opt-out by proposing that a determination with respect to any such matter is an initial determination for purposes of § 405.803. The effect of this provision is that the appeals mechanism found in Part 405, Subpart H is made available to physicians or practitioners for the purpose of administrative review of Medicare determinations on matters addressed in this subpart. Although we believe that these procedures will rarely be needed for this purpose, we believe that it is important to provide this mechanism because of the potential adverse impact on the physician or practitioner of any such determination.

In § 405.450(b), we propose that a determination by Medicare that no payment can be made to the beneficiary as a result of the application of any provision of this subpart is a initial determination for the purposes of § 405.803. We believe that the beneficiary must have the right to appeal a denial of Medicare payment on a claim submitted by or on behalf of the beneficiary when the basis for that denial is the application of the provisions of this subpart. The effect of this provision is that the appeals mechanism of Part 405, Subpart H is made available to beneficiaries whose claims for Medicare payment are denied on the basis of the opt-out provisions of this rule.

Under the BBA 1997 requirements, the physician who opts out under these provisions must sign an affidavit agreeing for 2 years not to furnish services to any Medicare beneficiary without signing a private contract. We expect that the vast majority of opt-out physicians will fully comply with these terms. Although we expect that physicians will tell beneficiaries that they have opted-out, we are concerned that there may be cases when an opt-out physician delivers non-emergency or non-urgent services to a beneficiary without entering into a private contract. The beneficiary may be unaware that the physician has opted out. Nevertheless, the beneficiary would be billed for the physician's full charges for the service. If the beneficiary seeks reimbursement from Medicare, the claim would be denied and the beneficiary would be informed that the reason for denial is that the physician has opted-out of the Medicare program. We do not believe that the Congress intended that beneficiaries who have

not chosen to sign a private contract would be financially harmed because they unknowingly received services from an opt-out physician. While the statute does not provide a specific remedy for this situation and we expect the physician will tell beneficiaries that they have opted-out, we believe that we have authority to develop some beneficiary protections in this case in the limited cases when physicians do not do so. One possibility would be to indemnify the beneficiary for the amount that Medicare would have normally paid, ensuring that the beneficiary is informed that the physician is an opt-out physician. The program would then recoup this amount from the physician and the physician would refund to the beneficiary any balanced billing amounts above Medicare's limiting charge. The beneficiary would remain liable for any coinsurance and deductible amounts that would have been paid in the absence of a private contract. A means of informing beneficiaries enrolled in M+C organizations may be to require that such organizations disclose information on opt-out physicians upon request by the beneficiary. We would welcome comments on these and other approaches to providing protection for beneficiaries in these circumstances.

Medicare+Choice

In § 405.455, we propose to specify the requirements that are to be imposed on an organization that has a contract with us to provide one or more M+C plans to beneficiaries (Part 422 of this chapter). The location of this section may change to part 422 with the final rule, once the M+C interim rules are published. Part 422 will be the location of the regulations that govern Part C of Medicare, commonly known as M+C.

In § 405.455(a), we propose that the M+C organization must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

In § 405.455(b), we specify that the M+C organization must make no payment directly or indirectly for Medicare-covered services furnished to an enrolled Medicare beneficiary by a physician or practitioner who has opted-out of Medicare. The services of physicians and practitioners who properly opt-out are excluded from Medicare under section 1862(a)(19) of the Act. Therefore, no payment may be made for them as Medicare-covered services.

In § 405.455(c), we specify that M+C organizations may make payment to a physician or practitioner who has properly opted-out if he or she furnishes emergency or urgent care services to a beneficiary who has not previously entered into a private contract with the physician or practitioner. This is consistent with our policy in § 405.440 where Medicare payment is made by carriers rather than through M+C contracts.

C. Payment for Outpatient Rehabilitation Services

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

1. Overview of Policies Before BBA 1997

a. Coverage. Section 1861(p) of the Act defines outpatient physical therapy services as physical therapy services furnished to a beneficiary as an outpatient who meets the following criteria:

- Is under the care of a physician.
- Has a plan of treatment or care established by either a physician or by a qualified physical therapist.
- Has the plan of treatment or care periodically reviewed by a physician.

The statute also incorporates speech language pathology services within the definition of outpatient physical therapy services.

Section 1861(g) of the Act states that the term ''outpatient occupational therapy services'' has the same meaning given the term ''outpatient physical therapy services'' in section 1861(p), except that the word ''occupational'' is substituted for the word ''physical'' each time it is used in section 1861(p).

b. Providers of Outpatient Rehabilitation Services. Outpatient physical therapy services (including speech-language pathology services) and outpatient occupational therapy services are furnished by providers of services, clinics, rehabilitation agencies, public health agencies, or by others under an arrangement with, and under the supervision of such entities. As defined in section 1861(w) of the Act, the term ''arrangements'' is limited to arrangements under which receipt of payment by the provider discharges the liability of the beneficiary to pay for services.

Providers that furnish outpatient physical and occupational therapy services include hospitals, skilled nursing facilities (SNFs), rehabilitation agencies, home health agencies (HHAs), hospices, and comprehensive outpatient rehabilitation facilities (CORFs) furnishing services to patients other than those who receive SNF or inpatient hospital benefits.

Hospital inpatients who have exhausted their hospital inpatient benefits and who are entitled to Part B, and SNF patients who have exhausted their SNF benefits and who are entitled to Part B may receive outpatient physical therapy services (including speech-language pathology services) and outpatient occupational therapy services even though they are inpatients of the provider. Section 1861(p) of the Act defines outpatient physical therapy services as those services that meet the requirements of the first sentence of 1861(p), yet that are furnished to a beneficiary as an inpatient of a hospital or extended care facility. Section 1861(p) of the Act must be read in conjunction with section 1833(d) of the Act. The latter section provides that Medicare Part B payments, such as payment for outpatient physical and occupational therapy services, may be made only when there is no eligibility for Medicare Part A payments for the service, such as payments for inpatient hospital or SNF care. Part B payment may be made for inpatients only when there is no eligibility for Medicare Part A payments; this means only a beneficiary who is not entitled to Medicare Part A benefits or who has exhausted his or her Part A benefits. Also see § 410.60(b) (Outpatient physical therapy services: Conditions, Outpatient physical therapy services to certain inpatients of a hospital or a CAH or SNF).

Outpatient physical therapy (including speech-language pathology) and occupational therapy services furnished by a home health agency may be covered as ''medical and other health services'' under section 1861(s) of the Act when the beneficiary is not entitled to receive home health benefits under section 1814(a)(2)(C) because he or she is not homebound. To qualify for home health benefits, the beneficiary must be homebound and need or have needed skilled nursing care on an intermittent basis or physical or speech therapy, or in the case of an individual who no longer has need for such care or therapy, continues to need occupational therapy. Thus, most rehabilitative services furnished by home health agencies under section 1861(s)(2)(D) provisions are furnished to beneficiaries who are not homebound.

Section 1861(cc)(1) of the Act defines the services that can be provided by a CORF. In addition to outpatient rehabilitation services, CORF services include: physician services; respiratory therapy; prosthetic and orthotic devices; social and psychological services; nursing care; drugs and biologicals that cannot be self-administered; supplies

and medical equipment; and, such other services as are medically necessary and are ordinarily furnished by CORFs.

Services furnished by either a qualified physical therapist or a qualified occupational therapist in his or her office or in the beneficiary's home, for example, services of a physical therapist in independent practice (PTIP) or occupational therapist in independent practice (OTIP), are included as outpatient physical therapy services and outpatient occupational therapy services. Medicare does not cover the services of a speech-language pathologist in independent practice.

c. Payment for Services. (1) Reasonable Cost-Based Payments Outpatient physical, occupational, and speech-language pathology services furnished by a provider of services, a clinic, a rehabilitation agency or public health agency are paid based on the lesser of the charges imposed for the services or the reasonable costs of providing the services.

The reasonable cost of services furnished under arrangements may not exceed an amount equivalent to the prevailing salary and additional costs that would reasonably have been incurred by such provider or other organization had the services been performed by an employee. See § 413.106 (Reasonable cost of physical and other therapy services furnished under arrangements).

The salary equivalency guideline amounts currently in effect were published as a final rule on January 30, 1998, (63 FR 5106). In that final rule, we updated the physical and respiratory therapy guideline amounts and introduced new salary equivalency guidelines for occupational therapy and speech-language pathology services furnished under an arrangement. These guideline amounts are effective for services furnished on or after April 10, 1998. The guidelines are used by fiscal intermediaries to determine the maximum allowable cost of those services. In general, the salary equivalency guideline amounts are comprised of a prevailing hourly salary rate based on the 75th percentile of the range of salaries paid to full-time employee therapists by providers in the geographic area, by type of therapy, and a fringe benefit and expense factor; a standard travel allowance and additional allowances for costs incurred for services furnished by an outside supplier.

(2) Fee Schedule Payments. Physical and occupational therapy services furnished by physicians and certain other recognized practitioners are payable by the carriers under the physician fee schedule. This includes services of PTIPs and OTIPs. The fee schedule also applies to nonphysician practitioners who furnish services that would be physician services if furnished by a physician. Nonphysician practitioners include physician assistants (section 1861(s)(2)(K)(i) of the Act); and nurse practitioners and clinical nurse specialists (sections 1861(s)(2)(K)(ii) and 1861(s)(2)(K)(iii) of the Act) operating within the scope of their State licenses and within certain settings. Physical and occupational therapy services provided incident to the services of physicians or incident to the services of the recognized nonphysician practitioners cited above are payable by the carriers under the physician fee schedule.

d. Financial Limitation. Outpatient physical therapy services provided by a PTIP and outpatient occupational therapy services furnished by an OTIP are subject to an annual financial limitation. This annual limitation or cap is $900 per beneficiary of incurred expenses for physical therapy services and $900 per beneficiary of incurred expenses for occupational therapy services. There is a beneficiary liability that is comprised of the Part B deductible amount and 20-percent coinsurance. If a beneficiary has already satisfied the Part B deductible, the maximum amount payable by the Medicare program under each of these benefits is $720, for example, 80 percent of $900. The limit on expenses applies only to items and services covered under the therapy benefit. When a beneficiary exceeds the annual limitation or cap, the beneficiary is financially liable for any additional therapy services that are furnished during the calendar year.

2. 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) of the Act. Section 1834(k)(2) established 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 or critical access hospitals. In accordance with this provision, we are proposing 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 shall 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.

The salary equivalency guidelines will continue to remain in effect until all BBA 1997 provisions regarding a prospective payment system for outpatient rehabilitation services are implemented. The prospective payment system will negate 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.

b. Prospective Payment System for Outpatient Rehabilitation Services. (1) Overview. Section 4541 of BBA 1997 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)(3) 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 PTIPs and OTIPs, physicians, and certain nonphysician practitioners or incident to the services of such 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. 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, 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 1997, these services will be paid on a reasonable cost basis.

(2) Services Furnished by Skilled Nursing Facilities. Section 4432(a) of BBA 1997 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 which encompass all costs of ''covered skilled nursing facility services'' furnished to a SNF resident. The statute defines covered SNF services to include (1) post-hospital extended care services paid for under Part A, as well as (2) certain services that may be paid under Part B and which 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 a 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 1997, services furnished to SNF residents that are not covered under Part A may nevertheless be covered under Part B. Section 4432(b) of BBA 1997 amended section 1842(b)(6) of the Act to require that payment for most services furnished to an individual who is a resident of a 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 is effective for services furnished on or after July 1, 1998.

Section 4432(b)(3) of BBA 1997 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 a SNF resident, the amount of payment for the service shall be 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 1997. Section 4541 added a new section 1833(a)(8) to specify that the amounts payable for outpatient rehabilitation services furnished by a SNF will be the amounts determined under section 1834(k) of the Act. Section 1834(k) of the Act provides that payment in 1998 shall be based on adjusted reasonable costs and in 1999 and thereafter, the physician fee schedule. Thus, we are proposing that SNF Part B inpatient services remain payable on a reasonable cost basis until January 1, 1999. Effective January 1, 1999, the services will be paid under the physician fee schedule.

The physician fee schedule amount applicable to services furnished in a non-facility setting will apply to the Part B services to inpatients and other outpatient rehabilitation services furnished by the SNF. The non-facility 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.

(3) Services Furnished by Home Health Agencies. Section 1833(a)(8)(A) requires that the physician fee schedule applies to outpatient rehabilitation services furnished by a HHA to an individual who is 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. Therefore, most outpatient rehabilitation services furnished by a HHA under section 1861(s)(2)(D) is to individuals who are not homebound. There may be, however, some individuals who are not homebound and have not required a qualifying service for home health benefits but who need occupational therapy services. If provided by a HHA, these services could be provided under section 1861(s)(2)(D) of the Act. Since section 4541 of BBA 1997 did not expressly address these services, they 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 (effective October 1, 1999 with respect to home health services). Section 1861(v)(1) provides that the reasonable cost of any service shall be the cost actually incurred, excluding any costs unnecessary to the efficient delivery of needed health services. Since all other outpatient rehabilitation services are to be paid under the physician fee schedule, we believe it would be unreasonable for the costs of the services furnished to homebound beneficiaries who are not entitled to home health benefits to exceed the amount payable under the physician fee schedule. Therefore, we are proposing to modify § 413.125 to provide that effective for services furnished on or after January 1, 1999, the reasonable cost of outpatient rehabilitation services furnished by a HHA to homebound patients who are not entitled to home health benefits may not exceed the amounts payable under the physician fee schedule.

(4) Services Furnished by Comprehensive Outpatient Rehabilitation Facilities. Section 4541(a)(1) adds a new section 1832(a)(2)(D)(9) of the Act to provide that all services furnished by a CORF, and not just outpatient rehabilitation services, will be paid the applicable fee schedule amount. In cases where there is no physician fee schedule amount for the services, section 1834(k) specifies that the applicable fee schedule amount will be the amount established for comparable services as specified by the Secretary. Therefore, we are proposing that the existing fee schedules for prosthetic and orthotic devices, durable medical equipment, and supplies, and drugs and biologicals apply when these services are furnished by a CORF. We believe that these fee schedules, together with the physician fee schedule, will encompass all CORF services other than nursing services. The physician fee schedule amount applicable to services furnished in a non-facility setting will apply to the services furnished by the CORF since no separate payment will be made for facility costs.

To establish a fee schedule amount for nursing services delivered within a CORF, we created a new HCPCS code, G0128. We are defining this code as

direct face-to-face skilled nursing services delivered to a CORF patient as part of a rehabilitative plan of care. It is a timed code and can be billed for 10-minute intervals (when the initial interval is longer than 5 minutes). G0128 is to be used for services that are not included in the work or practice expense of another therapy or physician service. An example might be a nurse who spends 33 minutes instructing a patient in the proper procedure of ''in and out'' urethral catheterization; in this situation, 3 units of G0128 would be billed. We are proposing to set the RVUs for this code at 0.26, based upon half the value of the lowest level physician follow-up visit, HCPCS code 99211, in the non-facility setting. This results in a payment for the time slightly more than the average wage reported by the Bureau of Labor Statistics (BLS) for RNs, inflated to reflect benefits and overhead (using the fringe benefit and expense factor used to establish the salary equivalency guideline).

(5) Site-of-Service Differential. Providers of outpatient rehabilitation services have suggested that we should consider making a site-of-service differential, specifically, a payment amount greater than that provided by the physician fee schedule for some of the types of providers or sites at which outpatient rehabilitation services are furnished. We are not proposing such a differential.

First, the law requires that these services be paid the amount determined ''under the fee schedule established under section 1848.'' Furthermore, we believe higher payment amounts for certain facilities, such as CORFs or rehabilitation agencies, would create payment incentives that favor one site or setting over another. We believe the statute establishes a ''level playing field'' for these services. We find no direction in the statutory language or legislative history that we recognize higher costs that some providers argue might be associated with furnishing services in a provider setting. To the extent that CORFs or rehabilitation facilities provide services to patients who need additional care, CORFs or rehabilitation facilities may bill for additional, medically necessary services. For these reasons, a site of service adjustment or higher payment amount for specific settings is not being proposed; however, we welcome any comments that you may present regarding differences in services furnished in the various settings that would justify a differential payment.

(6) Mandatory Assignment. Section 1834(k)(6) of the Act, as added by BBA 1997, establishes a restraint on billing for outpatient rehabilitation therapy services; that is, this provision requires that services paid under section 1834(k) of the Act are subject to mandatory assignment under the same terms applicable to practitioners under section 1842(b)(18) of the Act. We propose, therefore, in accordance with this provision to require mandatory assignment for services provided under the outpatient rehabilitation prospective payment system by hospitals, SNFs, HHAs, rehabilitation agencies, public health agencies, clinics, and CORFs. The mandatory assignment provision does not apply to therapy services furnished by a physician or ''incident to'' a physician's service or to services furnished by a physical therapist in private practice or an occupational therapist in private practice. However, when these services are not furnished on an assignment-related basis, the limiting charge applies.

3. Uniform Procedure Codes for Outpatient Rehabilitation Services

Section 4541(a)(2) of BBA 1997 added section 1834(k)(5) of the Act. This new statutory provision requires that claims submitted on or after April 1, 1998 for outpatient physical therapy services, including speech language pathology services and outpatient occupational therapy services, include a code under a uniform coding system that identifies the services furnished.

The uniform coding requirement is needed to assure proper payment under the physician fee schedule. Hospitals, SNFs, HHAs (for individuals who are not eligible for home health services), CORFs, and outpatient physical therapy providers must use HCPCS codes to report outpatient rehabilitation services when furnished to their outpatients. Hospitals and SNFs that provide outpatient rehabilitation services to their inpatients who are entitled to benefits under Part A but who have exhausted their benefits for inpatient services during a spell of illness or to their inpatients who are not entitled to benefits under Part A are also required to report HCPCS codes.

In March, 1998, we issued a program memorandum AB–98–8 which described the coding for outpatient rehabilitation services. This memorandum identifies the HCPCS codes that will be considered to be outpatient rehabilitation services and specifies how these codes will be reported on the UB–92. We assigned the various codes to revenue centers, that is, physical therapy, occupational therapy, and speech-language pathology, for purposes of applying the financial limitation described below. Assigning codes to revenue centers was not intended to limit the scope of practice or range of procedures that could be furnished by therapists in a particular discipline. We are in the process of revising AB–98–8 because we intend to implement the financial limitation by using modifiers, as described below, rather than assigning the HCPCS codes to revenue centers.

In the program memorandum, we also identify certain HCPCS codes available for billing by CORFs that are not generally rehabilitation services, including vaccinations and nursing services.

4. Financial Limitation

Outpatient rehabilitation therapy services are subject to annual financial limitations or caps commencing January 1, 1999. (The amount of the current cap is $900.) There will be a $1,500 per beneficiary annual limitation or cap on incurred expenses for outpatient physical therapy services including outpatient speech-language pathology services. A separate $1,500 per beneficiary limitation will apply on incurred expenses for outpatient occupational therapy services. The annual limitation does not apply to services furnished directly or under arrangements by a hospital or critical access hospital to an outpatient or to an inpatient who is not in a covered Part A stay. The limitation will apply to outpatient rehabilitation services furnished by a separately certified hospital-based provider, such as a hospital-based SNF. The limitation also applies to outpatient rehabilitation services furnished by a physician or nonphysician practitioner, or incident to a physician's professional services or to a nonphysician practitioner's professional services.

As stated above, there is a single $1,500 limitation for outpatient physical therapy services and outpatient speech-language pathology services. As amended, section 1833(g) of the Act applies a single $1,500 limitation to ''physical therapy services of the type described in section 1861(p).'' Section 1861(p) defines outpatient physical therapy services and includes speech-language pathology services within that definition.

Outpatient rehabilitation services are subject to a 20 percent coinsurance amount. Under the outpatient prospective payment system, the beneficiary will be responsible for 20 percent of the applicable fee schedule amounts. The $1,500 limitation is on incurred expenses. If a beneficiary has already satisfied the Part B deductible, the maximum amount payable by the

Medicare program is $1,200, that is, 80 percent of $1,500. Beginning January 1, 2002, the $1,500 annual limitations or caps will be increased by the percentage increase in the MEI.

In addition to outpatient physical therapy services and outpatient occupational therapy services (other than those provided by a hospital), the limitation applies to physical therapy services (including speech-language pathology services) and occupational therapy services ''of such type which are furnished by a physician or as incident to a physician service.'' As discussed elsewhere in this document, Medicare covers under certain conditions services performed by nurse practitioners, clinical nurse specialists, and physician assistants that would be physicians' services if furnished by a physician. We are proposing to apply the financial limitation to therapy services furnished by these nonphysician practitioners since such therapy services are by definition the same type as are furnished by physicians. Similarly, we propose to apply the financial limitation to therapy services furnished incident to these nonphysician practitioner's services. We have included in Addendum D a listing of the specific services that we propose would be subject to the limitation when furnished by a physician or practitioner directly or incident to their services. Such outpatient rehabilitation services included in Addendum D furnished either directly or incident to the services of a physician or practitioner are always subject to the financial limitation. Other services such as casting, splinting, and strapping may be used in the treatment of conditions (for example, fractures or sprains) or as part of the postsurgical treatment or medical treatment when no other rehabilitation services are delivered. If the services are delivered by a physical or occupational therapist, speech-language pathologist, therapy assistant or therapy aide, are part of a rehabilitation plan of care, or involve services included in the aforementioned Addendum D, then the services are subject to the cap. These outpatient rehabilitation services are delineated in Addendum E and must be identified with a discipline-specific modifier.

Addendum E contains a listing of outpatient rehabilitation therapy codes. Payment for certain HCPCS codes will be made on a basis other than the physician fee schedule in hospital outpatient departments. Other HCPCS codes are considered as CORF services. Further program instructions will be provided in a forthcoming program memorandum regarding the use of HCPCS codes for outpatient rehabilitation therapy services.

With regard to ''incident to'' services, we note that section 4541(b) of BBA 1997 amended section 1862(a) of the Act to require that outpatient physical therapy service (including speech-language pathology services) and outpatient occupational therapy services furnished ''incident to'' a physician's professional services meet the standards and conditions (other than any licensing requirement specified by the Secretary) that apply to therapy services furnished by a therapist. This provision was effective January 1, 1998 and was implemented through program instructions.

The financial limitations apply only to items and services furnished by non-hospital providers and therapists under the outpatient physical therapy (including speech-language pathology) and the outpatient occupational therapy benefit (section 1861(s)(2)(D) of the Act) and therapy services furnished by physicians and nonphysician practitioners or incident to their services. The limitations do not apply to diagnostic tests covered under section 1861(s)(3) of the Act.

To track the financial limitation or cap, we are proposing to use modifiers that will be discipline-specific. Many of the services, for example, physical modalities or therapeutic procedures as described by HCPCS codes, are commonly delivered by both physical and occupational therapists. Other services may be delivered by either occupational therapists or speech-language pathologists. For these services, we expect the claim to include a modifier which describes the type of therapist who delivered the service; if the service was not delivered by a therapist, then the type of therapy plan of care under which the service is delivered would be specified. If the type of therapy is not listed in the modifier field, the claim would be rejected and sent to the provider for resubmission.

As required by section 1833(g) of the Act, as amended by section 4541 of BBA, we propose to establish two annual per beneficiary limits of $1,500. There will be (1) an annual per beneficiary limit for all outpatient physical therapy services excluding hospital outpatient therapy services and (2) an annual per beneficiary limit for all outpatient occupational therapy services excluding hospital outpatient therapy services. As stated previously, outpatient physical therapy services include speech-language pathology services. A provider of outpatient rehabilitation services with a provider agreement under section 1866 of the Act as will as physicians, PTIPs and OTIPs will be allowed to collect payment from a beneficiary for therapy services after the $1,500 limit is reached. This is consistent with current policy allowing PTIPs and OTIPs to collect payment from a beneficiary for therapy services in excess of the current $900 limit.

We note that a report to the Congress is due from the Secretary no later than January 1, 2001. This report is to include recommendations on the establishment of a revised coverage policy of outpatient physical therapy services, including speech-language pathology services and outpatient occupational therapy services. The revised policy is to be based on a classification of individuals by diagnosis category and prior use of services in both inpatient and outpatient settings. The report should include recommendations on how such durational limits by diagnostic category could be implemented in a budget-neutral manner.

5. Qualified Therapists

Section 1861(p) includes services furnished an individual by a physical therapist who meets licensing and other standards prescribed by the Secretary if the services meet such conditions relating to health and safety as the Secretary may find necessary. The services must be furnished in the therapist's office or the individual's home. By regulation, we have defined therapists meeting the conditions for coverage of services under this provision as physical therapists in independent practice. The conditions for coverage are set forth in Part 486, Subpart D (Conditions for coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice) and require that the services be provided by a therapist in independent practice under § 410.60. Under § 410.60, a therapist in independent practice is one who:

- Engages in the practice of therapy on a regular basis.
- Furnishes services on his or her own responsibility without the administrative and professional control of an employer.
- Maintains at his or her own expense office space and equipment.
- Furnishes services only in the office or patient's home.
- Treats individuals who are his or her own patients and collects fees or other compensation for the services.

Under § 486.151 (Conditions for coverage: Supervision), all therapy services must be furnished under the direct supervision of a qualified therapist in independent practice. In

other words, the therapist in independent practice must be on the premises whenever services are provided to Medicare beneficiaries, including services provided by a licensed physical therapist. This long-standing requirement has been controversial with therapists in independent practice. For example, a therapist in independent practice cannot have more than one office open for services at the same time since he or she could not be on both premises at once.

We are proposing to replace the existing ''Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice'' (Part 486, Subpart D), which requires survey and certification, with a simplified criteria for physical therapists in private practice that would use a carrier enrollment process. The impetus for this change comes from congressional statements associated with the fiscal year 1997 appropriations process. Statements in both the House and Senate committee reports accompanying HCFA's fiscal year 1997 appropriations addressed the issue of requiring that the certified physical or occupational therapist in independent practice directly supervise all services performed by his or her employees, even if those employees are fully licensed therapists. The House committee report urged that we modify the regulations so that the certified therapist need not be on premises to supervise other licensed therapists. The Senate urged us to review this concern and recommend regulatory or instructional changes.

We are proposing to redefine those therapists who are qualified pursuant to section 1861(p) of the Act. That is, we would discontinue the focus of the regulation on their ''independent'' status (which is not statutory) and recognize therapists in private practice who are employed by others and therefore, do not meet our current ''independent'' criteria. This would be consistent with health and safety concerns and would conform to normal private sector practice standards. The following new requirements would replace the current ones for qualified therapists:

- The term ''independent'' would be dropped and the benefit would be for an individual physical therapist or occupational therapist in private practice.

Private practice would include an ''individual'' whose practice is in an unincorporated solo practice, unincorporated partnership, or unincorporated group practice. Private practice also would include an ''individual'' who is practicing therapy as an employee of one of the above or of a professional corporation or other incorporated therapy practice. However, private practice would not include individuals when they are working as employees of a provider. A provider as defined in § 400.202 includes a hospital, CAH, SNF, HHA, hospice, CORF, CMHC, or an organization qualified under Part 485, Subpart H (Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), as a clinic, rehabilitation agency, or public health agency.

- In implementing the statutory requirement that services be furnished to an individual in the therapist's office, or in the individual's home, ''in his office'' would be defined as the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location.

A therapist in private practice would not be required to maintain a private office, if services always are furnished in patients' homes. However, when services are furnished in private practice office space, that space would have to be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. For example, because of the statutory restriction on the site of services, a therapist in private practice cannot furnish covered services in a SNF. Therefore, if a therapist wished to locate his or her own private office on site at a nursing facility, special care would need to be taken. The private office space could not be part of the Medicare-participating SNF's space, and the therapist's services could be furnished only within that private office space. Neither the therapist nor any assistants or aides who help render services could be employed by the SNF during the same hours that they are working in the private practice. Another example where special attention would be needed is space that generally serves other purposes and is only used by a therapy practice during limited hours. For example, a therapist in private practice may furnish aquatic therapy in a community center pool on Wednesday mornings. The practice would have to rent or lease the pool for those hours, and the use of the pool during that time would have to be restricted to the therapist's patients, in order to recognize the pool as part of the therapist's own private office during those hours.

In describing other services that are specifically limited to the patient's home, the statute uses qualifying language. For example, the durable medical equipment definition in section 1861(n) refers to a patient's home as ''including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1).'' This definition of home is codified at § 410.38(b). The same definition always has been used in the Medicare Carriers Manual for purposes of covering therapists' services in a patient's home. We propose to continue the current practice and to adopt that definition formally in this regulation.

- Assistants and aides would have to be personally supervised by the therapist and employed directly by the therapist, by the partnership or group to which the therapist belongs, or by the same private practice that employs the therapist. Personal supervision requires that the therapist be in the room during the performance of the service. Levels of supervision are defined in § 410.32.
- The therapist must be licensed or otherwise legally authorized to engage in private practice. We understand that all States license or certify physical therapists, so no alternative personnel qualifications need to be specified.
- Each therapist would enroll ''as an individual'' with the carrier.

There would be no survey and no certification by HCFA. The Medicare carrier would verify that the qualifications proposed in § 410.59(c)(1) or § 410.60(c)(1) are met. All applicants for new enrollment would become subject to these new rules and procedures upon the effective date of the final rule. For transition purposes, we intend that independent therapists who are certified and enrolled at that time would be ''grandfathered'' temporarily and would become subject to the new enrollment rules and procedures at the time of their next regular periodic reenrollment.

These changes would address the concern that current rules require each independent therapist to personally supervise services performed by any other licensed therapists that he or she employs. Under our proposal, each individual therapist in a practice could qualify to separately enroll, and enrolled therapists would not be required for purposes of Medicare to be supervised by their employer. These changes also address the concern that current rules prohibit an independent therapist from being employed by any entity. Under our proposal, a variety of

employment situations would be permitted. The following examples illustrate how our proposals would apply:

- Three PTs operate an unincorporated group practice, which employs several physical therapy assistants and aides and maintains two offices in two towns. Each therapist could enroll as a physical therapist in private practice and could furnish services in either office, while personally supervising any of the assistants or aides who are helping to render therapy.
- A corporation operates a physical therapy practice which employs four physical therapists and several physical therapy assistants and aides. Each therapist could enroll as a physical therapist in private practice and could personally supervise any of the assistants or aides who help to render therapy. If two additional PTs are hired, each must enroll before their services could be covered without supervision by one of the enrolled physical therapists.

A physical therapist works for a hospital's rehabilitation department during the day. During evening hours, he operates his own incorporated professional practice and goes to patient's homes to furnish therapy. He could enroll as a physical therapist in private practice for the evening hours and would not need to maintain an office for furnishing therapy.

A physician's professional corporation employs three physical therapists and six physical therapy assistants in a private therapy practice associated with the physician's office. Each of the PTs could enroll as a therapist in private practice. The physician is not required to supervise any of the therapy. All physical therapy services for which Medicare payment is sought are supervised by one of the physical therapists.

These new requirements would be established in a revised § 410.60(c) for physical therapists. To date, the statutory requirements for coverage of outpatient occupational therapy services have not been codified. We are proposing to codify these requirements by establishing a new § 410.59 for outpatient occupational therapy services. The proposed regulations section for outpatient occupational therapy parallels the § 410.60 requirements for outpatient physical therapy, as revised in this proposed rule. We are also proposing to make conforming changes in § 410.61 to include occupational therapy.

Therapists in private practice do not participate in the Medicare program in the same way that ''providers of services'' do. Though they must be approved as meeting certain requirements, unlike ''providers of services,'' they do not execute a formal provider agreement with the Secretary as described in Part 489 (Provider Agreements and Supplier Approval) of the CFR. Like physicians, they do have the option of accepting a beneficiary's assignment of his or her claim for Medicare Part B benefits and of becoming a Medicare participating supplier who agrees to accept assignment in all cases.

6. Plan of Treatment

We are proposing to revise §§ 410.61(e), 424.24(c)(4)(i), and 485.711(b), which concern the plan of treatment review requirements for outpatient rehabilitation therapy services. Section 1861(p) of the Act defines these therapy services, in part, as services furnished to an individual who is under the care of a physician and for whom a plan, prescribing the type, amount, and duration of therapy services that are to be furnished, has been established by a physician or a qualified therapist and is periodically reviewed by a physician.

Currently, providers that furnish outpatient rehabilitation therapy services are required to have a physician review the plan of treatment and recertify the need for care at least every 30 days. We are proposing that the physician review and recertify the required plan of treatment within the first 62 days and at least every 31 days after the first review and recertification. The current requirement for the review of a plan of treatment for patients of physical therapists in independent practice is similar in that the physician must review the plan at least every 30 days. We are proposing to change this review requirement as well to require that the physician review and recertify the plan of treatment within the first 62 days and at least every 31 days thereafter.

We are recommending these changes because it is our understanding that an initial 2-month (62 day) review is consistent with usual therapy course of treatment. It is also consistent with our current therapy requirements in the home health setting. These changes would reduce the burden on providers, patients, and physicians by eliminating the current requirement for an initial review within the first 30 days. After the first 62 days, we believe that patients receiving outpatient rehabilitation services are likely to show significant progress that warrants subsequent reviews every 31 days. Changes in the patients' level of function and need for continued therapy can be expected to occur more frequently after the first 2 months of therapy. We believe this subsequent review schedule will help control potential over-utilization that results in excessive therapy to some Medicare patients.

Under our proposal, the therapists would be required to immediately notify the physician of any changes in the patient's condition, and physicians would retain the ability to review the care at closer intervals if necessary.

D. Payment for Services of Certain Nonphysician Practitioners and Services Furnished Incident to Their Professional Services

Nonphysician practitioner services have been covered by Medicare since the inception of the program; originally the law did not provide for separate payments for these services. Coverage and payment of nonphysician services was primarily within the context of section 1861(s)(2)(A) of the Act as implemented by section 2050 of the Medicare Carriers Manual, for the payment of services incident to a physician's professional services. In recent years, the Congress has expanded Medicare coverage of nonphysician practitioner services in certain settings to improve beneficiary access to medical services. Separate Part B coverage is specifically authorized for certain nonphysician practitioner services and for services and supplies furnished as incident to those services.

For purposes of this proposal as it applies to nonphysician practitioners, we define nonphysician practitioners as nurse practitioners, clinical nurse specialists, certified nurse-midwives, and physician assistants. With respect to services and supplies furnished as incident to a nonphysician practitioner's services, we are proposing that to be covered by Medicare, the services must meet the longstanding requirements in section 2050 of the Medicare Carriers Manual applicable to services furnished as incident to the professional services of a physician. Therefore, we would specify, in proposed new §§ 410.74(b), 410.75(d), 410.76(d), and 410.77(c) that Medicare Part B covers services and supplies (including drugs and biologicals that cannot be self-administered) furnished as incident to the nonphysician's services only if these services and supplies would be covered if furnished by a physician or furnished as incident to a physician's professional services. In addition, §§ 410.74(b), 410.75(d), 410.76(d), and 410.77(c) would specify

the various requirements for these incidental services and supplies.

1. Coverage and Payment for Nurse Practitioner Services Before BBA 1997

Effective for services furnished on or after April 1, 1990, section 6114 of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101–239) authorized separate payment for the services of nurse practitioners when furnished to patients in SNFs and nursing facilities. The services of nurse practitioners are covered if they are furnished in collaboration with a physician, they are within the scope of services authorized by State law, and they are the type of services that would be covered when furnished by a physician. The term, collaboration is defined as a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines, or other mechanisms as defined by State law, in the State in which the services are performed.

Section 6114 of OBRA 1989 limited routine visits by nurse practitioners who are serving as members of a team to 1.5 team visits per month per resident of a SNF or nursing facility. The team must include a physician and a physician assistant acting under the supervision of the physician, or a nurse practitioner or a clinical nurse specialist working in collaboration with a physician.

Section 6114 of OBRA 1989 requires that payment for nurse practitioner services furnished to patients in SNFs and nursing facilities be made on an assignment-related basis to the nurse practitioner's employer only. This provision also limited the prevailing charges for the services of nurse practitioners furnished before January 1, 1992, to 85 percent of the prevailing charge rate determined for these services when furnished by nonspecialist physicians. For services furnished on or after January 1, 1992, OBRA 1989 limits the payment to 85 percent of the physician fee schedule amount for those services furnished by physicians who are not specialists.

The qualifications for nurse practitioners require individuals to:

- Be a registered nurse who is currently licensed to practice in the State where he or she practices, be authorized to perform the services of a nurse practitioner in accordance with State law, and have a master's degree in nursing;
- Be certified as a nurse practitioner by a professional association recognized by HCFA that has, at a minimum, eligibility requirements that meet the standards in the paragraph above; or
- Meet the requirements for a nurse practitioner set forth in the first paragraph, except for the master's degree requirement, and have received before 3 years prior to the effective date of a final rule, a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

Section 4155 of OBRA 1990 (Pub. L. 101–508) extended coverage of nurse practitioner services that was previously restricted to SNFs and nursing facilities, to all settings in rural areas. Additionally, nurse practitioners were authorized to either receive direct payment or arrange for payment to be made directly to their employer for services furnished in collaboration with a physician in all settings in a rural area, with the exception of hospitals. This provision also allowed for coverage of services and supplies furnished as an incident to a nurse practitioner's services if the services would have been covered if furnished as an incident to a physician's professional services.

The term, ''rural area'' as defined at section 1886(d)(2)(D) of the Act means any area outside a Metropolitan Statistical Area or New England County Metropolitan Area, as defined by the Executive Office of Management and Budget, or outside any similar area the Secretary has recognized by regulation as an urban area.

Sections 4155(b) and (c) of OBRA 1990 imposes a civil monetary penalty not to exceed $2,000 on any person who knowingly and willfully presents a bill or request for payment to a Medicare beneficiary (except for coinsurance and deductible amounts) for nurse practitioner services furnished in a rural area, or for services and supplies furnished as an incident to those services, and for nurse practitioner services furnished in a SNF or nursing facility.

Section 147(e)(4) of the Social Security Act Amendments of 1994 (SSAA'94) (Pub. L. 103–432) unbundled payment for nurse practitioner services in SNFs and nursing facilities. It also added nurse practitioner services to the list of services that are excluded from the definition of inpatient hospital services. Accordingly, nurse practitioners or their employer or contractor were authorized to bill directly for services furnished to patients in SNFs or nursing facilities and hospitals located in rural areas.

2. Coverage and Payment for Nurse Practitioner Services Subsequent to BBA 1997

Effective for services furnished on or after January 1, 1998, section 4511 of BBA 1997 authorizes nurse practitioners to bill the program directly for services furnished in any setting, regardless of whether the settings are located in rural or urban areas, but only if the facility or other providers of services do not charge or are not paid any amounts with respect to the furnishing of nurse practitioner services. Accordingly, a new § 410.75 of this proposed rule specifies the qualifications for nurse practitioners, lists the requirements for the professional services of a nurse practitioner and the requirements for services furnished incident to the professional services of a nurse practitioner. This new section also proposes a definition for the collaboration process that is applicable to the provision of nurse practitioner services.

A new § 405.520(a), (b), and (c) of this proposed rule provides the general rule, requirements, and penalties for nurse practitioners. A new paragraph (15) is added to § 410.150(b) to authorize payment for nurse practitioner services when furnished in collaboration with a physician in all settings located in both rural and urban areas. A new paragraph (c) is added to § 414.56 of this rule to set forth the payment amount for nurse practitioner services.

3. Coverage and Payment for Clinical Nurse Specialist Services Before BBA 1997

In addition to authorizing Medicare coverage of nurse practitioner services furnished in rural areas, section 4155 of OBRA 1990 also authorized the coverage of services furnished by clinical nurse specialists in rural areas. The coverage provisions for clinical nurse specialist services furnished in a rural area parallel those established for nurse practitioner services furnished in rural areas. That is, clinical nurse specialist services must be furnished in collaboration with a physician and be the type of physician services that would otherwise be covered if furnished by a physician. Additionally, the services must be services that the clinical nurse specialist is authorized by State law to furnish in the State in which they are practicing. Furthermore, services furnished as an incident to the professional services of a clinical nurse specialist are covered if they are the type of services that would be covered if furnished incident to a physician's

professional services and all the incident to requirements are met.

A clinical nurse specialist is defined as an individual who is legally authorized to perform such services in accordance with State law, and who meets training, education, and experience requirements as the Secretary may prescribe in regulations.

Section 147(e)(4) of the SSAA'94 also unbundled payment for clinical nurse specialist services furnished in SNFs, nursing facilities, and hospitals. The services of clinical nurse specialists are now paid under a separate benefit.

Payment for clinical nurse specialist services is made to the clinical nurse specialist or to his or her employer. As is the case with nurse practitioners, the services of clinical nurse specialists furnished to patients in rural health clinics (RHCs), federally qualified health centers (FQHCs), and health maintenance organizations (HMOs) are not paid under the respective nurse practitioner or clinical nurse specialist benefits. Instead, the services that nonphysician practitioners furnish in RHCs, FQHCs, and HMOs education, and experience requirements as the Secretary may prescribe in regulations.

Section 147 (e)(4) of the SSAA'94 also unbundled payment for clinical nurse specialist services furnished in SNFs, nursing facilities, and hospitals. The services of clinical nurse specialists are now paid under a separate benefit.

Payment for clinical nurse specialist services is made to the clinical nurse specialist or to his or her employer. As is the case with nurse practitioners, the services of clinical nurse specialists furnished to patients in rural health clinics (RHCs), federally qualified health centers paid under the respective nurse practitioner or clinical nurse specialist benefits. Instead, the services that nonphysician practitioners furnish in RHCs, FQHCs, and HMOs are a part of the facilities' services and cannot be billed or paid separately.

The payment provisions for clinical nurse specialist services furnished in a rural area parallel those established for nurse practitioner services furnished in rural areas. Accordingly, payment for services is made on an assignment-related basis, the civil monetary penalty provision for violation of the assignment agreement applies, and the current Medicare-approved amount for covered clinical nurse specialist services furnished in rural areas (other than in hospitals) is limited to the lesser of the actual charge or 85 percent of the physician fee schedule amount for nonspecialist physician services. For covered services furnished in hospitals located in rural areas, the Medicare-approved amount is limited to the lesser of the actual charge or 75 percent of the physician fee schedule amount for nonspecialist physician services.

4. Coverage and Payment for Clinical Nurse Specialist Services Subsequent to BBA 1997

Effective for services furnished on or after January 1, 1998, Section 4511 of BBA 1997 authorizes clinical nurse specialists to bill the program directly for services furnished in any setting, regardless of whether the settings are located in rural or urban areas, but only if the facility or other providers of services does not charge or is not paid any amounts with respect to the furnishing of nurse practitioner services. A new § 410.76(e) of this proposed rule sets forth this provision.

The new § 410.76(b) sets forth new qualifications for clinical nurse specialists. Section 410.76(c) describes the conditions of coverage for clinical nurse specialists services, defines the collaboration process, and paragraph (d) lists the requirements for services furnished incident to the professional services of a clinical nurse specialist.

A new § 405.520(a), (b), and (c) of this proposed rule provides the general rule, requirements, and civil monetary penalties for clinical nurse specialists. A new paragraph (15) is added to section 410.150(b) to authorize payment for clinical nurse specialist services when furnished in collaboration with a physician in all settings located in both rural and urban areas. A new paragraph (c) is added to section 414.56 of this rule to set forth the payment amounts for clinical nurse specialist services.

5. Coverage and Payment for Certified Nurse-Midwife Services

Certified nurse-midwife services were only covered under the Medicare program when furnished incident to the professional services of a physician or under the supervision of a physician in RHCs prior to these individuals gaining statutory authorization to perform services as independent nonphysician practitioners.

Certified nurse-midwives were defined initially section 1861(gg)(2) of the Act and 42 CFR 405.2401 (b) as a registered professional nurse who:

- Is currently licensed to practice in the State as a registered professional nurse;
- Is legally authorized under State law or regulations to practice as a certified nurse-midwife;
- Has completed a program of study and clinical experience for certified nurse-midwives, as specified by the State, or, if the State does not specify a program—

+ Is currently certified as a nurse-midwife by the American College of Nurse-Midwives;

+ Has satisfactorily completed a formal education program (of at least 1 academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives; or

+ Has successfully completed a formal educational program that prepares registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to newborns, and practiced as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976, to July 16, 1982.

Certified nurse-midwife services are defined at section 1861(gg)(1) of the Act as services furnished by a certified nurse-midwife, and services and supplies furnished as an incident to those services, that the certified nurse-midwife is legally authorized to furnished under State law and that would be covered by Medicare if furnished by a physician or as an incident to a physician's service.

Effective for services furnished on or after July 1, 1988, section 4073 of OBRA 1987 (Pub. L. 100–203) expanded Part B coverage of the services of certified nurse-midwives to include services furnished independently of the supervision of a physician. Subsequently, section 411(h)(4) of the Medicare Catastrophic Coverage Act (MCCA) of 1988 (Pub. L. 100–360) made several technical amendments to section 4073 of OBRA 1987 to categorize and cover certified nurse-midwife services as medical and other health services, specify that payment for the services of a certified nurse-midwife is 80 percent of the lesser of the actual charge or the amount determined by a fee schedule established by the Secretary, and limit the fee schedule to 65 percent of the prevailing charge that would be allowed for the same services furnished by a physician. Additionally, section 4073 of OBRA 1987 requires that payment for certified nurse-midwife services be paid on an assignment-related basis and that violators of the assignment requirements be subject to civil monetary penalties.

Section 6102(f)(7) of OBRA 1989 (Pub. L. 101–239) provided that for services furnished on or after January 1, 1992, payment is determined based on the lesser or the actual charge or 65 percent of the Medicare physician fee schedule.

In 1990, in section 4157 of OBRA 1990 (Pub. L. 101–508) the Congress

recognized certified nurse-midwife services as separate and distinct from hospital services. Accordingly, certified nurse-midwife services are unbundled from hospital services and are paid separately under the certified nurse-midwife benefit.

Ultimately, section 13554 of OBRA 1993 (Pub. L. 103–66) amended section 1861(gg)(2) of the Act to revise the definition of certified nurse-midwife. The revision eliminated the limitation on coverage to include services furnished by certified nurse-midwives outside the maternity cycle. This change was made effective for services furnished on or after January 1, 1994.

A new § 410.77 of this proposed rule lists the qualifications for certified nurse-midwives and provides for the conditions for coverage of certified nurse-midwife services. Paragraph (d) of § 410.77 lists the coverage requirements for the professional services of certified nurse-midwives, while paragraph (c) lists the requirements for services furnished incident to the professional services of a certified nurse-midwife.

6. Coverage and Payment for Physician Assistant Services Before BBA 1997

For physician assistant services furnished on or after January 1, 1987, section 9338(a) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 (Pub. L. 99–509) authorized physician assistants to bill the Medicare program for the type of services that would be considered as physicians' services, provided that the physician assistant is legally authorized by the State to furnish such services. Services furnished incident to the physician assistant's professional services are also covered if these same services would have been covered when furnished incident to the professional services of a physician. Under this OBRA provision, physician assistants furnished their services under the general supervision of a physician in a hospital, SNF, nursing facility, or as an assistant at surgery in both rural and urban areas. In order to have furnished services under the physician assistant benefit, individuals must have met the qualifications as follows:

1. Be certified currently by the National Commission on Certification of Physician Assistants to assist primary care physicians;

2. Have completed satisfactorily a program for preparing physician assistants that—

- Was at least 1 academic year in length;
- Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction that prepared students to deliver health care; and
- Is accredited by the AMA's Committee on Allied Health Education and Accreditation; or

3. Have completed satisfactorily a formal educational program for preparing physician assistants (that does not meet the requirements listed above) and assisted primary care physicians for a total of 12 months during the 18-month period immediately preceding January 1, 1987. Additionally, effective January 1, 1989, section 4076 of OBRA 1987 (Pub. L. 100–203) authorized physician assistants to furnish their services under the supervision of a physician in all settings located in rural areas that were designated under section 332(a)(1)(A) of the Public Health Service Act as health professional shortage areas (HPSAs).

Payment for physician assistant services prior to January 1, 1998 was made only on an assignment-related basis to the actual employer of the physician assistant at 85 percent of the physician fee schedule for professional services. Payment for the services of a physician assistant performing as an assistant at surgery was made at 65 percent of the physician fee schedule. The employer of a physician assistant might have been a physician, medical group, professional corporation, hospital, SNF, or nursing facility.

7. Coverage and Payment for Physician Assistant Services Subsequent to BBA 1997

Effective for services furnished on or after January 1, 1998, the majority of the conditions for coverage of physician assistant services as indicated by new §§ 410.74(a) and (b) remain unchanged with the exception of the condition for coverage of physician assistant services furnished in certain areas and settings. Section 4512 of BBA 1997 removes the restrictions on the site of services in which physician assistants may furnish their professional services, regardless of whether the settings are located in rural or urban areas. Physician assistants are authorized to furnish their professional services as independent nonphysician practitioners to practically all providers of services and suppliers of services only if the facility or other provider of services does not charge or is not paid any amounts with respect to the furnishing of physician assistant professional services. Accordingly, separate payment may be made for physician assistant services in all settings with the exception of rural health clinics (RHCs) and Federally qualified health centers (FQHCs) because Medicare payment for their services is included in the all-inclusive payment rate that the program makes to these facilities.

Under new § 410.74(c), we are proposing to amend the qualifications for physician assistants to recognize certification of physician assistants by the National Board of Certification of Orthopedic Physician Assistants. These qualifications will also recognize academic programs for physician assistants that are accredited by either the Commission on Accreditation of Allied Health Education Programs or the American Society of Orthopedic Physician Assistants.

Additionally, effective January 1, 1998, physician assistants have the option of furnishing services under a different employment arrangement with a physician. They can furnish services as an employee of a physician under a W–2 form employment arrangement or they can furnish services as an employee of a physician under a 1099 form, independent contractor arrangement. Under either arrangement, the employer of the physician assistant must bill the program for physician assistant services as required under § 410.150(b)(14). However, when an individual furnishes services ''incident'' to the professional services of a physician assistant, these ancillary services must meet the requirements under § 410.74(a)(2)(vi)(B).

The Medicare payment amount for physician assistant professional services as of January 1, 1998, as stated under new paragraph (d) of § 414.52, remains at 80 percent of the lesser of either the actual charge or 85 percent of the physician fee schedule amount for professional services. However, payment for physician assistant at surgery services, as also described at new paragraph (d) of § 414.52, increased to allow Medicare payment at 80 percent of the lesser of either the actual charge or 85 percent of the physician fee schedule amount paid to a physician assistant serving as an assistant at surgery. Also, new § 405.520 provides the general rule, requirements, and civil monetary penalties for physician assistants who furnish services under the Medicare program.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information

collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency.
- The accuracy of the agency's estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements (ICRs) discussed below.

- New ICRs and Related Burden.

§ 405.410 (Conditions for opting-out of Medicare.)

Section 405.410(a) states that each private contract between a physician or a practitioner and a Medicare beneficiary must meet the specifications of § 405.415.

The burden associated with these requirements is the time to draft, and then read, sign, photocopy and retain the private contract. It is estimated that it will take 300 physicians and/or practitioners 2 hours each to create a contract for a total of 600 hours. It is estimated that it will take 10 minutes for each to read, sign, photocopy and retain the private contract for 25,000 beneficiaries for a total of 4,167 hours. The burden for these ICRs total 4,767 hours.

Section 405.410(b) states that the physician or practitioner must submit to each Medicare carrier with which he or she files claims an affidavit that meets the specifications of § 405.420.

The burden associated with these requirements is the burden to draft, sign and submit the affidavit to the Medicare carrier. It is estimated that it will take 300 physicians and/or practitioners approximately 2 hours each for a total of 600 burden hours.

§ 405.445 (Renewal and early termination of opt-out.)

Section 405.445(b)(2) states that a physician or practitioner must notify all Medicare carriers with which he or she filed an affidavit of the termination of the opt-out no later than 90 days after the effective date of the opt-out period.

The burden associated with this requirement is the time for the physician or practitioner to notify all Medicare carriers of the affidavit. It is estimated that it will take 30 physicians and/or practitioners 10 minutes each for a total of 5 hours.

Section 405.445(b)(4) states that a physician or practitioner must notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's decision to terminate opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

The burden associated with this requirement is the time for the physician and/or practitioner to notify all beneficiaries of his or her decision to terminate opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare. It is estimated that it will take 30 physicians and/or practitioners each 2 hours to notify their beneficiaries via bulk mailings for a total of 60 hours.

§ 405.455 (Medicare+Choice.)

Section 405.455(a) states that an organization that has a contract with HCFA to provide one or more Medicare+Choice (M+C) plans to beneficiaries must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

The burden associated with these requirements is the time associated with acquiring and maintaining information provided by Medicare carriers on physicians and practitioners who have opted-out of Medicare. It is estimated that 500 organizations will spend 1 hour annually to acquire and maintain this information for a total of 500 hours. The total burden for these ICRs is 500 hours.

ESTIMATED ANNUAL BURDEN

CFR section	Responses	Average burden per response	Annual burden hours
405.410(a)			
—Draft document	300	2 hours	600
—Read, sign, photocopy, retain document	25,000	10 minutes	4,167
Sub-total			4,767
405.410(b)	300	2 hours	600
405.445(b)(2)	30	10 minutes	5
405.445(b)(4)	30	2 hours	60
405.455(a)	500	1 hour	500
Total			5,932

- *New ICRs Without Burden.*

The ICR below is subject to the Act. However, we believe the burden associated with this ICR is exempt since the burden is imposed by § 405.410 and meets the specifications in § 405.420.

§ 405.445 (Renewal and early termination of opt-out.)

Section 405.445(a) states that a physician or practitioner may renew opt-out by filing an affidavit with each carrier to which an affidavit was submitted for the first opt-out period (as specified in § 405.420), and to each carrier to which a claim was submitted under § 405.440 during the previous opt-out period, provided the affidavits are filed within 30 days after the current opt-out period expires.

The ICRs below are subject to the Act. However, we believe the burden associated with these ICRs are exempt, as defined by 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. Physicians and practitioners routinely develop and update a plan of treatment so the patient understands how often and when he or she will require care. In addition, physicians and practitioners routinely maintain

documentation in the patient's medical record.

§ 410.61 (Plan of treatment requirements for outpatient physical therapy and speech language pathology services.)

Section 410.61(e) states that the physician review the plan as often as the individual's condition requires, but at least within the first 62 days and at least 31 days after each previous review.

§ 415.110 (Conditions for payment: Medically directed anesthesiology services.)

Section 415.110(b) states that the physician inclusively documents in the patient's medical record that the conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting personal participation in the most demanding aspects of the anesthesia plan.

The ICRs below are subject to the Act. However, we believe the burden associated with these ICRs are exempt, as defined by 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We believe the record keeping requirements described below are a reasonable and customary part of the plan of treatment described in section 410.61.

§ 424.24 (Requirements for medical and other health services furnished by providers under Medicare Part B.)

In summary *§ 424.24(c)(1)(iii) and (3)* requires that the services that were furnished under a plan of treatment that meets the requirements in § 410.61. If the plan of treatment is established by a physical therapist or speech-language pathologist, the certification must be signed by a physician who has knowledge of the case.

Section 424.24(c)(4) states that the first recertification is required by no later than the 62nd day and subsequent recertifications are required at least every 31 days. The recertification statement must indicate the continuing need for physical therapy or speech-language pathology services and an estimate of how much longer the services will be needed. Recertifications must be signed by the physician who reviews the plan of treatment.

- Currently Approved ICRs.

While the ICRs below are subject to the Act; the burden associated with this requirement is captured in the HCFA–1500, OMB Number 0938–0008, Medicare Common Claim Form, which expires on August 31, 1998.

§ 405.430 (Failure to perfect opt-out.)

Section 405.430(b)(3) states that the physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

§ 405.435 (Failure to maintain opt-out.)

Section 405.435(b)(3) states that the physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

§ 405.440 (Emergency and urgent care services.)

Section 405.440(b)(1) states that when a physician or practitioner furnishes emergency or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, the physician or practitioner must submit a claim to Medicare in accordance with both 42 CFR Part 424 and Medicare instruction (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted-out of Medicare).

We have submitted a copy of this proposed rule to OMB for its review of the ICRs described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn.: Louis Blank, HCFA–1006,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, D.C. 20503, Attn.: Allison Herron Eydt, HCFA Desk Officer

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

We have examined the impacts of this proposed rule as required by Executive Order (EO) 12866, the Unfunded Mandates Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

This proposed rule is expected to have varying effects on the distribution of Medicare physician payments and services. With few exceptions, we expect that the impact would be limited.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This proposed rule will have no consequential effect on State, local, or tribal governments. We believe the private sector cost of this rule falls below these thresholds as well.

A. Regulatory Flexibility Act

Consistent with the provisions of the Regulatory Flexibility Act, we analyze options for regulatory relief for small businesses and other small entities. We prepare a Regulatory Flexibility Analysis (RFA) unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The RFA is to include a justification of why action is being taken, the kinds and number of small entities the proposed rule would affect, and an explanation of any considered meaningful options that achieve the objectives and would lessen any significant adverse economic impact on the small entities.

For purposes of the RFA, all physicians are considered to be small entities. There are about 700,000 physicians and other practitioners who receive Medicare payment under the physician fee schedule. Thus, we have prepared the following analysis, which, together with the rest of this preamble, meets all three assessment requirements. It explains the rationale for and purposes of the rule, details the costs and benefits of the rule, analyzes