the applicable fee schedule amount will be the amount established for comparable services as specified by the Secretary. Therefore, we revised our policy so 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 nonfacility 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 have defined 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 setting 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 nonfacility setting. This results in a payment that is slightly more than the average wage reported by the Bureau of Labor Statistics (BLS) for registered nurses, inflated to reflect benefits and overhead (using the fringe benefit and expense factor used to establish the salary equivalency guideline).

Comment: One commenter supported the use of the nonfacility physician fee schedule for therapy services performed in an SNF and CORF; however, clarification was requested as to whether the facility or the nonfacility physician fee schedule will be used for hospital outpatient departments.

Response: The physician fee schedule payment amount applicable to outpatient rehabilitation services furnished by hospitals is the same as that for SNFs, CORFs, and other outpatient rehabilitation providers. That is, hospitals will be paid for these services under the nonfacility component of the physician fee schedule.

(5) Site-of-Service Differential

We did not propose a site-of-service differential for providers of outpatient rehabilitation services as suggested by some of the providers prior to publication of our proposed rule. That is, we did not propose a payment amount greater or lesser than that provided by the physician fee schedule for some of the types of providers or sites at which outpatient rehabilitation services are furnished.

As explained in our proposed rule, 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 directive 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, we are not revising our policy to allow for a site of service adjustment or higher payment amount for specific settings.

Comment: One commenter believes the work RVU should be the same regardless of setting; however, the commenter contends that the practice expense component may differ among the settings. The commenter states that the impact of any unique regulatory requirements among settings on the cost of furnishing services should be determined.

Response: As stated above, we find no statutory or legislative basis for recognizing a distinct payment differential that is site specific. Therefore, we are not revising our policy to allow for a payment differential among settings.

(6) Mandatory Assignment

Section 1834(k)(6) of the Act, as added by BBA, 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. Therefore, we have revised our policy 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.

2. Uniform Procedure Codes for Outpatient Rehabilitation Services

Section 4541(a)(2) of BBA added section 1834(k)(5) to 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 ensure 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 Program Memorandum AB–98–8 which describes the coding for outpatient rehabilitation services and identifies certain HCPCS codes available for billing by CORFs that are not generally rehabilitation services, including vaccinations and nursing services. This memorandum also 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 recognize that many therapy services, for example, physical therapy

modalities or therapy 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.

Therefore, in July 1998, we issued PM A–98–24 which in effect constituted a reissuance of PM A–98–8 in its entirety. PM A–98–24 was intended, in part, to clarify PM AB–98–8 regarding the reporting of HCPCS codes for outpatient rehabilitation and CORF services and to instruct fiscal intermediaries to eliminate edits installed to match revenue centers to outpatient rehabilitation HCPCS codes in order to cap therapy services. HCFA did not intend for such edits to be installed and employed. Thus, PM A–98–24 instructed fiscal intermediaries to eliminate the edits for services furnished on or after October 1, 1998. However, in response to industry concerns, on August 6, 1998, we issued a memorandum to all fiscal intermediaries advising them to remove immediately any coding edits imposed to match outpatient rehabilitation HCPCS codes to revenue codes.

Comment: We received three comments regarding PM A–98-24 issued July 1998. The commenters stated that confusion remains regarding the effective date of the memorandum. Also, they urged that we instruct carriers to not deny claims based on the practitioners' failure to comply with coding requirements until there is a clarification regarding the manner in which the coding requirement is to be implemented. One commenter recommended that fiscal intermediaries be required to adhere to revised PM A–98–24, effective immediately. The commenter contended that claims wrongly denied based on PM AB–98–8 should be promptly paid based on the claims originally submitted by providers.

Response: We apologize for the confusion. As noted above, PM A–98–24 carried an effective date of October 1, 1998 for fiscal intermediaries to remove any edits installed to match revenue center to HCPCS coding for outpatient rehabilitation services. As also stated above, on August 6, 1998 we issued a subsequent memorandum to all intermediaries advising them to remove the edits immediately. Providers and practitioners were encouraged to resubmit any claims that were incorrectly denied due to misinterpretation of our instructions for billing outpatient rehabilitation services using HCPCS codes.

Comment: We received one comment recommending that the definition of outpatient rehabilitation services be expanded to include payment for low-vision training. The commenter stated that Medicare's failure to cover low-vision training places beneficiaries at risk for extreme out-of-pocket expenditures for transportation services, home-bound visits, and psychological counseling.

Response: We have not accepted the commenter's recommendation. Outpatient rehabilitation services are clearly defined in the statute. Low-vision training is not specifically mentioned in the statute, and we find no statutory or legislative basis for including low-vision training in the definition of outpatient rehabilitation services. Therefore, we cannot arbitrarily expand our definition of outpatient rehabilitation to encompass low-vision training.

Since the statute does not specifically identify low-vision training as a separate Medicare benefit and does not provide a basis for including it under the outpatient rehabilitation benefit, carriers have the discretion to cover these low-vision training services if they determine that they meet the statutory requirements applicable to covered services and are determined to be medically reasonable and necessary.

Comment: A commenter recommends that CPT codes 92520, 94799, and psychiatric therapeutic codes after 90804 be added to the list of outpatient rehabilitation services. The commenter stated that code 94799 is currently recognized by Blue Cross and Blue Shield of Florida. The commenter also stated that, in addition to code 90804, other psychiatric therapeutic codes should be added for assessments and community resource education, referral and advocacy, family conferences, and home assessments.

Response: The commenter asked that we add code 92520, laryngeal function studies, to our list of outpatient therapy codes. Our data show that this code is almost entirely billed by otolaryngologists. Our standard for the inclusion of diagnostic tests as outpatient rehabilitation services is as follows:

- If the primary purpose of a diagnostic test, at times performed by therapists, is to assess the appropriateness or effectiveness of outpatient therapy services or to guide additional treatment by a physical therapist, an occupational therapist or speech-language pathologist, then the test is considered to be outpatient therapy or rehabilitation services; or
- If the primary purpose of the diagnostic test is to provide information on decisions for future medical or surgical treatment or to assess the effect of previous medical or surgical treatment, then the diagnostic test is not considered to be an outpatient therapy or rehabilitation service.

Because the purpose of code 92520 is not clear to us and because our data show that it is performed overwhelmingly by otolaryngologists, we suggest that providers and practitioners who believe it meets the above criteria as an outpatient rehabilitation service provide information to their Medicare contractors and the contractors can approve it if it meets the coverage criteria of being ''medically necessary.'' We advised our carriers and fiscal intermediaries in PM AB–98–24 that they may recognize codes other than those identified in our instruction as outpatient rehabilitation services to the extent that the codes represent services that are determined to be medically necessary and within the scope of practice of the practitioner or therapist billing the service.

The commenter asked that code 94799, unlisted pulmonary services or procedures, be added to the list of outpatient rehabilitation services. Again, we suggest that practitioners and providers that wish to use this code to describe an outpatient rehabilitation service discuss with their Medicare contractor the specific services or procedures being provided when this code is used. Before this code can be used, the Medicare contractor needs to determine whether the services are ''medically necessary.''

The commenter also asked that we add other psychotherapy codes from the family of codes that includes 90804 that is on our list of outpatient rehabilitation services. Clinical psychologists and clinical social workers who deliver services in CORFs can bill any of the psychotherapy codes except for the ones that involve medical evaluation and management. These services are billed under Part B and are submitted to carriers on the HCFA form 1500. Therefore, these codes will not be added to our list of outpatient rehabilitation services.

Comment: One commenter recommended adding to our final rule the statement contained in PM A–98–24 that denotes that other codes may be considered to represent outpatient rehabilitation services to the extent that the services are determined to be medically reasonable and necessary and can be billed as outpatient rehabilitation services.

Response: Although we have included the statement in the text in the regulation, we will consider other codes to be outpatient rehabilitation codes under the terms we have stated.

Comment: One commenter requested that we clarify in the final rule that Addendum F contains the codes for reporting outpatient rehabilitation services.

Response: We appreciate the suggestion. It was inaccurately reported in the proposed rule that Addendum E contains a listing of outpatient rehabilitation therapy codes. It should have read that Addendum F contains such a listing. We have made the appropriate correction in this rule.

3. Financial Limitation

a. Overview. Outpatient rehabilitation therapy services are subject to annual financial limitations or caps beginning 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 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 which includes 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 applying the financial limitation to therapy services furnished by these nonphysician practitioners because such therapy services are by definition the same type as are furnished by physicians. Similarly, we have revised our policy 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 are subject to the limitation when furnished by a physician or practitioner directly or incident to his or her 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 F contains a listing of commonly-utilized outpatient rehabilitation therapy codes. Other codes may be considered for payment as outpatient rehabilitation services to the extent that the services are determined to be medically reasonable and necessary and those that can be performed within the scope of practice of the therapist, physician, or nonphysician practitioner billing the code. Payment for certain HCPCS codes will be made on a basis other than the physician fee schedule in hospital outpatient departments. Other HCPCS codes represent CORF services. Further, PM AB–98–63 dated October 1998 provides additional program instructions 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 amended section 1862(a) of the Act to require that outpatient physical therapy services (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 nonhospital 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 or to items furnished or covered under the durable medical equipment benefit.

Comment: Some commenters urged us to repeal the limitation.

Response: We have no authority to repeal the annual financial limitation as set forth in BBA. An annual per beneficiary limit of $1,500 will apply to all outpatient physical therapy services (including speech-language pathology services). A separate $1,500 limit will also apply to all occupational therapy services. As noted above the annual limitations do not apply to services furnished directly or under arrangements by a hospital to an outpatient or to an inpatient who is not in a covered Part A stay. This limitation applies to expenses incurred on or after January 1, 1999.

Comment: Several commenters want us to delay implementing the financial limitation while others asked that, if we proceed with implementation, we clarify how we would implement it. We received one comment suggesting that we delay the implementation of the annual limitation until we develop a

system of tracking the aggregate amount of speech-language pathology expenses incurred by a beneficiary.

Response: As previously stated, because of our efforts to become Y2K compliant, with the exception of qualified therapists in independent practice, we are not able to make the appropriate systems changes to fully implement the caps on a per-beneficiary basis at this time. Instead, we will use a transitional measure, whereby providers and practitioners (those not currently subject to the caps, for example, physicians and nonphysician practitioners) will be held accountable for tracking incurred expenses for each beneficiary to ensure they do not bill Medicare for beneficiaries that have met the annual $1,500 limitation at their facility for each separate limitation. This means that SNFs will be directly responsible for the billing of all outpatient rehabilitation services and the tracking of incurred expenses of those services when furnished to SNF residents not in a covered Part A stay and SNF nonresidents receiving outpatient rehabilitation services from the SNF.

However, the provider and the practitioner may submit bills to Medicare for the sole purpose of receiving no-pay notices to bill Medicaid or other insurers.

It is noted that the current annual per beneficiary financial limitation applied to outpatient physical therapy services including speech-language pathology services furnished by PTIPs is increased from $900 to $1,500 effective January 1, 1999 for PTPPs. In addition, the current annual per beneficiary financial limitation applied to outpatient occupational therapy services is increased from $900 to $1,500 effective January 1, 1999 for OTPPs. As cited, for these qualified therapists only, the financial limitations continue to be applied on an annual per beneficiary basis rather than on a per provider basis.

Comment: Many commenters believed there should be three separate annual financial limitations, that is, one each for physical therapy, occupational therapy, and speech-language therapy services. They argue that the Congress never intended to include speech-language pathology services within the physical therapy cap because speech therapists have never been defined as independent therapists and were never subject to the current $900 cap.

Response: As stated above, section 1861(p) of the Act defines the term outpatient physical therapy services to include speech-language pathology services. The language in BBA specifically makes provision for physical therapy services and occupational therapy services in applying the annual financial limitation and does not separately mention speech-language pathology services. It is our position that BBA does not include a separate cap for speech-language pathology services, and that there are only two financial limitations (OT and PT that includes speech-language therapy services).

Comment: Two commenters oppose the imposition of the $1,500 cap because it is not sufficient to cover the cost of physical therapy for many common diagnoses or cost of care for typical rehabilitation cases. One of the commenters noted that MedPAC found in its June 1998 report to Congress that one third of the patients receiving outpatient rehabilitation services from rehabilitation agencies and CORFs exceeded either the combined $1,500 cap on outpatient physical therapy and speech-language pathology or the $1,500 cap on outpatient occupational therapy.

Response: The commenter is correct in stating that the MedPAC's study of a 5-percent sample of Medicare outpatient rehabilitation claims for 1996 did find that about one-third of all patients receiving outpatient rehabilitation services from rehabilitation agencies and CORFs exceeded the $1,500 caps. However, the study noted that because most Medicare beneficiaries received the services in hospital outpatient departments in 1996, the percent of all patients impacted by the $1,500 caps is considerably less, that is, only 10 percent of all outpatient physical and speech therapy patients receiving services in hospital outpatient departments, rehabilitation agencies and CORFs and only 2 percent of all occupational therapy patients in those three settings.

We plan to carefully study this issue. As discussed elsewhere in this document, BBA requires that we submit a report to the Congress by January 1, 2001 that recommends viable options for replacing the current dollar caps that take into account patient diagnosis and prior use of services.

Comment: One commenter stated that the limitation should apply only to therapy services furnished by physical therapists and occupational therapists, and not to therapy services furnished by physicians. Another commenter contends that the cap applies solely to therapists and physicians furnishing outpatient rehabilitation services under a plan of care. Neither commenter believes that nonphysician practitioners should be allowed to perform therapy services. These commenters argue that only physical therapists or services provided under the supervision of a physical therapist should be reimbursed by Medicare. The commenters maintain that the definition of physical therapists as referenced in § 485.705(b) and the coverage guidelines specified in section 2210.B of the MCM and 3101.8B of the MIM are not met if the services are provided by persons other than physical therapists. In addition, the statute does not extend the cap to services furnished by practitioners other than OTIPs and PTIPs.

Response: Section 4541 of BBA provides for a prospective payment for outpatient rehabilitation services. The operative word in the statute is ''services''. Reference is made both to the payment for outpatient therapy services and comprehensive outpatient rehabilitation services on the basis of the physician fee schedule and to the financial limitation for all rehabilitation services. The fee schedule is applied to outpatient therapy or rehabilitation services without regard to the practitioner who furnishes the service. Physical and occupational therapy services furnished by physicians and certain other recognized practitioners are payable under the physician fee schedule. A nonphysician practitioner who provides services that would be physicians' services if furnished by a physician under a specific enumerated benefit in the statute would be considered as the physician treating the beneficiary. Thus, a nonphysician practitioner would be considered as the physician treating the beneficiary when he or she furnishes outpatient physical therapy and occupational therapy services. Nonphysician practitioners who meet this definition are 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.

B. Use of Modifiers to Track the Financial Limitation. We have established three discipline-specific modifiers for use in tracking the financial limitation or cap. They are listed below.

GN Services delivered personally by a speech-language pathologist or under an outpatient speech-language pathology plan of care;

GO Service delivered personally by an occupational therapist or under an outpatient occupational therapy plan of care; or

GP Service delivered personally by a physical therapist or under an outpatient physical therapy plan of care.

Reporting of these modifiers will also assist us in gathering data on who is providing the services, and the frequency and duration of the services. 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 that 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.

Comment: We received one comment that supports our proposal to use modifiers that will be discipline-specific to identify whether a plan of care is for physical therapy or occupational therapy. However, the commenter also favors the addition of modifiers that will allow for the identification of physician and nonphysician services that are provided under a plan of care. Claims from physicians and nonphysicians with a modifier would be subject to one of the caps, while claims without a modifier would not be subject to any cap. Another commenter stated that the proposed policy to reject a claim and send it to the provider for resubmission if the type of therapy is not listed in the modifier field is inappropriate and should not be adopted. The commenter contends that there are legitimate cases in which the codes in Addendum D will be reported but should not be applied against the caps, for example, if the services are furnished by a nonphysician practitioner or a physician but they are not provided under a therapy plan of care. This contention is also shared by another commenter who strongly opposed our proposal to apply services against the caps for occupational therapy and physical therapy including speech-language pathology services based strictly on an arbitrary reporting of certain CPT codes. The presumption with this approach is that therapy services are furnished whenever codes listed in Addendum D are reported

Response: At this time, we have decided to only use the discipline-specific modifiers listed in the response above. These modifiers will differentiate between either the type of therapist (physical therapist, occupational therapist, speech-language pathologist) personally providing the service or the discipline plan of care (physical, occupational, and speech-language pathology). For example, if modifier GP is used, the physical therapist must deliver personally the service or the service must be delivered under a physical therapy plan of care. Therefore, in addition to the personal provision of the therapy service by the physical therapist, a physician or nonphysician practitioner can also furnish the physical therapy service. We believe that additional modifiers are not needed to delineate services provided by physicians and nonphysician practitioners under a therapy plan of care; however, we believe that the commenter's statement is valid regarding the possible use of codes listed in Addendum D for other than therapy purposes, that is, not under a therapy plan of care. We are exploring the use of an additional modifier to indicate that the service denoted by the code was not provided under a therapy plan of care. By the time that the financial limitation or cap is fully implemented, we expect to have established the additional modifier. Until that modifier is in place, claims without a discipline-specific modifier will be returned for resubmission.

Comment: A commenter stated that the cap will be difficult to track administratively and recommended that there be a clearer delineation of when services will be subject to the limit and what the controlling factors will be (including the type of professional delivering the service, whether there is a rehabilitation plan of care, and the nature of the service), a listing or examples of services and the circumstances under which they would not be included under the cap.

Response: The commenter's request for clarification is based on a full implementation of the financial limitation or cap. Because of Y2K issues, the financial limitation or cap will not be fully implemented as mandated by statute effective January 1, 1999. Therefore, it is our intention to carefully review, consider, and address the commenter's concerns as we move from the transitional implementation of the cap on a per-provider basis to the full implementation of the cap on an annual per-beneficiary basis.

Comment: One commenter stated that the mechanics of implementing the cap should be clarified. The commenter said that there are serious concerns regarding the calculation of the cap, time of billing, and timing of processing payments that would be fed into the database. The commenter is concerned about the effect of medical review, for example, whether payment will be reserved when a claim is filed in a timely manner, subjected to medical review, denied, and successfully appealed, and the claim was originally filed well before the cap is met. Several commenters were of the opinion that it is administratively difficult for all parties (beneficiaries, providers, and contractors) to track the cap even with the use of the modifiers. They want us to address specific issues regarding tracking and the use of modifiers before implementation of the cap, and to also notify beneficiaries regarding the tracking procedure. These specific issues include a clear delineation of when services are subject to the limit, what the controlling factors will be (including the type of professional delivering the service, whether there is a rehabilitation plan of care, and the nature of the service), a listing or examples of the services and the circumstances under which they would be excluded from the cap.

Response: These are issues that will be addressed prior to the full implementation of the financial limitation or cap. Because there is the distinct possibility that systems requirements will change before such full implementation, it does not seem prudent at this time to detail the mechanics of the future implementation of the cap. However, it is our current thinking that these concerns will be discussed and clarified in companion program instructions issued to the Medicare carriers and fiscal intermediaries.

Comment: A commenter stated that there should be a timely, readily accessible means (such as a query system) for beneficiaries and providers to ascertain the status of the beneficiary's outpatient therapy benefits.

Response: This question relates to the full implementation of the financial limitation or cap on an annual per-beneficiary basis. We are exploring mechanisms by which both the beneficiary and the provider can be informed in a timely and accurate manner, the amounts that have been expended by the beneficiary for outpatient physical therapy services including speech language pathology services and for outpatient occupational therapy services. These methods will be discussed in any program memorandum or other program instruction that we determine will be the vehicle for the conveyance of the beneficiary cap status information.

C. Treatment of Services Exceeding the Financial Limitation. As required by section 1833(g) of the Act, as amended by section 4541 of BBA, we revised our

policy 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 furnished to an outpatient or an inpatient who is not in a covered Part A stay and, (2) an annual per beneficiary limit for all outpatient occupational therapy services excluding hospital outpatient therapy services furnished to an outpatient or an inpatient who is not in a covered Part A stay. 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 well 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.

Required Congressional Report on Financial Limitation

We note that a report to the Congress is due from the Secretary no later than January 1, 2001. This report must 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 must 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.

Comment: It was recommended by a commenter for the report to the Congress that, in addition to basing a revised policy on classification by diagnosis category and prior use of services, an individual's functional status should be a component of any system that purports to address a patient's need for rehabilitation.

Response: As we develop the report to the Congress, we will consider the feasibility of the recommendation.

4. 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 the conditions relating to health and safety the Secretary finds 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 revising our policy 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 redefining those therapists who are qualified under 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 replace the current ones for qualified therapists:

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

Private practice includes an ''individual'' whose practice is in an unincorporated solo practice, unincorporated partnership, or unincorporated group practice. Private practice also includes 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 does 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'' is 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 must maintain a private office, if services always are furnished in patients' homes. However, if 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 an SNF. Therefore, if a therapist wished to locate his or her 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 furnish 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) of the Act 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 under our regulations 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 are continuing the current practice and are adopting the definition formally in this regulation.

- Assistants and aides 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 of our regulations.
- 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 enrolls ''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) of our regulations 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.

These new requirements are 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 codifying these requirements by establishing a new § 410.59 for outpatient occupational therapy services. The regulations section for outpatient occupational therapy parallels the § 410.60 requirements for outpatient physical therapy, as revised in this final rule. We are also making 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 42 CFR part 489 (Provider Agreements and Supplier Approval). 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 that agrees to accept assignment in all cases.

Comment: One commenter strongly supports the carrier enrollment process for physical therapists instead of the existing conditions of coverage. However, the commenter wanted operational issues addressed such as a specification that payments will be made under the practice or corporation's tax ID number for services furnished by physical therapists in private practice who are employees of other practices or corporations. This is the same payment system used by a physician group practice, and the treating therapist's Medicare number or license number would be included on the bill. In addition, the commenter urged that the same process be used for the carrier enrollment process as for the current physician enrollment. Another commenter supported the changes for OTPPs; however, assuming that payment is made to the individual, the commenter inquired as to whether group numbers would be assigned so that payment could be issued to the group under the tax identification number of the business entity.

Response: We will use the same enrollment and billing process as is currently used for individual physicians and physician group practices. This process is delineated at section 1030.7 of the Medicare Carriers Manual, HCFA Pub. 14–Part 4. We note that payment is not made on the basis of the corporate or group practice tax identification number. This number is just one of the data elements that can be related to the Medicare individual and/or group billing number.

Comment: A commenter recommended that direct supervision of assistants and aides be required instead of personal supervision. The commenter provided that direct supervision would be consistent with state laws, the supervision requirements for nonphysician personnel performing services in a physician's office, and with the supervision requirements for aides and assistants of PTIPs.

Another commenter agreed that personal supervision over therapy aides by a qualified occupational therapist or qualified occupational therapy assistant is appropriate. However, the commenter strongly disagreed with the proposal to require personal supervision over occupational therapy assistants and instead urged the adoption of a policy for practicing occupational therapists whereby occupational therapy assistants can perform covered services under the general supervision (that is, initial direction and periodic inspection) of a qualified occupational therapist. In

addition, the commenter thought the policy should state that either a qualified occupational therapist or a qualified occupational therapy assistant must provide personal supervision when therapy aides are used to furnish services.

A commenter stated that qualified occupational therapists who are not Part B suppliers, but who are employed by a therapist who is enrolled as a Part B supplier, should not be subject to the personal supervision requirement. In addition, it was suggested that the proposed language at § 410.59(c)(2) regarding supervision of occupational therapy services should be revised as follows:

''Occupational therapy services are performed by, or under the general supervision of, the occupational therapist in private practice. Services provided by therapy aides must be performed under the personal supervision of an occupational therapist or occupational therapy assistant. All services not performed personally by the therapist in private practice must be performed by employees of the practice, under the applicable level of supervision by the therapist, and included in the fee for the therapist's services.''

Response: Statements contained in the House and Senate committee reports accompanying the 1997 appropriations recommended modifications in our supervision requirements for qualified therapists. As stated, the House committee report urged a regulatory change in the requirement that certified therapists be on the premises to supervise other licensed therapists. We were also urged by the Senate to review this concern and recommend regulatory or instructional changes. We have addressed the concern expressed in the House and Senate 1997 appropriations committee reports and will allow certified therapists to be off the premises when other licensed therapists are present. However, we do not believe that we have the authority to modify the supervision requirements for therapy (physical, occupational or speech-language pathology) assistants and aides. Therefore, we are maintaining our current requirement that therapy assistants and aides have to be personally supervised by the therapist and employed directly by the therapist, by the partnership or group to which the therapist belongs. In accordance with the aforementioned policy, there is no change in the proposed language found at § 410.59(c)(2).

Comment: We received one comment on our proposed qualifications for occupational therapists. One organization recommends that we require evidence of successful completion of a national certification examination recognized by the regulatory authority in the State of practice. Reasons given for the addition of this requirement are that practice varies by jurisdiction and unsuccessful exam candidates often move from State to State obtaining temporary licenses in spite of repeatedly failing qualifying exams. The commenter adds that the particular test they recommend is required in every jurisdiction.

Response: We believe that this recommendation has merit. However, we believe that it requires further study and discussion to assess its impact before we can consider it for adoption. Therefore, we believe it would be more appropriate to consider this recommendation as a proposal for a subsequent publication rather to accept it for adoption in this final rule.

Comment: One commenter supports our proposed set of changes addressing independent practicing occupational therapist services, but adds that as Medicare moves to embrace market based competition, the focus should be on the outcomes delivered rather than the input credentialing. There should be a commitment to move beyond burdensome input criteria that add costs and restrict competition. The commenter suggests that, as part of that initiative, we establish a meaningful time horizon for moving to outcomes-based performance measures.

Response: This is a welcomed recommendation. In recent years, when revising our conditions of participation for various entities, we have emphasized outcomes-based measures. However, this is an area that requires further study in order to apply this concept to our conditions for occupational therapists practice.

Comment: One commenter stated that verification should be provided in the final rule that section 1861(p) of the Act requires a physician to have services furnished by a licensed physical therapist or under the supervision of such a therapist when billing for physical therapist services incident to the physician's professional services.

Response: Section 1861(p) of the Act does not set forth the requirements as specified by the commenter. As previously stated, section 4541(b) of the BBA 1997 amended section 1862(a) of the Act to require that outpatient physical therapy services (including speech-language pathology services) and 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. In May 1998, we issued Transmittal No. 1606 of the Medicare Carriers Manual, Part 3—Claims Process which implemented this provision that was effective January 1, 1998. Section 2218(A) of the Medicare Carriers Manual requires that physical therapy services provided by a physician or by an incident-to employee of the physician in the physician's office or the beneficiary's home must be provided by, or under the direct supervision of, a physician (a doctor of medicine or osteopathy) who is legally authorized to practice physical therapy services by the State in which he or she performs such function or action.

5. 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 proposed revising our policy to allow the physician to 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 proposed changing this review requirement and requiring that the physician review and recertify the plan of treatment within the first 62 days and at least every 31 days thereafter.

We recommended these changes because it was our understanding that an initial 2-month (62 day) review is consistent with the usual therapy course of treatment. It is also consistent with our current therapy requirements in the home health setting. These changes were intended to 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 believed

that patients receiving outpatient rehabilitation services are likely to show significant progress that warrants subsequent reviews every 31 days. Changes in the patient's 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 proposed policy, the therapists would be required to immediately notify the physician of any changes in the patient's condition, and physicians retain the ability to review the care at closer intervals if necessary.

Comment: We received comments from six outpatient rehabilitation associations supporting our proposal and two comments from orthopedic surgical associations strongly opposing it. The opposing orthopedic associations informed us that 62 days is not the usual course of treatment. They argued that every patient's need for therapy is unique depending on the condition. While 62 days may be appropriate for some back injuries, they contend it would be inappropriate for a hand, foot, or shoulder injury. Therapy is appropriate as long as the patient continues to make progress and should be discontinued when the patient's condition has plateaued and no further progress is being made. They stated this can best be determined by the referring physician periodically evaluating the patient's progress and recovery. They believe the current 30-day requirement is appropriate and should be maintained.

Response: After careful review of the comments received and study of the issue by our medical staff, we are retaining our current 30-day requirement and rescind our proposal. As indicated above, our intent, in part, was to establish consistency with the initial review period for HHA therapy services. However, subsequent to our proposal we further learned that HHA patients may not receive the same level of intensity of therapy services as patients receiving them under the outpatient rehabilitation benefit. Our medical staff believes that patients in the latter group are seen more often by their therapists than are HHA patients. Therefore, the rate of progression between the two patient groups may be different and warrant a 30-day rather 62-day initial plan of treatment review for beneficiaries receiving outpatient rehabilitation services.

Comment: We received several comments to allow nonphysician practioners such as nurse practitioners, physician assistants, and clinical nurse specialist to certify the therapy plan of care.

Response: Because we allow nonphysician practioners, that is, nurse practitioners, clinical nurse specialists, and physician assistants to prescribe medicine, we have also decided that nonphysician practioners who have knowledge of the therapy case may certify therapy plans of treatment.

Result of the evaluation of comments: We are adopting our proposal to pay all outpatient rehabilitation services and CORF services under the physician fee schedule. We are delaying full implementation of the financial limitations on outpatient rehabilitation services furnished by nonhospital entities due to our Y2K efforts until after January 1, 2000. We are not adopting a site-of-service differential for outpatient rehabilitation providers as recommended by commenters. Regarding proposed qualifications for therapists, we are adopting them as proposed and are not accepting the recommendation that we require occupational therapists to provide evidence of successful completion of a national certification examination. We anticipate that this issue will be further studied and discussed in a subsequent rule. We are withdrawing our proposal to extend from 30 days to 60 days the time required for physician recertification of the plan of treatment.

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

Nonphysician practitioners' 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 nonphysicians' 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 practitioners' services in certain settings to improve beneficiary access to medical services. Separate Part B coverage is specifically authorized for certain nonphysician practitioners' services and for services and supplies furnished as incident to those services.

For purposes of this rule 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 requiring 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 specify, in 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) specify the various requirements for these incidental services and supplies.

Coverage and Payment for Nurse Practitioners' Services Subsequent to BBA

Effective for services furnished on or after January 1, 1998, section 4511 of BBA 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 practitioners' services. Accordingly, a new § 410.75 of this 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 specifies the process that applies to the provision of nurse practitioners' services.

New §§ 405.520(a), (b), and (c) of this rule provide the general rule and requirements for nurse practitioners. A new paragraph (16) is added to § 410.150(b) to authorize payment for nurse practitioners' 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.

All of the independent nurse practitioners and clinical nurse specialists commenting on the proposed rule and all of the major organizations representing these nonphysician practitioners vigorously opposed the proposed Federal guidelines for

collaboration; those provisions would apply only in States with no collaboration requirement.

Comment: The commenters that objected to the proposed guidelines for collaboration requested that we adopt a policy that strictly defers to State laws, rules, and regulations regarding collaboration. The commenters insisted that the absence of State guidelines for collaboration does not necessitate the intrusion of Federal guidelines. In fact, they claimed that where State laws or guidelines do not include a requirement for collaboration, or fail to provide specific detailed requirements for a collaborative relationship, it is not a matter of accident or simple omission, but of conscious State policy regarding professional scope of practice. In these cases, they believe that there should be *no* collaboration requirement.

Additionally, these commenters stated that they believe that there is a better understanding at the State level of the practice situations encountered and the evolving advancements in health care issues. Therefore, many States have determined that this relationship is best defined by the professionals themselves, rather than through detailed statutory legislation.

The commenters claimed that they are not aware of any substantial problems in interpreting or implementing the collaboration requirement in the 7½ years that carriers have been applying the collaboration requirement without the benefit of Federal rule. According to one commenter, currently at least 26 States have no statutory or regulatory requirement for collaboration as a condition that nurses must satisfy in order to practice, and in the 16 States that have physician collaboration or supervision practice requirements, none are as restrictive as the guidelines that we proposed.

One of the commenters that opposed the proposed collaboration guidelines stated that if more detailed provisions such as these are imposed on nurse practitioners and clinical nurse specialists, there will be a cost attached to be borne by the practitioner or consumers through cost shifting. Another commenter expanded upon this comment by posing the concern about how collaboration might affect States that authorize nurses to practice independently. The commenter stated that imposition of the collaboration requirement in ''independent practice States'' could create a new area for potentially fraudulent or abusive practices. For example, a physician may refuse to provide collaboration in a given area or may refuse to enter into a collaboration agreement unless the nurse pays a fee to the physician. This practice may violate the anti-kickback statute.

One commenter stated that our proposal restricted nurses to a collaboration arrangement with one physician, and that the State's nurse practice act does not restrict nurses to a collaborative practice arrangement with *one* physician. The requirement of collaboration with *one* physician raises the cost to patients, restricts access, and requires unnecessary, additional services. Additionally, this same commenter raised concerns about the phrase in the collaboration guidelines that states ''or as provided by other mechanisms defined by Federal regulations,'' because she believes that this is the first time this wording has appeared in the definition of collaboration and it appears to give unlimited authority for regulation of practice.

One of the professional organizations representing nurse practitioners maintained that the proposed collaboration guidelines would particularly harm Medicare beneficiaries located in rural areas, where nurse practitioners may be the sole source of health care within the community. If a nurse practitioner is not able to receive payment for care due to the inability to locate a physician in that geographic area who is able to perform the functions of a collaborating physician, these areas may not be served at all.

Response: Section 6114 of OBRA 1989 established the nurse practitioner benefit as a separate benefit under the Medicare Part B program and also required that nurse practitioners collaborate with a physician in order for their services to be covered under Medicare. Therefore, nurse practitioners have always been required by Medicare law to collaborate with a physician. The collaboration requirement is a specific and distinct requirement, separate from the requirement that these nonphysician practitioners must practice within the scope of the law of the State where the services are performed.

The 1989 Omnibus Budget Reconciliation Act, adding section 1861(aa)(6) of the Act, defined the term, ''collaboration'' 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 provided by the law of the State in which the services are performed. The BBA of 1997 increased payment amounts to nurse practitioners and expanded the settings where they can receive payments, but the BBA did not change the collaboration requirement. In the absence of State law regarding the collaborative relationship that nurse practitioners must share with a physician when furnishing their services to Medicare beneficiaries, we must implement the collaboration requirement as required by law.

However, we did not intend to introduce new burdensome requirements to address situations where there is no State requirement for collaboration. Therefore we are removing the proposed definition of collaboration that applies to these situations and will require that, in the absence of State law or regulations governing collaboration relationships, we will require nurse practitioners and clinical nurse specialists to document their scope of practice and indicate the relationships that they have with physicians to deal with issues outside their scope of practice. The proposed rule was not intended to require that a nurse practitioner must furnish services in collaboration with only one physician. We fully expect that these nonphysician practitioners may have collaborative relationships with numerous physicians and will continue to do so in the future. We did not intend to introduce any new costs to the practices of nurse practitioners and clinical nurse specialists.

Comment: Five major associations and professional organizations representing physicians, medical directors, and hospitals commented in favor of the proposed collaboration guidelines and suggested alternative criteria that they believed the Medicare program should use to determine coverage and payment for the services of nurse practitioners and clinical nurse specialists.

Two of these organizations commented that ''appropriateness'' is the key criterion that Medicare contractors should use in determining whether services of these nonphysician practitioners should be covered under the ''reasonable and necessary'' provisions of section 1862(a)(1)(A) of the Act. These commenters suggested that we consider services to be appropriate if they are furnished by qualified personnel; further, the commenters believed that, in the case of psychiatry services, these nonphysician practitioners are not qualified as physicians are to perform a psychiatric diagnostic interview examination (CPT codes 90801 and 90802), nor are they qualified to furnish services represented by any of the psychotherapy CPT codes

that include medical evaluation and management. Therefore, these commenters asserted, all of the pertinent sections of the regulations text should be revised to read that the nonphysician practitioners are not performing services otherwise precluded from coverage because of one of the statutory coverage exclusions listed under section 1862(a)(1)(A) of the Act.

Response: In order for any service to be covered under Medicare, it must be determined to be reasonable and necessary, and therefore, appropriate. Accordingly, we do not believe that it is necessary to revise the regulations text to specify that services furnished by these nonphysician practitioners can be covered only when they are not otherwise excluded from coverage under section 1861(a)(1)(A) of the Act. It is already stated in the proposed rule at sections 410.74(a)(2)(iii), 410.75(c)(3), and 410.76(c)(3) that services performed by any of these nonphysician practitioners are not covered if they are otherwise excluded from coverage because of a statutory exclusion. Additionally, it is our understanding that some nurse practitioners and clinical nurse specialists specialize in mental health. Therefore, if State law authorizes these nonphysician practitioners to perform mental health services and evaluation and management services that would otherwise be furnished by a physician or incident to a physician's services, psychiatric nurse practitioners and clinical nurse specialists could bill for psychiatric diagnostic interviews and any of the psychotherapy CPT codes that include medical evaluation and management.

Comment: One association representing hospitals urged us to clarify in the final rule all of the settings in which separate payment to nurse practitioners and clinical nurse specialists will not be made. Also, the commenter suggested clarification regarding whether Medicare will continue to pay hospitals for the facility component of hospital outpatient department services when separate payment is made to these nonphysician practitioners for their professional services furnished in hospital outpatient departments.

Response: Payment is made to nurse practitioners and clinical nurse specialists for their professional services furnished in all settings, with the exception of RHCs and FQHCs. (The professional services of all practitioners are bundled in these two settings, and Medicare payment is made to the facility for such services under an all-inclusive composite rate.) However, when these nonphysician practitioners furnish services in hospital outpatient departments, Medicare will continue to make payment to the hospital outpatient department for the facility component of hospital outpatient department services.

Comment: Two other organizations commented that we should require that the employer of a nurse practitioner or a clinical nurse specialist bill for his or her professional services. The commenter stated that technically, some nurses can practice without direct supervision, but not independently of the supervising physician since the physician must review all records within 2 weeks. The commenter believes that safe and high quality medical care requires that diagnosis, evaluation, treatment, and management decisions be made by physicians who directly supervise nonphysician practitioners on-site. The commenter argues that, if payment is made directly to the nurses, the physician has no way of verifying what is billed when an employer relationship does not exist. Also, because collaboration does not require that the physician be present while services are furnished, and it does not require a physician to make an independent evaluation of each patient, there is no assurance that safe, high quality services are being performed.

Response: The law no longer requires that the employers of nurse practitioners and clinical nurse specialists bill for their services, as it does for physician assistants. The law does maintain the requirement, however, that these nonphysician practitioners must furnish their services in collaboration with a physician. Nurse practitioners and clinical nurse specialists have been educated and specially trained to furnish primary care and certain other services that have traditionally been furnished by physicians. As long as the services that nonphysician practitioners furnish are medically reasonable and necessary, meet Medicare requirements, and fall within the scope of services that they are licensed to perform, the Medicare program covers the services.

Comment: Numerous nurse practitioners and clinical nurse specialists commented that §§ 410.75(d) and 410.76(d) that pertain to services and supplies furnished incident to the professional services of a nurse practitioner or clinical nurse specialist should be clarified to state that these nonphysician practitioners need not be present in the same room where the services are being provided, but may be present and available in the office suite.

Additionally, these same commenters requested the elimination of the list of examples of professional services performed by nurse practitioners and clinical nurse specialists at § § 410.75(e)(3) and 410.76(e)(3), asserting that the list is too limited, confusing, and ultimately unnecessary.

Response: We agree that it may be more appropriate to include the list of examples of services in manual instructions to provide guidance to contractors to use in processing claims. Therefore, we are removing the listing of examples of services that can be provided by physician assistants at section 410.74(d)(3), nurse practitioners at section 410.75(e)(3), and clinical nurse specialists at section 410.76(e)(3).

Comment: One commenter suggested a language change to the requirement that ''incident to'' services be of a type that are commonly furnished in a physician's office, to also include a reference to the offices of other health professionals.

Response: The ''incident to'' requirements for nonphysician practitioners are the same requirements that apply to physicians and that have been in place since the inception of the Medicare program. The various ''incident to'' requirements are currently interpreted at section 2050 of the Medicare Carriers Manual. We will not amend any of the ''incident to'' requirements at this time.

Comment: A few nurses' associations commented that the proposed qualifications for nurse practitioners and clinical nurse specialists should be amended to clarify that these individuals must be licensed or certified by a professional association or an accrediting body that has, at a minimum, eligibility requirements that meet certain standards. One commenter stated that the accrediting body could be one that is recognized by us. These commenters explained that most organizations that certify nurses are not professional associations themselves; rather they are separately incorporated accrediting bodies. For example, the American Nurses Association does not certify nurse practitioners or clinical nurse specialists, but the American Nurses Credentialing Center (ANCC) does by utilizing standards developed by the nurse profession.

Response: Currently, the qualifications for nurse practitioners at section 2158 of the Medicare Carriers Manual require that such an individual be certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates. (Section 2160 of the Medicare Carriers Manual does not contain a specific certification criteria

for clinical nurse specialists.) Thus, the manual recognizes the ANCC as an appropriate certifying body for nurse practitioners.

Comment: One comment made was directed specifically toward the qualifications for nurse practitioners at § 410.75(b) of the proposed rule. One academy representing nurse practitioners stated that the intent of the law is to pay nurse practitioners who are licensed in their States to practice as such. Therefore, the qualifications for nurse practitioners should be that the individual be a registered nurse who is authorized to practice as a nurse practitioner in accordance with State law. This academy believes that the inclusion of additional requirements will exclude some fully qualified nurse practitioners who are certified by national certifying bodies that recognize grandfathering laws in the States and by States that currently use program accreditation or certification rather than national certification in their licensing processes for nurse practitioners.

Response: We agree with the commenter that the intent of the law is to pay nurse practitioners who are licensed in their States to practice as such. However, we believe that State licensure should not be the only qualification criterion that would enable nurse practitioners to bill the Medicare program directly for their professional services. Therefore, we will revise the qualification requirements to ensure that for Medicare purposes, appropriate individuals can bill the program for services furnished to Medicare beneficiaries.

Comment: One college representing nurse practitioners raised concerns about the types of services for which nurse practitioners can bill the Medicare program. The college stated that it wishes to ensure that we intend to permit a nurse practitioner to bill within a group practice setting for the services of all other licensed health care professionals and technicians in that practice. The commenter stated that, although the proposed rule does not indicate a problem with this billing arrangement, it would appreciate a specific statement from us about the arrangement.

Response: A nurse practitioner within a group practice setting would be permitted to bill the Medicare program for the services of all other licensed health care professionals and technicians within the practice, provided the services of others in the practice are furnished incident to the nurse practitioner's professional services and all the ''incident to'' requirements are met.

Comment: The college also stated that it is concerned that the proposed rule does not list nurse practitioners as designated providers of outpatient physical therapy and outpatient speech-pathology services. The college asks that the language of §§ 410.60 and 410.62 be amended to include nurse practitioners as nonphysician practitioners who are authorized to bill for these types of services.

Response: Nurse practitioners, clinical nurse specialists, and physician assistants may order physical therapy, occupational therapy, and speech-language pathology services in the case where the services are medically reasonable and necessary and the State in which they are practicing authorizes them to do so. Also, these nonphysician practitioners may also certify and recertify the plan of treatment for physical therapy, occupational therapy, and speech-language pathology services providing they are authorized by State law to perform such services. Accordingly, § 410.60 and 410.62 regarding physical therapy, occupational therapy, and speech-language pathology will be revised to include these nonphysician practitioners as designated providers of such services.

Result of evaluation of comments: We have determined that for purposes of Medicare Part B payment, a nurse practitioner must—

- Possess a master's degree in nursing;
- Be a registered professional nurse who is authorized by the State in which the services are furnished, to practice as a nurse practitioner in accordance with State law; and
- Be certified as a nurse practitioner by the ANCC or other recognized national certifying bodies that have established standards for nurse practitioners as stated above.

We have removed the alternate proposed definition of collaboration in §§ 410.75(c)(2)(iv) and 410.76(c)(2)(iv) of the proposed rule. For purposes of Medicare coverage, the collaboration requirement will state that nurse practitioners and clinical nurse specialists must meet the standards for a collaborative process, as established by the State in which they are practicing. In the absence of State law governing collaborative relationships, collaboration is a process in which these nonphysician practitioners have a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by nurse practitioners or clinical nurse specialists documenting their scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Nurse practitioners and clinical nurse specialists must document this collaborative process with physicians. The collaborating physician does not need to be present with the nurse practitioner or clinical nurse specialist when the services are furnished or to make an independent evaluation of each patient who is seen by the nurse practitioner or clinical nurse specialist.

Also, we are deleting the proposed listing of examples of services that can be provided by physician assistants, nurse practitioners and clinical nurse specialists.

Coverage and Payment for Clinical Nurse Specialists' Services Subsequent to BBA

Effective for services furnished on or after January 1, 1998, section 4511 of BBA 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 do not charge or are not paid any amounts with respect to the furnishing of nurse practitioners' services. A new § 410.76(e) of this 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.

New § § 405.520(a), (b), and (c) of this rule provide the general rule, requirements, and civil monetary penalties for clinical nurse specialists. A new paragraph (c) is added to § 414.56 of this rule to set forth the payment amounts for clinical nurse specialists' services.

Comment: Numerous nurses associations commented specifically about the qualifications for clinical nurse specialists at § 410.76(b) of the proposed rule. They suggested that the qualifications for clinical nurse specialists be amended to require that a clinical nurse specialist be an individual who is a registered nurse currently licensed to practice as in the State in which he or she practices and have a master's degree in a defined clinical area of nursing from an accredited educational institution. The commenters emphasized that there is no need to provide for an exception as included in the proposed qualifications

for clinical nurse specialists, because the nursing profession has long held consensus that clinical nurse specialists be required to have a master's degree. Additionally, they believed that the definition of a clinical nurse specialist under the BBA makes it clear that a clinical nurse specialist must hold a master's degree. Furthermore, they stated that the proposed exception requirement contains erroneous information about the educational focus of clinical nurse specialist programs that may be preparatory both for primary care and specialty care.

Response: Prior to the BBA, section 2160 of the Medicare Carriers Manual required that a clinical nurse specialist had to satisfy the applicable requirements for a clinical nurse specialist in the State in which the services are performed. In the absence of State requirements, Medicare contractors had the discretion to determine whether an individual's qualifications warranted Medicare payment for clinical nurse specialist services. However, the BBA, which established qualifications for clinical nurse specialists, defines a clinical nurse specialist as an individual who is a registered nurse and is licensed to practice nursing in the State in which the services are performed and holds a master's degree in a defined clinical area of nursing from an accredited educational institution. Therefore, we will implement the BBA qualifications for clinical nurse specialists without an exception for clinical nurse specialists who do not possess a master's degree.

Comment: One independently practicing clinical nurse specialist argued that access to psychiatric clinical nurse specialists, in particular, is being denied even though they are the only mental health providers, other than psychiatrists, whose education, experience, and legal scope of practice include the management of co-morbid medical and psychiatric illness. Psychiatric clinical nurse specialists also provide services that include patient and family education to manage symptoms of illness and medications, evaluation and management of side effects, identification of adverse reactions, and evaluation of effectiveness of medications and psychotherapy. The commenter explained that all clinical nurse specialists in psychiatric nursing hold master's or doctoral degrees; have completed 2-years post-graduate, supervised, clinical experience; have passed a national board certification exam; and are required to obtain 75 hours of continuing education credit every 5 years. The commenter concluded that psychiatric clinical nurse specialists are the only group of mental health providers whose practice is being restricted.

Response: Psychotherapy services are listed in the AMA's CPT coding book as ''physician services''. Nurse practitioners and clinical nurse specialists are authorized by the Medicare program to bill for services that would otherwise be furnished by a physician or incident to a physician's services. Accordingly, it is appropriate for the Medicare program to pay these nonphysician practitioners who have the specific training mentioned for psychotherapy services that are determined to be medically reasonable and necessary.

Result of evaluation of comments: We have determined that for purposes of Medicare Part B payment, a clinical nurse specialist must—

- Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;
- Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and
- Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

Coverage and Payment for Certified Nurse-Midwives' Services

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 a limitation on coverage and included, as covered services, those 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 rule lists the qualifications for certified nurse-midwives and provides the conditions for coverage of certified nurse-midwives' 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.

The comments that we received from a major college representing certified nurse-midwives mainly addressed the proposed qualifications for these individuals.

Comment: The commenter urged that the qualifications for certified nurse-midwives be revised to read that the individual must—

(1) Be legally authorized to practice as a certified nurse-midwife under State law or regulations;

(2) Have successfully completed a program of study and clinical experience accredited by an accrediting body approved by the U.S. Department of Education; and

(3) Be currently certified as a nurse-midwife by the American College of Nurse-Midwives or by the American College of Nurse-Midwives Certification Council.

The college believed that these revised qualifications at § 410.77(a) would eliminate the possibility of individuals being able to practice as certified nurse-midwives in the Medicare program without having to take and pass appropriate certification examinations that are explicitly linked to a demonstrated mastery of the ''core competencies'' for basic nurse-midwife practice. These revised qualifications would, the commenter stated, also assure greater uniformity of quality and competency among certified nurse-midwives who wish to be paid by Medicare for services that they provide to Medicare patients.

Response: Section 1861(gg)(2) of the Act states that the term, ''certified nurse-midwife'' means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary. Accordingly, we are implementing qualifications for certified nurse-midwives that implement these statutory requirements.

Comment: The other comment that the college representing certified nurse-midwives made was directed toward the criteria for determining payment to certified nurse-midwives for their professional services. The college stated that § 410.77(d)(1) should clarify that, while supervision of nonphysician staff by a nurse-midwife does not constitute a professional service, the service provided by the nonphysician may be paid to the certified nurse-midwife if it meets the requirements of a service incident to his or her service.

Additionally, the college suggested that § 410.77(d)(3) be revised to state that Medicare will pay a certified nurse-midwife for all services that he or she is legally authorized under State law or regulations to furnish as a certified nurse-midwife in the State, if those services are also covered services under the Medicare program. The college suggested this change because it maintains that certified nurse-midwives are qualified to perform ''other services'' that might not be interpreted to include

newborn care or certain primary care services, or primary care case management in a managed care context, and certain States license them to perform these ''other services.''

Response: The requirements pertaining to services furnished incident to the professional services of a certified nurse-midwife are listed separately at § 410.77(c) of the proposed rule. We do not want to confuse the requirements for the professional services of certified nurse-midwives with the requirements that pertain to services furnished incident to the professional services of certified nurse midwives.

Section 1861(gg)(1) defines the term, ''certified nurse-midwife services'' as services furnished by a certified nurse-midwife and services and supplies furnished as an incident to the nurse-midwife's service which the certified nurse-midwife is legally authorized to perform under State law as would otherwise be covered if furnished by a physician or as an incident to a physicians' service. Therefore, we agree with the statement made by the commenter that coverage of the professional services of certified nurse-midwives are not restricted to newborn care, certain primary care services, or primary care case management services if State law authorizes them to furnish ''other services.''

Result of Evaluation of Comments: We have determined that for purposes of Medicare Part B payment, a nurse-midwife must—

- Be a registered nurse who is legally authorized to practice as a nurse-midwife in the State where services are performed;
- Have successfully completed a program of study and clinical experience for nurse-midwives that is accredited by an accrediting body approved by the U.S. Department of Education; and
- Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American College of Nurse-Midwives Certification Council. The Secretary reserves the right to determine that these accrediting bodies' standards are no longer sufficient for qualifying nurse midwives for Medicare Part B payment.

Also, a nurse-midwife may provide services that he or she is legally authorized to perform under State law as a nurse-midwife, if the services would otherwise be covered by the Medicare program when furnished by a physician or incident to a physicians' professional services.

Coverage and Payment for Physician Assistants' Services Subsequent to BBA

Effective for services furnished on or after January 1, 1998, the majority of the conditions for coverage of physician assistants' services as indicated by new §§ 410.74(a) and (b) remain unchanged with the exception of the condition for coverage of physician assistants' services furnished in certain areas and settings. Section 4512 of BBA removes the restrictions on the sites 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, provided the facility or other provider of services do not charge or is not paid any amounts with respect to the furnishing of physician assistants' professional services. Accordingly, separate payment may be made for physician assistants' services in all settings, except in RHCs and FQHCs; physician assistant services are included as RHC and FQHC services for which Medicare payment is made based on an all-inclusive payment rate that the program makes to these facilities.

In new § 410.74(c), we proposed 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 would also have recognized 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 employees of a physician under a W–2 form employment arrangement or they can furnish services as an independent contractor to a physician and receive a 1099 form. Under either arrangement, the employer of the physician assistant must bill the program for physician assistants' services as required under § 410.150(b)(15). Moreover, 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 a physician assistant's professional services as of January 1, 1998, as stated in 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. Also, new § 405.520 provides the general rule, requirements, and civil monetary penalties for physician assistants who furnish services under the Medicare program.

We received a total of 140 comments on the proposed physician assistant qualifications. Half of all of the commenters strongly opposed the inclusion of orthopedic physician assistants (OPAs) under the qualifications for physician assistants. The others commenting on the inclusion of OPAs applauded and supported their inclusion and suggested a few minor changes to the qualifications overall.

Comment: The commenters who strongly opposed the proposed physician assistant qualifications included professional organizations, individual physician assistants, State level professional societies and academies, congressional representatives, educational institutions, hospitals, and a board of medical examiners. The commenters stated overwhelmingly that the proposed qualifications for physician assistants inappropriately included orthopedic physician assistants and that orthopedic physician assistants are not physician assistants even if the acronyms (PA and OPA) appear to be similar. The majority of commenters who opposed the inclusion of OPAs noted that they would not object, however, if the Congress implemented a Medicare benefit that recognizes orthopedic physician assistants as separate independent nonphysician practitioners, and, in that case, there should be a payment differential in the amounts of payment made to physician assistants and orthopedic physician assistants that would reflect a higher payment to PAs because they have a greater career investment, patient care responsibility, and higher malpractice insurance costs than OPAs.

The commenters stated that PAs and OPAs do not receive the same education and training, accreditation, certification, or State licensure, and their continuing medical education requirements are not similar. These commenters stated that the curricula for the physician assistant educational programs reveal that these programs emphasized primary care involving diagnosis and treatment of five major clinical disciplines (medicine, surgery, pediatrics, psychiatry, and obstetrics), as well as pharmacology. The training period for

PAs lasts anywhere from 24 to 28 months. The orthopedic educational programs train technical assistants to assist orthopedic surgeons, with an emphasis on orthopedic disease and injury, management of equipment and supplies, operating room techniques, cast application and removal, office procedures, and orientation to prosthetics and orthotics. The training period for OPAs lasted for no more than 24 months.

The commenters asserted that the Commission on Accreditation of Allied Health Education Programs (CAAHEP) must accredit all physician assistant educational programs. CAAHEP is a national independent accrediting agency that is recognized by the U.S. Department of Education and sponsored by medical, allied health, and educational organizations. However, there are currently no existing OPA programs to be accredited. The AMA accredited eight orthopedic physician assistant educational programs from 1969 to 1974. Accreditation ceased in 1974 when the American Academy of Orthopedic Surgeons withdrew sponsorship of the accreditation process.

The commenters stated that PAs are required to take and pass a national examination after graduation from a physician assistant educational program that is certified by the National Council on Certification of Physician Assistants (NCCPA). The NCCPA national certification examination is open only to those individuals who have graduated from accredited physician assistant educational programs. The NCCPA, which provides the certified national examination, is an independent organization whose governing board has representatives from the American Medical Association, American Hospital Association, American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, American College of Surgeons, National Medical Association, Association of American Medical Schools, Federation of State Medical Boards, U.S. Department of Defense, Association of Physician Assistant Programs, and the American Academy of Physician Assistants. The NCCPA also includes three public members.

OPAs who have had on-the-job training or other mid-level paraprofessionals who challenge the exam and have had on-the-job training may take the examination for OPAs that is certified by the National Board on Certification for Orthopedic Physician Assistants (NBCOPA). The NBCOPA certification examination is an open examination and is currently reached through the Professional Testing Corporation, a for-profit business that administers tests for various organizations. The NBCOPA is comprised of six members of the American Society of Orthopedic Physician Assistants (ASOPA), the orthopedic physician assistant professional society, and an unspecified number of advisory members who are presumably non-voting physicians and educators. There is no organized medical group that sponsors or oversees the national certification examination for OPAs other than ASOPA.

The commenters emphasized that all States except Mississippi license and regulate PAs. Forty-three States, the District of Columbia, and Guam have enacted laws to authorize PAs to prescribe medicine. Thirty-three States authorize PAs to write prescriptions for controlled medications. Conversely, only Tennessee specifically licenses OPAs. Tennessee's licensure of OPAs is, however, separate from its licensure of PAs. California and New York have laws referencing OPAs, but the laws refer to OPAs as distinct from PAs. California refers to OPAs who successfully completed training as OPAs from an approved California orthopedic physician assistant educational program in any year between 1971 to 1974 to perform only those orthopedic medical tasks that a physician and surgeon may delegate. New York defines the qualifications for PAs in terms broad enough to include OPAs. The New York State regulations do not limit the acceptable examination to the NCCPA certification examination. Therefore, the NBCOPA certification examination could be considered to adequately assess entry level skills for the physician assistant profession. None of the other States, however, recognize OPAs, and none of the States specifically grant OPAs prescribing privileges.

Additionally, the commenters explained that PAs are required to log 100-hours of continuing medical education over a 2-year cycle and to take a recertification exam every 6 years to maintain certification as PAs. On the other hand, OPAs are required to complete 120 hours of continuing medical education every 4-years or retake the initial NBCOPA certification examination to maintain certification as OPAs.

The professional organizations representing PAs and numerous independent PAs and congressional representatives argued that the proposed changes to the PA qualifications run counter to our twin goals of controlling costs to the Medicare program and maintaining the quality of services furnished to Medicare beneficiaries. There are approximately 49,000 surgical technologists and 3,000 registered nurse first assistants and an uncounted number of unlicensed medical school graduates (for example, from other countries). These individuals could potentially qualify as PAs under the proposed qualifications by getting the requisite orthopedic work experience and passing the orthopedic physician assistant examination that is certified by NBCOPA. Thus, the number of individuals who could qualify for payment under the PA benefit ultimately is substantial.

Additionally, these commenters argued that the proposal to include OPAs as PAs runs counter to congressional intent because the BBA, which amends coverage payment for PAs, does not include any mention of OPAs. They state that the debate on the BBA provisions for physician assistants, nurse practitioners, and clinical nurse specialists did not include any discussion of orthopedic physician assistants or any other types of physician extenders, nor did the Congressional Budget Office consider orthopedic physician assistants or other types of specialty physician extenders when projecting the costs of physician assistant services under the BBA. Furthermore, these commenters stated that the primary sponsors of the 1977 Rural Health Clinic Services Act acknowledged the educational preparation of PAs to provide a wide range of primary care services to Medicare beneficiaries living in areas experiencing a shortage of primary care physicians. While orthopedic technicians may provide valuable, specialized services in assisting orthopedic surgeons, they do not have an educational background in primary care. Consequently, they are not qualified to provide the wide range of primary care services that the Congress anticipated when it recognized the need to cover and pay for the services of PAs under Medicare.

Finally, the commenters urged us to require that, in order for an individual to qualify as a PA under Medicare, he or she must (1) possess State approval to practice as a PA, and (2) demonstrate either graduation from a physician assistant educational program accredited by CAAHEP or certification by NCCPA.

The commenters who supported the inclusion of OPAs under the physician assistant benefit were represented by a national society and academy, orthopedic surgeons, independent orthopedic physician assistants,

hospitals, universities, and organizations that provide orthopedic surgical services. The national society representing OPAs declared that our clarification of the PA qualifications does not relate to payment because orthopedic surgeons are already paid for many services provided by OPAs incident to their professional services. Rather, it believes that the clarification is about recognition of OPAs.

The national academy representing orthopedic surgeons, numerous independent orthopedic surgeons, and OPAs stated that OPAs are specially trained to assist orthopedic surgeons in surgical procedures and other services involving the total care of patients with orthopedic conditions of the anatomy and pathophysiology of the musculoskeletal organ system. Commenters state that OPAs receive extensive training that includes rotations in general medicine and surgery, history and physical assessment, and pharmacology. Additionally, they say, OPAs are trained to obtain medical histories, perform physical examinations, assist the physician in developing and implementing patient management plans, perform common laboratory, radiologic, and other routine diagnostic procedures, and provide injections, immunizations, suturing and wound care, among other services. Other services that these groups have stated that OPAs may perform include the application, fabrication and removal of casts, splints, braces and orthopedic hardware, emergent care of trauma patients, pre- and post-operative care, and serving as first and second assistants to orthopedic surgeons for all procedures. A few commenters noted that the only orthopedic experience that the primary care physician assistants have is received during a 6-week rotation within the 4-year primary care educational program.

Many orthopedic surgeons and others stated that the specialty training that OPAs receive has enabled them to become extremely valuable to their practices freeing up orthopedic surgeons to perform other tasks. Also, some commenters stated that they have found PAs and OPAs to be equally competent and in some cases, OPAs have proven to be more competent than PAs. Therefore, OPAs are very quickly becoming an integral part of their patient care teams. A professional organization commented that the inclusion of OPAs under the PA benefit should not result in exorbitant costs to the Medicare program because there are only approximately 1,000 OPAs who could meet the proposed PA qualifications. Also, when Tennessee established State licensure for OPAs, the State Comptroller's office found that there was an increase in State revenues from fees collected and a slight, but not significant, increase in State expenditures for administering the program.

The national society representing OPAs suggested specific language be added to the proposed PA qualifications to require formal education programs for OPAs.

Response: After reviewing more closely information about the distinctions between PAs and OPAs, and after reviewing the comments that we received on the proposal to include OPAs as PAs, we have determined that it would not be appropriate to treat OPAs in the same way as PAs. There are substantial differences in education and training, certification examinations, accreditation of educational programs, and State licensure and regulation of PAs and OPAs. Additionally, we believe that the 1977 Rural Health Clinic Services Act, which first recognized and paid for the services of PAs under Part B of the Medicare program, would have specifically recognized OPAs as within its scope if it intended to do so. We also believe that a significant number of individuals, exceeding the approximately 1,000 currently practicing OPAs, could qualify as PAs under the proposed rule because the national certification examination for OPAs is currently open to other mid-level nonphysician practitioners who challenge the examination and have had on-the-job training.

Comment: We did not specifically solicit public comment in the proposed rule on the BBA provision that authorized PAs to provide services under an arrangement as independent contractors, in addition to performing services as an employee of entities or individuals such as a physician, medical group, professional corporation, hospital, skilled nursing facility, or nursing facility. However, we discussed, in the background section of the proposed rule, that effective January 1, 1998, PAs have the option of furnishing services under an independent contractor arrangement. Under either arrangement, we explained that the employer of the PA must bill the program for services furnished by the PA. As a result of this discussion, one commenter stated that, generally, PAs have been under the direction of a physician, and they have not been viewed as independent contractors. Therefore, the commenter emphasized that clarification is needed about PAs performing in an independent contractor employment relationship.

Response: Regardless of whether a PA performs services under an employment relationship or under an independent contractor relationship, the Medicare statute requires that he or she furnish services under the general supervision of a physician, and the employer of the PA must always bill for the services furnished.

However, just as we adopt the Internal Revenue Service's definition of an employer/employee employment relationship, we also adopt the Internal Revenue Service's definition of an independent contractor relationship.

Some of the distinctions between an employer/employee and an independent contractor relationship are that, under an independent contractor relationship, the employer does not generally have to withhold or pay any taxes on payments to independent contractors and the employer has virtually no behavioral or financial control over the independent contractor. That is, under an independent contractor relationship, the independent contractor works autonomously without any instructions from his or her employer about when, where, and how to work. The contractor is engaged to perform services for a specific project or period of time, for which he or she is paid at the completion of the project. Independent contractors can make a profit or loss. The services that the independent contractor performs may not be a key aspect of the employer's regular business and, therefore, an independent contractor may have a significant investment in the facilities he or she uses in performing services for the employer. Additionally, the employer of an independent contractor may not provide employee-type benefits such as insurance, a pension plan, vacation pay, or sick pay.

Result of evaluation of comments: We have determined that for purposes of Medicare Part B payment, a physician assistant is an individual who—

- Has graduated from a physician assistant educational program that is accredited by the National Commission on Accreditation of Allied Health Education Programs;
- Has passed the national certification examination that is certified by the National Commission on Certification of Physician Assistants; and
- Is licensed by the State to practice as a physician assistant.

E. Payment for Teleconsultations in Rural Health Professional Shortage Areas

In section 4206 of BBA, the Congress required that, not later than January 1, 1999, Medicare Part B pay for professional consultations by a physician via interactive telecommunications systems (teleconsultations).

Under section 4206(a) of BBA, payment may be made under Part B, provided the teleconsultation service is furnished to a beneficiary who resides in a county in a rural area designated as a Health Professional Shortage Area (HPSA). This payment is notwithstanding that the individual physician or practitioner providing the professional consultation is not at the same location as the physician or practitioner furnishing the service to that beneficiary. (For the purposes of convenience, in this section the term ''practitioner'' is used to mean physicians and practitioners as specified.)

Section 4206(b) of BBA also required that the Secretary establish a methodology for determining the amount of payments made for a teleconsultation within the following parameters:

- The payment is to be shared between the referring practitioner and the consulting practitioner.
- The amount of the payment is not to exceed the current fee schedule amount that would be paid to the consulting practitioner.
- The payment is not to include any reimbursement for any telephone line charges or any facility fees, and a beneficiary may not be billed for these charges or fees.
- The payment is to be subject to the coinsurance and deductible requirements under section 1833 (a)(1) and (b) of the Act.
- The payment differential of section 1848(a)(3) of the Act is to be applied to services furnished by nonparticipating physicians.
- The provisions of sections 1848(g) and 1842(b)(18) of the Act are to apply.
- Further, payment for the consultation service is to be increased annually by the update factor for physicians' services determined under section 1848(d) of the Act.

In addition, the statute directs that, in establishing the methodology for determining the amount of payment, the Secretary take into account the findings of the report required by section 192 of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), the findings of the report required by section 4206(c) of BBA, and any other findings related to clinical efficacy and cost-effectiveness of telemedicine applications.

Provisions of HCFA–1906–P

On June 22, 1998, we published a proposed rule titled ''Payment for Teleconsultations in Rural Health Professional Shortage Areas'' (HCFA–1906–P) (63 FR 33882) that would implement the provisions of section 4206 of the BBA addressing Medicare reimbursement for telehealth services.

Regulatory Provisions

In proposed § 410.75(a)(1), we required that as a condition for Medicare Part B payment for a teleconsultation, the referring and the consulting practitioner be any of the following:

- A physician as described in existing § 410.20.
- A physician assistant as defined in existing § 491.2.
- A nurse practitioner as defined in existing § 491.2.
- A clinical nurse specialist as described in existing § 424.11(e)(6).
- A certified registered nurse anesthetist or anesthesiologist's assistant as defined in existing § 410.69.
- A certified nurse-midwife as defined in existing § 405.2401.
- A clinical social worker as defined in section 1861(hh)(1) of the Act.
- A clinical psychologist as described in existing § 417.416(d)(2).

We required, in proposed § 410.75(a)(2), that teleconsultation services be furnished to a beneficiary residing in a rural area as defined in section 1886(d)(2)(D) of the Act that is designated as an HPSA under section 332(a)(1)(A) of the Public Health Service Act. For purposes of this requirement, the beneficiary is deemed to be residing in such an area if the teleconsultation presentation takes place in such an area.

In proposed §§ 410.75(a)(3) through 410.75(a)(5) we specified further that teleconsultations must meet the following requirements in order to be covered by Medicare Part B:

- The medical examination of the beneficiary must be under the control of the consultant practitioner.
- The consultation must involve the participation of the referring practitioner, as appropriate to the medical needs of the patient, and as needed to provide information to and at the direction of the consultant.
- The consultation results must be in a written report that is furnished to the referring practitioner.

We defined ''interactive telecommunications systems'' in paragraph (b) of proposed § 410.75, as multimedia communications equipment that includes, at a minimum, audio-video equipment permitting two-way, real-time consultation among the patient, consulting practitioner, and referring practitioner as appropriate to the medical needs of the patient and as needed to provide information to and at the direction of the consulting practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of interactive telecommunications systems.

Payment Provisions

Proposed regulatory provisions: We proposed adding § 414.62 (Payment for consultations via interactive telecommunication systems) to our regulations.

We specified, in paragraph (a) of proposed § 414.62, that Medicare total payments for a teleconsultation may not exceed the current fee schedule amount for the service when furnished by the consulting practitioner. We further specified that the payment (1) may not include any reimbursement for any telephone line charges or any facility fees, and (2) is subject to the coinsurance and deductible requirements of section 1833(a)(1) and (b) of the Act. We also specified in paragraph (b) that the payment differential of section 1848(a)(3) of the Act applies to services furnished by nonparticipating physicians.

In paragraph (c) of proposed § 414.62, we provided that payment to nonphysician practitioners is made only on an assignment-related basis. Paragraph (d) provided that only the consultant practitioner may bill for the consultation, and paragraph (e) required the consultant practitioner to provide the referring practitioner 25 percent of any payments, including any applicable deductible or coinsurance amounts, he or she received for the consultation.

Paragraph (f) specified that a practitioner may be subject to the sanctions provided for in 42 CFR chapter V, parts 1001, 1002, and 1103 if he or she (1) knowingly and willfully bills or collects for services in violation of the limitations of proposed § 414.62 on a repeated basis, or (2) fails to timely correct excess charges by reducing the actual charge billed for the service to an amount that does not exceed the limiting charge or fails to timely refund excess collections.

Analysis of and Response to Public Comments to HCFA–1906–P Eligibility Provisions

Comment: Most commenters applauded HCFA's decision to include

both partial and full county geographic HPSAs when determining eligibility. However, a few commenters believed we should not limit eligibility to rural HPSAs. One commenter stated that the proposed eligibility criteria discriminated against elderly persons living in other remote areas. Another commenter suggested that travel time or distance to the specialist, not the availability of primary care physicians in the community, are the most important criteria for elderly patients in need of specialty consultation.

Response: BBA limits eligibility for teleconsultation to rural areas as defined by section 1886(d)(2)(D) of the Act designated as an HPSA as defined by section 332(A)(1)(a) of the Public Health Service Act. This section of the Public Health Service Act defines an HPSA as an area that the Secretary determines has a shortage of health professionals and is not reasonably accessible to an adequately serviced area.

We believe that, it is likely that in an area where sources of primary care are a considerable distance and travel time away, the same would be true for specialty care. In any event, we do not have the authority to expand eligibility for teleconsultation beyond what is specified by BBA.

Comment: One commenter questioned whether psychiatric, dental, and facility HPSAs are eligible for teleconsultation.

Response: As discussed above, HPSA eligibility is limited to eligibility under section 332(a)(1)(A) of the Public Health Service Act. This section of the law references geographic HPSAs only.

Coverage Provisions

Comment: Many commenters requested that we include payment for the use of store-and-forward technology within the scope of coverage of this provision. Commenters believed that, for many specialties, store-and-forward technology provided the same information that would be provided in a live consultation.

For instance, several commenters recommended that we broaden the definition of a consultation to allow stored full-motion video exams or other representations to substitute for the presence of the patient. Other commenters recommended payment for store-and-forward applications such as dermatology photos and orthopedic digital x-rays.

Other justifications for coverage of store-and-forward technology included lack of infrastructure and scheduling difficulties. A few commenters mentioned congressional interest in providing coverage and payment for the use of store-and-forward technology in providing a consultation.

Response: We believe that a teleconsultation is a different method of delivering a consultation service. To that end, we view a teleconsultation as an interactive patient encounter that must meet the criteria for a given consultation service included in the American Medical Association's (AMA) Current Procedure Terminology.

In the proposed rule, we specified that the minimum technology necessary to deliver a consultation must include interactive audio and video equipment permitting two-way real-time communication between the beneficiary, consulting practitioner, and referring practitioner as appropriate. For Medicare payment to occur, the patient must be present, and the telecommunications technology must allow the consulting practitioner to conduct a medical examination of the patient.

The telecommunications requirements do not mandate full motion video. If the telecommunications technology permits two-way interactive audio and video communication allowing the consulting practitioner to conduct a medical exam, Medicare would make payment for a teleconsultation.

These requirements would not prohibit the use of higher end store-and-forward technology in which less than full motion video is sufficient to perform an interactive examination at the control of the consulting practitioner. When performed in real-time, with the patient present, store-and-forward may allow the consultant physician to control the examination by requesting additional, real-time pictures of the patient that are transmitted immediately to the online consultant.

Traditional store-and-forward technology in which an examination, diagnostic test, or procedure is filmed and later transmitted can be used in conjunction with the interactive (via audio-video technology) examination to facilitate the consultant's decision making. However, for Medicare payment to occur, the patient must be present in real-time.

We do not propose to make separate payment provisions for the review of medical records via telecommunications in this final rule. BBA gives payment authority for consultation via telecommunications with a physician or practitioner described in section 1842(b)(18)(C) of the Act, furnishing a service for which payment may be made under Medicare. Medicare currently does not make separate payment for the review and interpretation of medical records.

Separate payment for traditional store-and-forward applications may be appropriate for many forms of diagnostic testing including radiology, electrocardiogram, and electroencephalogram interpretations, as well as imaging studies such as magnetic resonance imaging and ultrasound. Medicare currently allows coverage and payment for medical services delivered via telecommunications systems that do not require a face-to-face ''hands on'' encounter. Section 2020(A) of the Medicare Carriers Manual addresses this issue and lists radiology, electrocardiogram, and electroencephalogram interpretations as examples of such services.

Review of dermatology photos would not be considered a consultation. We believe that this would be a new service for which payment could not currently be made under Medicare. BBA limits the scope of coverage to professional consultations for which payment may be made under Medicare.

Comment: Many commenters believed that we should be more stringent regarding practitioners who can be consultants. For instance, a number of commenters believed that a certified registered nurse anesthetist, anesthesiologist assistant, clinical psychologist, or clinical social worker should not be eligible to be a consulting practitioner because Medicare does not make payment for consultations provided by these practitioners. Additionally, commenters stated that consultation is beyond the scope of practice for these practitioners.

Response: In the proposed rule for teleconsultation we specified that all practitioners described in section 1842(b)(18)(C) of the Act qualify to be a consulting and a referring practitioner. These practitioners include: a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, anesthesiologist assistant, certified nurse midwife, clinical psychologist, and clinical social worker.

After further review of this proposal, we have determined that allowing clinical psychologists, clinical social workers, certified nurse anesthetists, and anesthesiologist assistants to provide a teleconsultation is inconsistent with the Medicare benefit.

We believe that a professional consultation delivered via telecommunications is a method of delivering a consultation service, rather than a new service. For instance, BBA section 4206(a) states that ''payment

shall be made for professional consultations via telecommunications systems with a physician or practitioner described in section 1842(b)(18)(C) of the Act furnishing a service for which payment may be made * * * '' Moreover, section 4206(b) of BBA states ''the amount of such payment shall not be greater than the current fee schedule of the consulting physician or practitioner.''

Under existing Medicare policy, clinical psychologists, clinical social workers, certified registered nurse anesthetists, and anesthesiologist assistants cannot bill, nor receive payment, for consultation services under Medicare. Therefore, these particular practitioners are prohibited from billing for a teleconsultation because, under the Medicare program, no payment would be made for a consultation service provided by these practitioners.

In addition, we have reviewed our proposed policy which allowed certified registered nurse anesthetists and anesthesiologist assistants to refer Medicare beneficiaries for teleconsultation. After review, we have decided to omit these practitioners as eligible to refer patients for teleconsultation. Section 1861(bb) of the Social Security Act defines services provided by these practitioners as anesthesia services and related care. Currently, our view is that the nature of these services is such that certified registered nurse anesthetists and anesthesiologist assistants would not request a consultation as defined by the Physicians' Current Procedure Terminology. Thus, we are excluding certified registered nurse anesthetists and anesthesiologist assistants from the list of referring practitioners. We invite specific comments regarding this issue.

To implement this policy change, we are omitting clinical psychologists, clinical social workers, certified nurse anesthetists, and anesthesiologist assistants from being consulting practitioners as follows at redesignated § 410.78(a)(1):

(1) The consulting practitioner is any of the following:
(i) A physician as described in § 410.20.
(ii) A physician assistant as defined in § 410.74.
(iii) A nurse practitioner as defined in § 410.75.
(iv) A clinical nurse specialist as defined in § 410.76.
(v) A nurse-midwife as defined in § 410.77.

Additionally, a new section is added to omit certified nurse anesthetists and anesthesiologist assistants as referring practitioners as follows at redesignated § 410.78(a)(2):

(2) The referring practitioner is any of the following:
(i) A physician as described in § 410.20.
(ii) A physician assistant as defined in § 410.74.
(iii) A nurse practitioner as defined in § 410.75.
(iv) A clinical nurse specialist as defined in § 410.76.
(v) A nurse-midwife as defined in § 410.77.
(vi) A clinical psychologist as described at § 410.71.
(vii) A clinical social worker as described in section 410.73.

Comment: We received a number of comments regarding the referring practitioner participation requirements. Several commenters believed that requiring the participation of the referring practitioner as a condition of payment is unreasonable. They believed this responsibility can usually be delegated to a midlevel practitioner or, in some cases, no presenting practitioner. Commenters made the case that the referring practitioner does not travel to the consultant's office for a traditional consultation and therefore should not be required to participate in a teleconsultation.

Response: We have reviewed our proposed policy requiring the participation of the actual referring practitioner as appropriate to the medical needs of the patient. After review we have decided to amend this policy to allow all practitioners listed as referring practitioners in this rule to be eligible to present a Medicare beneficiary for teleconsultation. However, if the practitioner is not the actual referring practitioner, he or she must be an employee of the referring practitioner.

Hence, if a primary care physician determines that a specialty consultation is necessary, he or she could delegate the presentation of the beneficiary to an eligible referring practitioner (i.e., nurse practitioner, physician assistant, nurse midwife, clinical nurse specialist, clinical psychologist, or clinical social worker) who is an employee.

We clarify, that for circumstances where the condition of the patient may not medically require the participation of a presenting practitioner, we would not require the participation of a presenting practitioner as a condition of payment for the teleconsultation.

When no practitioner is present with the patient, the consultant will continue to share 25 percent of total payments with the referring practitioner. As discussed in the payment provision section of this document, the 25-percent allocation is intended to reflect the average amount of new work performed by the referring practitioner over many teleconsultations. However, because of the potential for fraud or abusive practices in these situations where the referring practitioner is not present with the patient, HCFA in consultation with the Office of the Inspector General will monitor these services in our review of the Medicare teleconsultation benefit.

To execute this policy in this final rule, proposed § 410.75(a)(5), redesignated as § 410.78(a)(5), specifies that as a condition of payment, the teleconsultation involves the participation of the referring practitioner or a practitioner described in section 1842(b)(18)(C) of the Act (other than a certified registered nurse anesthetist or anesthesiologist assistant) who is an employee of the referring practitioner, as appropriate to the medical needs of the beneficiary and to provide information to and at the direction of the consulting practitioner.

Comment: Several commenters requested clarification regarding the availability of the referring practitioner while the teleconsultation takes place.

Response: A practitioner who is eligible to be a referring practitioner, as described in redesignated § 410.78(a)(2) (formerly § 410.75(a)(2)), is required to be present in the office suite or hospital wing and available to participate in the teleconsultation as necessary. We do not mandate that a practitioner be present in the room while the teleconsultation is taking place.

As discussed earlier in this document, a presenting practitioner's participation is required as appropriate to the medical needs of the beneficiary and to provide information at the direction of the consulting practitioner. However, if the medical needs of the beneficiary require the participation of a presenting medical professional, that professional must be a practitioner described in redesignated § 410.78(a)(2).

Comment: A few commenters requested clarification regarding whether the referring practitioner may bill for other services on the same day that the teleconsultation takes place. A suggestion was made that a referring practitioner should be permitted to bill for a primary care visit on the same day as a teleconsultation if the primary care visit is the basis of the consultation or for a medical problem unrelated to the consultation.

Response: On the day the teleconsultation occurs, the referring practitioner may bill for the office, outpatient, or inpatient visit that preceded the need for a consultation. Additionally, the referring practitioner could bill for other services as ordered by the consultant, or for services unrelated to the medical problem for which a consultation was requested.

However, the referring practitioner is prohibited from billing for a second visit for his or her role in presenting the patient at the time of teleconsultation. The consulting practitioner is responsible for billing Medicare for the consultation service.

Comment: Many commenters suggested an expansion in the scope of coverage beyond consultation services including speech pathology, occupational therapy, diabetic self management, psychotherapy, office and other outpatient visits for new and established patients, nursing facility services, and patient education and diagnostic interviews. Additionally, the nature of the comments indicated a belief that consultation can only be requested for a limited number of conditions or specialties and that a consultation service can only be provided once per patient.

Response: Section 4206(a) of BBA limits the scope of coverage to professional consultation for which payment is currently made under Medicare. We believe that a consultation is a specific service that meets the criteria specified for a consultation service in the AMA 1998 Current Procedure Terminology. BBA does not give authority to cover services beyond consultation under this provision.

We clarify that a consultation can be requested by a physician or practitioner for many medical specialties including, but not limited to: cardiology, pulmonary, neurology, dermatology, gastrology, and psychiatry. Additionally, the scope of coverage for teleconsultation is not limited to the initial request for consultation from the referring practitioner. If an additional request for consultation regarding the same or new problem is received from the attending practitioner and documented in the medical records, another teleconsultation may be billed.

Comment: Two commenters requested clarification of whether a physician assistant is eligible to be a consultant under this provision.

Response: A physician assistant, as defined in existing § 410.74, is eligible to bill for a teleconsultation.

Comment: A number of commenters believed that, in many cases, a registered nurse, or other medical professional, is qualified to present the patient to the consultant. One commenter believed that patient care has never suffered when a medical professional not recognized as a Medicare practitioner is used to present the patient and only a small percentage of cases actually require a physician, nurse practitioner, or physician assistant to be present for the teleconsultation.

Response: Section 4206(a) of BBA specifies that the individual physician or practitioner providing the professional consultation does not have to be at the same location as the physician or practitioner furnishing the service to the beneficiary. We believe this language is limiting and requires that a practitioner, as recognized under section 1842(b)(18)(C) of the Act, must be present with the patient during the teleconsultation. Since the same phrase describes the medical professional at both ends of the teleconsultation, we believe that it would be difficult to interpret the phrase to have one meaning for purposes of identifying the consultant and a different meaning for purposes of identifying who may be physically with the patient. Therefore, registered nurses, and other medical professionals not recognized as practitioners under section 1842(b)(18)(C) cannot act as presenters during teleconsultations.

Comment: A few commenters believed that the range of medical professionals eligible to provide a teleconsultation should be expanded beyond what is allowed by BBA. Suggestions included physical therapists, respiratory therapists, and occupational therapists. Commenters stated that outpatient rehabilitation following a stroke or other disorder is less expensive and better than prolonged inpatient care. Other commenters suggested that nurse specialists and registered nurses be allowed to provide a consultation service. Commenters stated that nurses provide education to patients without the presence of a physician or other practitioner.

Response: BBA limits the medical professionals who may be consultants to physicians or practitioners described in section 1842(b)(18)(C) of the Act. These practitioners include a clinical nurse specialist as described in § 410.76; however, nurses who are not recognized as practitioners under section 1842(b)(18)(C) of the Act are not eligible to provide a teleconsultation. This section of the law does not include physical therapists, respiratory therapists, and occupational therapists. We have no authority to expand the statutory definition.

Comment: One commenter stated that a certain State law requires the referring practitioner to have the ultimate authority over the care of the patient. The commenter believed that this requirement conflicts with our proposed rule which specifies that the examination be at the control of the consulting practitioner.

Response: We clarify that the language at proposed § 410.75(a)(4), redesignated in this final rule as § 410.78(a)(4), ''The medical examination of the beneficiary is under the control of the consultant practitioner,'' does not mean that the referring practitioner relinquishes the overall responsibility for a beneficiary's care. The intent of this requirement is to clarify that the consulting practitioner is conducting a real-time examination with the patient present, rather than reviewing a prior examination, diagnostic test, or procedure prepared in advance by the referring practitioner.

Payment and Billing Provisions

Comment: One commenter believed that the discussion of general Medicare payment policy is unclear. The commenter specifically questioned the applicability of coinsurance.

Response: Generally, under Medicare part B, Medicare pays 80 percent of the lower of the actual charge or appropriate fee schedule amount, presuming the beneficiary has met his or her Medicare part B deductible. Under the Medicare program and for purposes of this provision, the maximum Medicare payment for a teleconsultation provided by a participating physician would be based on 80 percent of the physician fee schedule, presuming that the deductible had been met. For all other eligible consulting practitioners, the maximum Medicare payment amount would be 80 percent of 85 percent of the physician fee schedule. The beneficiary would be responsible for 20 percent of the appropriate payment amount.

An example of this formula using $100 as the Medicare physician fee schedule amount is provided below.

Payment for a teleconsultation when a participating physician is the consultant:

- Medicare Physician Fee Schedule: $100.
- Max. Medicare Payment Amount (80% of $100): $80.
- Coinsurance (20% of $100): $20.
- Total Payment Amount: $100.

Payment for a teleconsultation when an eligible non-physician practitioner is the consultant:

- Medicare Physician Fee Schedule: $100.
- Practitioners Respective Percentage of the Physicians Fee Schedule and Resulting Non-Physician Fee Schedule Amount (85% of $100): $85.
- Max. Medicare Payment Amount (80% of $85): $68.
- Coinsurance (20% of $85): $17.
- Total Payment Amount: $85.

Comment: One commenter questioned whether Medigap, Medicaid, and other supplemental insurance will pay the 20-percent coinsurance for teleconsultations.

Response: Medicare Supplemental Insurance (MSI) will pay the 20-percent coinsurance for covered teleconsultations. MSI coverage including Medigap, Medicaid, or employer plans have been standardized across the country. All MSI plans provide what are known as ''basic benefits,'' which are defined to include Medicare Part B coinsurance for covered services (20 percent of the Medicare-approved amount). Teleconsultation is a consultation service delivered via telecommunications systems and is covered under Medicare in rural HPSAs effective January 1, 1999.

Comment: We received a number of comments regarding the proposed payment allocation in which the consultant would receive 75 percent and the referring practitioner would receive 25 percent of the consulting practitioners fee schedule. Several recommendations were made to vary the distribution of payment based on the work performed by each practitioner. A few commenters suggested that if it is not medically necessary for a presenting practitioner to participate in the teleconsultation, the consultant should receive 100 percent of the payment. Other commenters suggested that the payment allocation be determined by the practitioners involved.

Response: We recognize that the level of involvement of the presenting practitioner will vary from case to case, and our model for payment allocation reflects this belief. In determining the payment allocation, we developed a model simulating the combined intensity level for both the referring and consulting practitioners by using relative value units (RVUs) applicable to consultation services and primary care visits (primary care visits were used as proxy for the role of a presenting practitioner during a teleconsultation).

The model reflects that some consultations will require more preparation and medical expertise from the presenting practitioner. For instance, in the first scenario we used the full primary care RVUs. In the second scenario we reduced the work component by 50 percent to reflect that some consultations will require less new work from the presenting practitioner.

The consultation service and primary care visit RVUs were calculated as a percentage of the combined total and resulted in a 75-percent payment to the consulting practitioner and 25-percent payment to the referring practitioner. This percentage allocation is intended to reflect the average level of new work performed by each practitioner over the course of various teleconsultations. It would not be practical for us to develop varying fee amounts for the referring practitioner's role in presenting the patient given our lack of program experience with teleconsultation. However, we are not eliminating the possibility of making changes to the allocation methodology if program experience demonstrates that a modification is warranted.

We considered making a single payment to the consulting practitioner without specifying the amount to be shared with the referring practitioner, however we wished to avoid raising issues of prohibitions against ''fee splitting.'' For more information on the payment allocation see page 33886 of the June 22, 1998 proposed rule.

Comment: A few commenters believed that the regulation should specify the consequences in the event that a consultant fails to share payment in a timely fashion. A suggestion was made to amend the regulation to require the consultant to share payment within 30 days of receipt from the Medicare carrier. The commenter also requested that, in the event of untimely sharing of payment, the referring practitioner have the right to contact the consultant's Medicare carrier directly for the required percent of payment.

Response: We are not mandating or imposing time limits or dictating how sharing of payments should occur. We believe the specific details of how the payment should be shared, including the appropriate time frame, should be up to the practitioners involved. We believe that specifying a time frame in which sharing must occur, would impose an unnecessary burden on the consulting practitioner.

Comment: One commenter stated that the proposed rule is unclear regarding when the consulting practitioner should share 25 percent of the total payment with the referring practitioner. Specifically, the commenter provided two examples of how payment could possibly be shared. The first example involved sharing Medicare and coinsurance payments separately (upon the receipt by the consultant), while the second example involved sharing 25 percent of the total fee schedule amount before coinsurance was received by the consulting practitioner. The commenter believed that the amount of payment allocation changes depending on when sharing occurs.

Response: The consulting practitioner is responsible for billing Medicare for the consultation service and sharing 25 percent of total payments received with the referring practitioner. Whether the consulting practitioner shares payments as he or she receives them, waits until all payments are received, or shares the Medicare and coinsurance payments up-front, the total payment amount allocated to each practitioner remains the same. We are not imposing further guidelines on the sharing arrangement between the two practitioners.

Comment: Several commenters questioned whether our proposed payment methodology of making a single payment to the consultant and requiring him or her to share payment violates section 1877 of the Act. This section provides penalties for certain prohibited referrals. A few commenters questioned the applicability of State laws that prohibit fee splitting.

Response: The payment provisions for teleconsultation specify that the consulting practitioner must submit the claim for the consultation service and must share 25 percent of total payment with the referring practitioner. Given that we require the sharing of payments and predetermine by law the payment amount allocated to the referring practitioner, we believe that our regulation does not constitute a prohibited compensation arrangement between the consulting and referring practitioners. We do not regard the consulting practitioner as actually making a payment to the referring practitioner, but rather acting as a ''conduit'' to pass a portion of the Medicare payment on. Therefore, we believe that physicians and practitioners, under our payment policy, are not in violation of the Act. For more discussion regarding the bundled payment approach see page 33887 of the June 22, 1998 proposed rule.

Comment: A few commenters questioned how this payment sharing arrangement is treated for tax purposes and whether requiring the consultant to share payment is in conflict with the tax laws.

Response: HCFA does not give tax advice. However, we believe that what the commenter presents as a tax problem is merely a matter of bookkeeping. We note that the law requires the sharing of payment, and the regulation requires the consultant to give 25 percent of the payment received to the referring practitioner. We do not believe that the consultant would ever account for the portion of the Medicare payment for which he serves as a ''conduit'' as income of his or her own. Each practitioner should consult his or her own tax adviser for specific

information about his own bookkeeping practices.

Comment: Many commenters believed that it will be an administrative burden for the consultant to share payments with the referring practitioner. We received suggestions for two alternative billing proposals. The first alternative proposal maintained the single bill approach, but required us to issue separate checks to the consulting and referring practitioner from the same claim form. The second alternative proposal required the submission of separate claims from the consulting and referring practitioner with HCFA issuing separate checks.

Response: We understand the commenters' concern regarding the additional administrative requirements placed on the consulting practitioner. As a result of public comment, we examined the possibility of issuing two separate checks from the same claim form. Under this approach, we would pay the consultant 75 percent of the appropriate fee schedule amount and the referring practitioner would be paid 25 percent based upon the claim submitted by the consultant. However, this option could not be implemented to meet the January 1, 1999, effective date of this provision as mandated by section 4206 of BBA. For instance, the Medicare claims processing system is currently designed to accept only one ''pay to'' personal identification number (PIN) per claim on the electronic claim record and the HCFA–1500 paper claim fields that are used as the source for generating a check to a practitioner.

Currently there is only one scenario in which two checks can be issued from one claim form. That situation occurs when a beneficiary overpays his or her deductible and/or coinsurance on an assigned claim. In this case, one check is issued to the provider and a second check is issued to the beneficiary reflecting the amount the beneficiary overpaid. It is possible to issue two checks in this one instance because there is only one personal identification number.

Additionally, the Medicare claims processing system is designed to accommodate only one provider signature per claim. As such, if the consulting practitioner bills on behalf of the referring practitioner, we would not have a valid claim from the referring practitioner upon which to base payment and issue a check.

Another administrative difficulty concerns the possibility that the consulting and referring practitioners may be located in different carrier jurisdictions. This would make it difficult for one carrier to make separate payments to both practitioners. This option may be more feasible once national practitioner identification numbers are implemented as mandated by the Health Insurance Portability and Accountability Act of 1996.

When developing the proposed rule we considered requiring each practitioner to submit a separate claim. This alternative was rejected due to the administrative difficulties in linking claims to assure that the payment ceiling as allowed by section 4206 of BBA is not exceeded. Total payment could exceed what the consultant would have otherwise received if the presenting practitioner were to submit a claim for a consultation at a higher intensity level than the consultant. The task of linking claims becomes increasingly difficult if two carriers are involved because the practitioners' locations fall within separate carrier jurisdictions. The systems modifications necessary to accommodate separate claims could not have been implemented by the January 1, 1999, effective date as mandated by BBA.

Although the final rule requires the consulting practitioner to submit a claim for the teleconsultation and share payment with the referring practitioner, we are not foreclosing the possibility of making changes to this policy in the future.

Comment: One commenter had concerns regarding language in the proposed rule that stated that the teleconsultation transfers the patient to the consulting practitioner. The commenter believed that we should clarify that this statement was made only for administrative requirements of the physician fee schedule and that we did not intend it as a comment on the scope of medical practice.

Response: Our determination of the consultant's location as the site of service is for Medicare payment purposes only. Given that BBA allows payment up to the consultant's current fee schedule, we believe that it is appropriate to use the Geographic Practice Cost Index (GPCI) relevant to the location of the consulting practitioner, rather than the GPCI applicable to the referring practitioner. We did not intend to make a comment regarding the scope of medical practice.

Coding Provisions

Comment: The majority of commenters were strongly in favor of using a modifier to identify a consultation delivered via telecommunications systems. A few commenters suggested new codes to identify a teleconsultation. One commenter stated that modifiers are not always handled correctly by the Medicare carriers and that separate codes would offer the most reliable way of identifying services subject to their own payment rules.

Response: Using a modifier to identify a consultation delivered via telecommunications conforms with our view that a teleconsultation is a method of delivering a consultation service, rather than a new service. We considered developing a separate coding structure for teleconsultation, however, we rejected this option because we believe that new codes would be administratively cumbersome for the medical community and the Medicare program. We believe it will be easier for practitioners to use a single modifier rather than an entirely new set of codes.

Issues Not Addressed in the Proposed Rule

Comment: One commenter asked whether we plan to evaluate the impact of this rule on beneficiaries, providers, other payers, or Medicare. The commenter further stated that data has been limited from the current teleconsultation demonstration project.

Response: We believe that it would be beneficial to evaluate the impact of expanding eligibility for teleconsultation beyond the existing demonstration sites. We plan to evaluate program data resulting from this provision, such as utilization patterns, service intensity, and the type of practitioners providing a teleconsultation.

Comment: A few commenters suggested we provide clarification regarding both intra- and inter-state scope of practice and licensure issues. One commenter expressed concern that the proposed rule may unintentionally involve us in State-based scope of practice and recommended that we clarify that midlevel practitioners are prohibited from operating outside the licensed health professionals scope of practice in their State.

Response: BBA specifies that a nonphysician practitioner may refer a beneficiary for consultation. We clarify that midlevel practitioners would need to meet the governing requirements of the State in which they are licensed. Therefore, if the law of the State in which they are licensed would prohibit a midlevel practitioner (for example, a nurse practitioner or a physician assistant) from referring a patient for consultation, the practitioner could not refer a patient for teleconsultation. Likewise, if the law of the State in which the teleconsultation occurs prohibits a nonphysician from providing a consultation service, the

practitioner could not provide a teleconsultation under Medicare. Moreover, if State law precludes an out-of-State practitioner from delivering a teleconsultation, Medicare would not pay for that consultation.

Comment: One commenter believed that this rule would disadvantage specialists located in a rural HPSA by drawing patients to specialists outside of the local area. The commenter stated that managed care organizations may possibly be able to negotiate a better price from consultants outside the community and believed we should develop safeguards to prohibit such possibilities.

Response: We believe this comment is beyond the scope of this provision as authorized by BBA. BBA provides for payment of teleconsultation when the requirements of this benefit are met. However, HCFA is not authorized by the law to direct physicians and other medical practitioners to a specific consultant.

Comment: A few commenters suggested that we consider guidelines regarding beneficiary consent and safeguards for confidentiality.

Response: We agree that the beneficiary should be thoroughly informed regarding the nature of a teleconsultation and that confidentiality of medical records is of great concern. However, we assume that practitioners are already cognizant of their responsibility to obtain patients' informed consent and to protect patients' medical records. Therefore, we are not establishing guidelines regarding beneficiary consent or confidentiality at this time. We invite specific comments regarding this issue.

We recognize that this rule is a first step in refining face-to-face ''hands on'' requirements for a medical service under Medicare to reflect a telemedicine service. We are not eliminating the possibility of the development of modifications to Medicare telemedicine coverage and payment policies as the law permits and as more program experience in this area is obtained.

To that end, we intend to explore several issues, including: (1) The use of store and forward technologies as a method for delivering medical services; (2) the use of registered nurses and other medical professionals not recognized as a practitioner under the teleconsultation provision to present the patient to the consulting practitioner; and (3) the appropriateness of current consultation codes for reporting consultations delivered via communications systems.

In a year we will send recommendations to Congress regarding these issues along with any necessary legislative changes.

Clarifications and Modifications

Teleconsultation in Rural Health Clinics

As a result of further analysis and evaluation, we have decided to clarify payment policy for teleconsultations provided in a Rural Health Clinic (RHC).

We believe that Congress did not intend to include teleconsultation, as provided for by BBA, as part of the RHC benefit. Section 4206(a) of BBA specifies that Medicare payment shall be made for a professional consultation delivered via telecommunications with a physician as defined in section 1861(r) of the Social Security Act or practitioner as defined by section 1842(b)(18)(C) of the Act. Services furnished by an RHC are treated as ''RHC services'' and lose their identity as physicians' services or services of other practitioners.

Moreover, section 4206(b) of BBA instructs us to create a system of payment for teleconsultation that requires that payment be shared between the referring and consulting professionals, precludes payment for any sort of capital or facility fees, and applies the mandatory claims submission and limiting charge provisions of section 1848(g) of the Social Security Act. The method of payment for teleconsultation services under this benefit is not congruent with the method of payment for services under the RHC benefit. Under the RHC benefit, payment is made on the basis of an all-inclusive rate per visit (see 42 CFR 405.2462). These provisions are another indication that we should not include teleconsultation services furnished by physicians in RHCs as RHC services for which we make payment to the RHC.

While, some argument could be made that Congress simply did not intend for teleconsultation services ever to be paid for under section 4206 if they are furnished within the confines of an RHC, this would be an unusual conclusion since section 4206 specifically provides payment for consultation services in rural areas similar to those areas serviced by RHCs that may lack sufficient specialists to provide necessary beneficiary care.

Since Congress did not address how we should treat the services of physicians and other practitioners providing teleconsultation in RHCs, we are interpreting the law to permit practitioners in RHCs to bill for teleconsultation as do other practitioners. The law and the legislative history indicate that the intent of the teleconsultation benefit was to expand services to beneficiaries in rural areas. The same intent informs the RHC benefit, so we believe it would be anomalous to read the teleconsultation benefit as being unavailable to rural beneficiaries who receive a teleconsultation in an RHC.

Section 402 of the RHC manual (HCFA Pub. 27) describes ''services furnished by RHCs . . . which are not RHC/FQHC services.'' These services include durable medical equipment, ambulance services, diagnostic tests (''unless an interpretation of the test is provided by the RHC/FQHC physician''), prosthetic devices, braces, and artificial limbs. Thus, services created by other benefit provisions and not explicitly enumerated as part of the RHC benefit have been paid not under the RHC benefit (even if furnished in an RHC), but rather under the appropriate authority in section 1833 of the Act. We believe that it is consistent with this policy to pay for teleconsultations under the authority of section 4206 of BBA, not as an RHC service.

Therefore, consulting practitioners providing a teleconsultation in an RHC setting will be paid according to the payment methodology specified in this final rule. A teleconsultation would not generate an RHC visit and would not be paid for under the all-inclusive rate methodology. For instance, the consulting practitioner providing a teleconsultation in an RHC would bill the applicable Medicare carrier using his or her own identification number rather than the identification number of the RHC. Payment would be based on the consultant's fee schedule amount and he or she would be required to share 25 percent of total payments with the referring practitioner.

When a practitioner in an RHC refers a Medicare beneficiary for a teleconsultation, he or she will receive 25 percent of the approved Medicare consultation fee schedule. An RHC visit would not be billed by either the referring or consulting practitioner for the teleconsultation. However, the referring practitioner could bill for the initial visit which prompted the need for a consultation as an RHC visit.

Note: These requirements would also apply to Federally Qualified Health Centers located in a rural HPSA.

Result of Evaluation of Comments

- Eligibility for Teleconsultation—Medicare beneficiaries residing in rural HPSAs are eligible to receive teleconsultation services. This final rule stipulates the use of the site of presentation (patient location) as a proxy for beneficiary residence. However, if a beneficiary can

demonstrate that he or she resides in a rural HPSA, Medicare would make payment regardless of the site of consultation. Eligibility for teleconsultation includes both full and partial county HPSAs designated by section 332(a)(1)(A) of the Public Health Service Act.

- Scope of Coverage—Covered services include initial, follow-up, or confirming consultations in hospitals, outpatient facilities, or medical offices delivered via interactive audio and video telecommunications systems (CPT codes 99241–99245, 99251–99255, 99261–99263, and 99271–99275).

- Practitioners eligible to be consulting and referring practitioners—Clinical psychologists, clinical social workers, certified registered nurse anesthetists, and anesthesiologist assistants do not provide for consultation services payable under Medicare and therefore cannot provide a teleconsultation under this provision. Additionally, certified nurse anesthetists and anesthesiologist assistants are not eligible to be referring practitioners for a teleconsultation. Practitioners who may provide teleconsultations include the following: physicians, physician assistants, nurse practitioners, clinical nurse specialists, and nurse-midwives. Practitioners who may refer patients for teleconsultation include the following: physicians, physician assistants, nurse practitioners, clinical nurse specialists, nurse-midwives, clinical psychologists, and clinical social workers.

- Conditions of Payment—The patient must be present at the time of consultation, the medical examination of the patient must be under the control of the consulting practitioner, and the consultation must take place via an interactive audio and video telecommunications system. Interactive telecommunications systems must be multi-media communications that, at a minimum, include audio and video equipment permitting real-time consultation among the patient, consulting practitioner, and referring practitioner (as appropriate). Telephones, facsimile machines, and electronic mail systems do not meet the requirements of interactive telecommunications systems.

- We amended the proposed rule to allow another practitioner who can be a referring practitioner under this provision to present the patient to the consultant provided that he or she is an employee of the actual referring practitioner.

- Registered nurses and other medical professionals not included within the definition of a practitioner in section 1842(b)(18)(C) of the Act are not permitted to act as presenters during teleconsultations.

- Medicare Payment Policy—A single payment will be made to the consulting practitioner. The amount will be equal the consultant's current fee schedule payment for a face-to-face patient consultation. The statute requires that the fee be shared by the referring and consulting practitioners. This final rule implements this requirement by providing that the consulting practitioner receive 75 percent, and the referring practitioner 25 percent, of the consulting practitioner's Medicare fee. The patient continues to be responsible for the 20 percent Medicare coinsurance.

- Billing for Teleconsultation—The consulting practitioner will submit one claim for the consultation service and will provide the referring practitioner with 25 percent of any payment, including any deductible or coinsurance received for the consultation. A coding modifier will be used to identify the claim as a teleconsultation. The referring practitioner cannot submit a Medicare claim for the teleconsultation.

IV. Refinement of Relative Value Units for Calendar Year 1999 and Responses to Public Comments on Interim Relative Value Units for 1998

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

Section IV.B. of this final rule describes the methodology used to review the comments received on the RVUs for physician work and the process used to establish RVUs for new and revised CPT codes. Changes to codes on the physician fee schedule reflected in Addendum B are effective for services furnished beginning January 1, 1999.

B. Process for Establishing Work Relative Value Units for the 1999 Physician Fee Schedule

Our October 31, 1997 final rule on the 1998 physician fee schedule (62 FR 59048) announced the final RVUs for Medicare payment for existing procedure codes under the physician fee schedule and interim RVUs for new and revised codes. The RVUs contained in the rule apply to physicians' services furnished beginning January 1, 1998. We announced that we considered the RVUs for the interim codes to be subject to public comment under the annual refinement process. In this section, we summarize the refinements to the interim work RVUs that have occurred since publication of the October 1998 final rule and our establishment of the work RVUs for new and revised codes for the 1999 physician fee schedule.

Work Relative Value Unit Refinements of Interim and Related Relative Value Units (Includes Table 4—Work Relative Value Unit Refinements of 1998 Interim and Related Relative Value Units)

Although the RVUs in the October 1997 final rule were used to calculate 1998 payment amounts, we considered the RVUs for the new or revised codes to be interim. We accepted comments for a period of 60 days. We received comments from approximately 8 specialty societies on approximately 34 CPT codes with interim RVUs. Only comments received on codes listed in Addendum C of the October 1997 final rule were considered this year.

Due to the content of the comments received, we did not convene multi-specialty refinement panels (see the November 22, 1996 final rule on the physician fee schedule (61 FR 59536) for a detailed explanation of the refinement of CPT codes with interim RVUs). Instead, determinations were made by HCFA medical officers in conjunction with our carrier medical directors.

Table 4—Work Relative Value Unit Refinements of 1998 Interim and Related Relative Value Units

Table 4 lists the interim and related codes reviewed during the 1998 refinement process described in this section. This table includes the following information:

- *CPT Code.* This is the CPT code for a service.

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

- *1998 Work RVU.* The work RVUs that appeared in the October 1997 rule are shown for each reviewed code.

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

- *1999 Work RVU.* This column contains the final RVUs for physician work.

The new values emerged from analysis of the specialty society's written comments on the 1998 interim valued CPT codes.

TABLE 4.—WORK RELATIVE VALUE UNIT REFINEMENTS OF 1998 INTERIM AND RELATED RELATIVE VALUE UNITS

CPT	MOD	Description	1998 work RVU	Requested work RVU	1999 work RVU
11055	.....	Paring or cutting of nails	0.27	0.43	0.27
11056	.....	Paring or cutting of nails	0.39	0.61	0.39
11057	.....	Paring or cutting of nails	0.50	0.79	0.50
11719	.....	Paring or cutting of nails	0.11	0.17	0.11
17003	.....	Destruction of lesions	0.15	0.18	0.15
17004	.....	Destruction of lesions	2.79	3.05	2.79
90804	.....	Psytx, office (20–30)	1.11	1.30	1.21
90805	.....	Psytx, office (20–30) w/e&m	1.47	1.47	1.37
90806	.....	Psytx, office (45–50)	1.73	1.99	1.86
90807	.....	Psytx, office (45–50) w/e&m	2.00	2.16	2.02
90808	.....	Psytx, office (75–80)	2.76	2.99	2.79
90809	.....	Psytx, office (75–80) w/e&m	3.15	3.16	2.95
90810	.....	Intac psytx, office (20–30)	1.19	1.42	1.32
90811	.....	Intac psytx, off 20–30 w/e&m	1.58	1.59	1.48
90812	.....	Intac psytx, office (45–50)	1.86	2.11	1.97
90813	.....	Intac psytx, off 45–50 w/e&m	2.15	2.28	2.13
90814	.....	Intac psytx, office (75–80)	2.97	3.11	2.90
90815	.....	Intac psytx, off 75–80 w/e&m	3.39	3.28	3.06
90816	.....	Psytx, hosp (20–30)	1.24	1.34	1.25
90817	.....	Psytx, hosp (20–30) w/e&m	1.65	1.51	1.41
90818	.....	Psytx, hosp (45–50)	1.94	2.03	1.89
90819	.....	Psytx, hosp (45–50) w/e&m	2.24	2.20	2.05
90821	.....	Psytx, hosp (75–80)	3.09	3.03	2.83
90822	.....	Psytx, hosp (75–80) w/e&m	3.53	3.20	2.99
90823	.....	Intac psytx, hosp (20–30)	1.33	1.46	1.36
90824	.....	Intac psytx, hsp 20–30 w/e&m	1.77	1.63	1.52
90826	.....	Intac psytx, hosp (45–50)	2.08	2.15	2.01
90827	.....	Intac psytx, hsp 45–50 w/e&m	2.41	2.32	2.16
90828	.....	Intac psytx, hosp (75–80)	3.32	3.15	2.94
90829	.....	Intac psytx, hsp 75–80 w/e&m	3.80	3.32	3.10
99343	.....	Home care visits	2.27	No Rec	2.27
99345	.....	Home care visits	3.79	No Rec	3.79
99348	.....	Home care visits	1.26	No Rec	1.26
99350	.....	Home care visits	3.03	No Rec	3.03

*All CPT and descriptors copyright 1998 American Medical Association.

Paring or cutting of nails (CPT codes 11055 through 11057 and 11719)

Comment: A commenter disagreed with our decision to decrease the RUC-recommended RVUs for this family of codes. (''RUC'' refers to the American Medical Association's Specialty Society Relative Value Scale Update Committee.) They believed our budget-neutral approach decreased the recommended RUC work RVUs by too large a factor. (See the section on the establishment of interim work Value Units for a brief discussion of the budget-neutral approach.)

Response: We disagree with the commenter's view that the RUC recommendations were decreased by too large a factor. CPT codes 11055 through 11057 can be performed in conjunction with CPT code 11719. The methodology that was used accounts for these combinations. Therefore, the 1998 interim work RVUs will be made final for this series of CPT codes. The final work RVUs, effective January 1, 1999, will be as follows: CPT code 11055 (0.27), CPT code 11056 (0.39), CPT code 11057 (0.50), and CPT code 11719 (0.11).

Destruction of lesions (CPT codes 17003 and 17004)

Comment: A commenter disagreed with our decision to accept the RUC recommendations for CPT codes 17003 and 17004. The commenter believed that the work RVUs associated with these codes were decreased by the RUC without any rationale.

Response: We disagree with the commenter's belief that we should not have accepted the RUC recommendation for CPT codes 17003 and 17004. The RUC determined the work RVUs for these two codes by crosswalking the utilization of existing procedure codes (which were to be deleted for CPT 1998) into these two new CPT codes for the same services. Compliance with our guidelines for budget neutrality resulted in the reduction of the society's recommended work RVUs by the RUC. Therefore, the 1998 interim RVUs for CPT codes 17003 and 17004 will be made final. The final work RVUs, effective January 1, 1999, will be as follows: CPT code 17003 (0.15) and CPT code 17004 (2.79).

Psychotherapy (CPT codes 90804 through 90829)

Comment: In May of 1997, the RUC recommended that HCFA-assigned RVUs for the 24 HCPCS psychotherapy codes be crosswalked to the 1998 CPT codes. The RUC also recommended that the work RVUs remain interim until such time as a survey is conducted by each of the professions that furnish the services.

Response: We received recommendations that were based upon the cooperative efforts of the American Academy of Child and Adolescent Psychiatry, The American Nurses Association, the American Psychiatric Association, the American Psychological Association, and the National Association of Social Workers. The RUC accepted these recommendations.

The cooperative effort by the referenced specialties used frequency estimations to maintain budget neutrality within the family of new CPT codes. Based upon actual 1997

frequencies, the recommended work RVUs are not budget-neutral. We will retain the relative relationships that were recommended but will attain budget neutrality by applying a uniform 6.7 percent reduction across all of the codes. The final 1999 work RVUs will be as follows:

TABLE 5.—PSYCHOTHERAPY (CPT CODES 90804 THROUGH 90829)

CPT code	Descriptor	1999 work RVUs
90804	Psytx, office (20–30)	1.21
90805	Psytx, office (20–30) w/e&m	1.37
90806	Psytx, office (45–50)	1.86
90807	Psytx, office (45–50) w/e&m	2.02
90808	Psytx, office (75–80)	2.79
90809	Psytx, office (75–80) w/e&m	2.95
90810	Intac psytx, office (20–30)	1.32
90811	Intac psytx, off 20–30 w/e&m	1.48
90812	Intac psytx, office (45–50)	1.97
90813	Intac psytx, off 45–50 w/e&m	2.13
90814	Intac psytx, office (75–80)	2.90
90815	Intac psytx, off 75–80 w/e&m	3.06
90816	Psytx, hosp (20–30)	1.25
90817	Psytx, hosp (20–30) w/e&m	1.41
90818	Psytx, hosp (45–50)	1.89
90819	Psytx, hosp (45–50) w/e&m	2.05
90821	Psytx, hosp (75–80)	2.83
90822	Psytx, hosp (75–80) w/e&m	2.99
90823	Intac psytx, hosp (20–30)	1.36
90824	Intac psytx, hsp 20–30 w/e&m	1.52
90826	Intac psytx, hosp (45–50)	2.01
90827	Intac psytx, hsp 45–50 w/e&m	2.16
90828	Intac psytx, hosp (75–80)	2.94
90829	Intac psytx, hsp 75–80 w/e&m	3.10

Home care visits (CPT codes 99341 through 99350)

Comment: A commenter suggested that, when we increased the RUC's work RVU recommendations by a uniform 10 percent intensity factor, we used incorrect base intra-service time. The commenter believed the RUC survey of intra-service time was more accurate than the typical time agreed to by CPT.

Response: We maintain that the correct intra-service times were used and thus will finalize these interim valued codes for home visits. Effective January 1, 1999, the final work RVUs for the home care visit codes will be as follows: CPT code 99341 (1.01), CPT code 99342 (1.52), CPT code 99343 (2.27), CPT code 99344 (3.03), CPT code 99345 (3.79), CPT code 99347 (0.76), CPT code 99348 (1.26), CPT code 99349 (2.02), and CPT code 99350 (3.03).

Establishment of Interim Work Relative Value Units for New and Revised Physicians' Current Procedural Terminology Codes and New HCFA Common Procedure Coding System Codes for 1999 Methodology (Includes Table 6—American Medical Association Specialty Society Relative Value Update Committee and Health Care Professionals Advisory Committee Recommendations and HCFA's Decisions for New and Revised 1999 CPT Codes)

One aspect of establishing work RVUs for 1999 was related to the assignment of interim work RVUs for all new and revised CPT codes. As described in our November 25, 1992 notice on the 1993 fee schedule (57 FR 55938) and in section III.B. of our November 26, 1996 final rule (61 FR 59505 through 59506), we established a process, based on recommendations received from the AMA's RUC, for establishing interim RVUs for new and revised codes.

We received work RVU recommendations for approximately 70 new and revised codes from the RUC. Physician panels consisting of carrier medical directors and our staff reviewed the RUC recommendations by comparing them to our reference set or to other comparable services on the physician fee schedule for which work RVUs had been established previously, or to both of these criteria. The panels also considered the relationships among the new and revised codes for which we received RUC recommendations. We agreed with the majority of those relationships reflected in the RUC values. In some cases, when we agreed with the RUC relationships, we revised the work RVUs recommended by the RUC to achieve work neutrality within families of codes. That is, the work RVUs have been adjusted so that the sum of the new or revised work RVUs (weighted by projected frequency of use) for a family of codes will be the same as the sum of the current work RVUs (weighted by their current frequency of use). For approximately 93 percent of the RUC recommendations, proposed work RVUs were accepted or increased, and, for approximately 7 percent, work RVUs were decreased.

We received only one recommendation from the Health Care Professionals Advisory Committee (HCPAC) for a new code for which the RUC did not provide a recommendation. This HCPAC recommendation was accepted.

There were also 10 CPT codes for which we did not receive a RUC recommendation. After review of these codes by HCFA medical officers, we established interim work RVUs for 8 of these codes and identified the remaining 2 CPT codes as carrier-priced for 1999.

Table 6 is a listing of those codes that will be new or revised in 1999 as well as their associated work RVUs. This table includes the following information:

- A ''#'' identifies a new code for 1999.
- *CPT code.* This is the CPT code for a service.
- *Modifier.* A ''26'' in this column indicates that the work RVUs are for the professional component of the code.
- *Description.* This is an abbreviated version of the narrative description of the code.
- *RUC recommendations.* This column identifies the work RVUs recommended by the RUC.
- *HCPAC recommendations.* This column identifies work RVUs recommended by the HCPAC.
- *HCFA decision.* This column indicates whether we agreed with the RUC recommendation (''agree''); we established work RVUs that are higher than the RUC recommendation (''increase''); or we established work RVUs that were less than the RUC recommendation (''decrease''). Codes for which we did not accept the RUC recommendation are discussed in greater detail following Table 6 below. An ''(a)'' indicates that no RUC recommendation was provided. A discussion follows the table.
- *HCFA work RVUs.* This column contains the RVUs for physician work based on our reviews of the RUC recommendations. The RVUs shown for global surgical services have not been adjusted to account for the 1998 increases for work RVUs in evaluation and management services.

1999 work RVUs. This column contains the 1999 RVUs for physician work. The RVUs shown for global surgical services have been adjusted to account for the 1998 increases for work RVUs in evaluation and management.

This table includes only those codes that were reviewed by the full RUC or for which we received a recommendation from the HCPAC.

TABLE 6.—AMERICAN MEDICAL ASSOCIATION SPECIALTY SOCIETY RELATIVE VALUE UPDATE COMMITTEE AND HEALTH CARE PROFESSIONALS ADVISORY COMMITTEE RECOMMENDATIONS AND HCFA'S DECISIONS FOR NEW AND REVISED 1999 CPT CODES

CPT * code	MOD	Description	RUC recommendation	HCPAC recommendation	HCFA decision	NCFA Work RVU	1998 Work RVU
15000	.....	Skin graft procedure	4.00	.....	Agree	4.00	4.00
15001# ..	.....	Skin graft procedure	1.00	.....	Agree	1.00	1.00
15100	.....	Skin split graft procedure	9.05	.....	Agree	9.05	9.05
15101	.....	Skin split graft procedure	1.72	.....	Agree	1.72	1.72
15120	.....	Skin split graft procedure	9.83	.....	Agree	9.83	9.83
15121	.....	Skin split graft procedure	2.67	.....	Agree	2.67	2.67
15350	.....	Skin homograft procedure	4.00	.....	Agree	4.00	4.00
15351# ..	.....	Skin homograft procedure	1.00	.....	Agree	1.00	1.00
15400	.....	Skin heterograft procedure	4.00	.....	Agree	4.00	4.00
15401# ..	.....	Skin heterograft procedure	1.00	.....	Agree	1.00	1.00
19364	.....	Breast reconstruction	41.00	.....	Agree	41.00	41.00
27347# ..	.....	Excision tendon sheath	5.78	.....	Agree	5.78	5.78
28289# ..	.....	Hallux rigidus correction	7.04	.....	Agree	7.04	7.04
31622	.....	Bronchoscopic procedures	.....	.....	(a)	2.67	2.67
31623# ..	.....	Bronchoscopic procedures	.....	.....	(a)	3.07	3.07
31624# ..	.....	Bronchoscopic procedures	.....	.....	(a)	3.11	3.11
31643# ..	.....	Bronchoscopy for brachytherapy	3.50	.....	Agree	3.50	3.50
32001# ..	.....	Bronchoscopic procedures	.....	.....	(a)	5.71	5.71
33975	.....	Ventricular assist devices	21.60	.....	Agree	21.60	21.60
33976	.....	Ventricular assist devices	29.10	.....	Agree	29.10	29.10
35500# ..	.....	Bypass grafts	.....	.....	(a)	carrier	carrier
35681	.....	Bypass grafts	3.93	.....	Decrease	1.60	1.60
35682# ..	.....	Bypass grafts	7.20	.....	Agree	4.80	4.80
35683# ..	.....	Bypass grafts	8.50	.....	Agree	6.10	6.10
35875	.....	Thrombectomy of grafts	10.13	.....	Agree	10.13	10.13
35876	.....	Thrombectomy of grafts	17.00	.....	Agree	17.00	17.00
36823# ..	.....	Arteriovenous Chemo	carrier	.....	Agree	carrier	carrier
36831# ..	.....	Thrombectomy of grafts	8.00	.....	Agree	8.00	8.00
36832	.....	Thrombectomy of grafts	10.50	.....	Agree	10.50	10.50
36833# ..	.....	Thrombectomy of grafts	11.95	.....	Agree	11.95	11.95
36860	.....	Thrombectomy of grafts	2.01	.....	Agree	2.01	2.01
38792# ..	.....	Sentinel node biopsy	.....	.....	(a)	carrier	carrier
45126# ..	.....	Pelvic exenteration	38.39	.....	Agree	38.39	38.39
56321# ..	.....	Laparoscopic adrenalectomy	carrier	.....	Agree	carrier	carrier
57106# ..	.....	Radical vaginectomy	6.36	.....	Agree	6.36	6.36
57107# ..	.....	Radical vaginectomy	23.00	.....	Agree	23.00	23.00
57109# ..	.....	Radical vaginectomy	27.00	.....	Agree	27.00	27.00
57110	.....	Radical vaginectomy	14.29	.....	Agree	14.29	14.29
57111# ..	.....	Radical vaginectomy	27.00	.....	Agree	27.00	27.00
57112# ..	.....	Radical vaginectomy	29.00	.....	Agree	29.00	29.00
67208	.....	Destruction of choroid lesion	6.70	.....	Agree	6.70	6.70
67210	.....	Destruction of choroid lesion	8.82	.....	Agree	8.82	8.82
67220# ..	.....	Destruction of choroid lesion	13.13	.....	Agree	13.13	13.13
67320	.....	Strabimus surgery	4.33	.....	Agree	4.33	4.33
67331	.....	Strabimus surgery	4.06	.....	Agree	4.06	4.06
67332	.....	Strabimus surgery	4.49	.....	Agree	4.49	4.49
67334	.....	Strabimus surgery	3.98	.....	Agree	3.98	3.98
67335	.....	Strabimus surgery	2.49	.....	Agree	2.49	2.49
67340	.....	Strabimus surgery	4.93	.....	Agree	4.93	4.93
69990# ..	.....	Microsurgery	.....	.....	(a)	3.46	3.46
73560	26	Radiological examination, knee	0.17	.....	Agree	0.17	0.17
73562	26	Radiological examination, knee	0.18	.....	Agree	0.18	0.18
73564	26	Radiological examination, knee	0.22	.....	Agree	0.22	0.22
76006# ..	.....	Stress views	0.41	.....	Agree	0.41	0.41
76977# ..	26	Bone density	.....	.....	(a)	0.22	0.22
78020# ..	.....	Thyroid carcinoma metastases	0.67	.....	Decrease	0.60	0.60
78205	26	Liver imaging	0.71	.....	Agree	0.71	0.71
78206# ..	26	Liver imaging	0.96	.....	Agree	0.96	0.96
78472	26	Cardiac blood pool imaging	0.98	.....	Agree	0.98	0.98
78494# ..	26	Cardiac blood pool imaging	1.19	.....	Agree	1.19	1.19
78496# ..	26	Cardiac blood pool imaging	0.50	.....	Agree	0.50	0.50
78588# ..	26	Pulmonary perfusion imaging	1.09	.....	Agree	1.09	1.09
88291# ..	26	Cytogenetic studies	0.52	.....	Agree	0.52	0.52
92135# ..	26	Confocal Scanning	0.35	.....	Agree	0.35	0.35
93571# ..	26	IV distal blood velocity measure	2.99	.....	Decrease	1.80	1.80
93572# ..	26	IV distal blood velocity measure	1.70	.....	Decrease	1.44	1.44
94014# ..	26	Pulmonary function	0.52	.....	Agree	0.52	0.52

TABLE 6.—AMERICAN MEDICAL ASSOCIATION SPECIALTY SOCIETY RELATIVE VALUE UPDATE COMMITTEE AND HEALTH CARE PROFESSIONALS ADVISORY COMMITTEE RECOMMENDATIONS AND HCFA'S DECISIONS FOR NEW AND REVISED 1999 CPT CODES—Continued

CPT* code	MOD	Description	RUC recommendation	HCPAC recommendation	HCFA decision	NCFA Work RVU	1998 Work RVU
94016# ..	.....	Pulmonary function	0.52	.....	Agree	0.52	0.52
94060	26	Pulmonary function	0.31	.....	Agree	0.31	0.31
94620	26	Pulmonary function	.....	.....	(a)	0.88	0.88
94621# ..	26	Pulmonary function	.....	.....	(a)	0.88	0.88
95920	26	Neurotransmitter analysis	2.11	.....	Agree	2.11	2.11
95970# ..	.....	Neurotransmitter analysis	0.45	.....	Agree	0.45	0.45
95971# ..	.....	Neurotransmitter analysis	0.78	.....	Agree	0.78	0.78
95972# ..	.....	Neurotransmitter analysis	1.50	.....	Agree	1.50	1.50
95973# ..	.....	Neurotransmitter analysis	0.92	.....	Agree	0.92	0.92
95974# ..	.....	Neurotransmitter analysis	3.00	.....	Agree	3.00	3.00
95975# ..	.....	Neurotransmitter analysis	1.70	.....	Agree	1.70	1.70
97140# ..	.....	Manual therapy techniques	0.45	.....	Decrease	0.43	0.43
99298# ..	.....	Neonatal care	2.75	.....	Agree	2.75	2.75

[a] No RUC recommendation provided.
New Codes.
* All numeric HCPCS CPT Copyright 1997 American Medical Association.

Discussion of Codes for Which the RUC Recommendations Were Not Accepted

The following is a summary of our rationale for not accepting particular recommendations. It is arranged by type of service in CPT code order. This summary refers only to work RVUs. Furthermore, the RVUs in the following discussion have not been adjusted by the budget-neutrality adjustment factor.

Bypass grafts (CPT code 35681).

We received RUC recommendations for three of the four add-on codes (codes that may be billed only in conjunction with selected primary procedure codes) related to composite bypass grafts. We rejected the RUC recommendation of 3.93 work RVUs for CPT code 35681 (Bypass graft, composite, prosthetic and vein). These work RVUs were suggested during the 5-year review of work RVUs at a time when this family of composite codes had not been established. The recommendation was based on the assumption that the work could be estimated at 12 percent of an independent procedure, CPT code 35102. We believe that a more appropriate evaluation is based on the work involved in anastomosing the vein and prosthetic grafts, which we estimate at 1.60 work RVUs. Effective January 1, 1999, CPT code 35681 will be valued at 1.60 work RVUs.

Thyroid carcinoma metastases uptake (CPT code 78020)

We received a RUC recommendation of 0.67 for CPT code 78020. The survey data indicated that CPT code 78020 was previously reported with unlisted CPT code 78099. The survey estimated that CPT code 78020 will be billed approximately 15 percent of the time CPT code 78018 is billed. CPT code 78099 was only billed 61 times in 1997, while the projected utilization of CPT code 78020 for 1999 is approximately 575 claims annually. To retain budget neutrality within this family of codes, the total work RVUs that will be paid in 1999 were scaled to what would have been paid in 1999 if CPT code 78020 had not been established. This results in work RVUs of 0.60 for CPT code 78020 and 0.86 for CPT code 78018.

Intravascular distal blood flow velocity measurements (CPT code 93571 and 93572)

The RUC recommended work RVUs of 2.99 and 1.70, respectively, for CPT codes 93571 and 93572. The RUC recommendation was constructed based upon a building block approach. Our analysis of this approach raised concerns about the inclusion of certain items in the building block for each respective code. We chose to value these procedures based upon analogous CPT codes 92978 (IV ultrasound) and 92979 (IV ultrasound, each additional vessel) for which the RUC time estimates were identical. For this reason, we assigned 1.80 work RVUs to CPT code 93571 and 1.44 work RVUs to CPT code 93572.

Physical medicine and rehabilitation (CPT code 97140) CPT code 97140 (RUC-recommended work RVU=0.45 replaces CPT codes 97122, 97250, 97260, 97261, and 97265.)

To retain budget neutrality within this family of codes, the total work RVUs that will be paid in 1999 were scaled to the total work RVUs that would have been paid if CPT code 97140 had not been established. This results in work RVUs of 0.43 for CPT code 97140.

V. Physician Fee Schedule Update and Conversion Factor for Calendar Year 1999

The 1999 physician fee schedule conversion factor is $34.7315.

In accordance with section 1848(d)(1)(D) of the Act, as amended by section 4504 of the BBA 1997, the separate conversion factor for anesthesia services for a year shall be equal to 46 percent of the single conversion factor for other physicians' services, except as adjusted for changes in work, practice expense, or malpractice relative value units. This calculation yields a 1999 anesthesia conversion factor of $17.24.

The specific calculations to determine the conversion factor for physicians' services for calendar year 1999 are explained below.

Detail on Calculation of the Calendar Year 1999 Physician Fee Schedule Update and the 1999 Conversion Factor

Physician Fee Schedule Update and Conversion Factor

The conversion factor is affected by section 1848(c)(2)(B)(ii)(II) of the Act, which requires that changes to the relative value units of the Medicare physician fee schedule not cause expenditures to increase or decrease by more than $20 million from the amount of expenditures that would have been made if such adjustments had not been made. We implement this requirement through a uniform budget-neutrality adjustment to the conversion factor.

The conversion factor is also affected by the elimination of the separate 0.917 budget-neutrality adjustment to the work relative value units. This adjustment and its elimination are described in the October 31, 1997 final rule.

The conversion factor is further affected by adjustments made to the practice expense and malpractice relative value units to ensure that the percentages of fee schedule allowed charges for work, practice expense, and malpractice premiums equal the new percentages that those categories represent in the revised Medicare Economic Index (MEI) weights.

Taking all of these factors into account, as well as the percent change in the MEI and Sustainable Growth Rate (SGR) adjustments described below, the 1999 conversion factor is calculated as follows:

1998 Conversion Factor: 36.6873
1999 Update: 2.3%
Other 1999 Factors: −7.45944%
1999 Conversion Factor: 34.7315

The 2.3 percent 1999 update is calculated as follows:

MEI: 2.3%
SGR adjustment: 0.0%
1999 Update: 2.3%

The −7.45944 percent adjustment for other factors is calculated as follows:

Elimination of the separate work adjuster: −8.30%
Adjustment to match MEI weights: 1.20%
Volume and Intensity adjustment: −0.28%
Other 1999 factors: −7.45944%

Note that the elimination of the separate work adjuster and the adjustment to match the MEI weights does not affect aggregate Medicare payments because offsetting changes have been made to the practice expense and malpractice relative value units. As described earlier, the volume-and-intensity adjustment does not affect aggregate payments because our actuaries assume an offsetting increase in the volume and intensity of services provided in 1999.

The MEI and the SGR adjustments are described below.

The Percentage Change in the Medicare Economic Index

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide labor productivity. This index, which has 1996 base weights, is comprised of two broad categories: (1) physician's own time, and (2) physician's practice expense.

The physician's own time component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: wages and salaries and fringe benefits. These components are adjusted by the 10-year moving average annual percent change in output per man-hour for the nonfarm business sector to eliminate double counting for productivity growth in physicians' offices and the general economy.

The physician's practice expense category represents the rate of price growth in nonphysician inputs to the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. Like physician's own time, the nonphysician staff categories are adjusted for productivity using the 10-year moving average annual percent change in output per man-hour for the nonfarm business sector. The physician's practice expense component also includes the following categories of nonlabor inputs: office expense, medical materials and supplies, professional liability insurance, medical equipment, professional car, and other expense. The table below presents a listing of the MEI cost categories with associated weights and percent changes for price proxies for the 1999 update. The calendar year 1999 MEI is 2.3 percent.

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 1999 [1]

	1996 weights [2]	CY 1999 percent changes
Medicare Economic Index Total	100.0	2.3
1. Physician's Own Time [3 4]	54.5	2.6
a. Wages and Salaries: Average hourly earnings private nonfarm, net of productivity	44.2	2.9
b. Fringe Benefits: Employment Cost Index, benefits, private nonfarm, net of productivity	10.3	1.2
2. Physician's Practice Expense [3]	45.5	2.1
a. Nonphysician Employee Compensation	16.8	2.4
1. Wages and Salaries: Employment Cost Index, wages and salaries, weighted by occupation, net of productivity	12.4	2.7
2. Fringe Benefits: Employment Cost Index, fringe benefits, white collar, net of productivity	4.4	1.5
b. Office Expense: Consumer Price Index for Urban Consumers (CPI–U), housing	11.6	2.3
c. Medical Materials and Supplies: Producer Price Index (PPI), ethical drugs/PPI, surgical appliances and supplies/CPI–U, medical equipment and supplies (equally weighted)	4.5	4.3
d. Professional Liability Insurance: HCFA professional liability insurance survey [5]	3.2	−0.8
e. Medical Equipment: PPI, medical instruments and equipment	1.9	−1.1
f. Other Professional Expense	7.6	1.7
1. Professional Car: CPI–U, private transportation	1.3	−1.1
2. Other: CPI-U, all items less food and energy	6.3	2.2
Addendum:		
Productivity: 10-year moving average of output per man-hour, nonfarm business sector	n/a	1.1
Physician's Own Time, not productivity adjusted	54.5	3.7
Wages and salaries, not productivity adjusted	44.2	4.0
Fringe benefits, not productivity adjusted	10.3	2.3
Nonphysician Employee Compensation, not productivity adjusted	16.8	3.5
Wages and salaries, not productivity adjusted	12.4	3.8
Fringe benefits, not productivity adjusted	4.4	2.6

[1] The rates of change are for the 12-month period ending June 30, 1998, which is the period used for computing the calendar year 1999 update. The price proxy values are based upon the latest available Bureau of Labor Statistics data as of September 15, 1998.

[2] The weights shown for the MEI components are the 1996 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for calendar year 1996. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 1996 weight. The sum of these products (weights multiplied by the price index levels) over all cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

[3] The Physician's Own Time and Nonphysician Employee Compensation category price measures include an adjustment for productivity. The price measure for each category is divided by the 10-year moving average of output per man-hour in the nonfarm business sector. For example, the wages and salaries component of Physician's Own Time is calculated by dividing the rate of growth in average hourly earnings by the 10-year moving average rate of growth of output per man-hour for the nonfarm business sector. Dividing one plus the decimal form of the percent change in the average hourly earnings (1+.040=1.040 by one plus the decimal form of the percent change in the 10-year moving average of labor productivity (1+.011=1.011) equals one plus the change in average hourly earnings net of the change in output per man hour (1.040/1.011=1.029). All Physician's Own Time and Nonphysician Employee Compensation categories are adjusted in this way. Due to a higher level of precision the computer calculated quotient may differ from the quotient calculated from rounded individual percent changes.

[4] The average hourly earnings proxy, the Employment Cost Index proxies, as well as the CPI–U, housing and CPI–U, private transportation are published in the Current Labor Statistics Section of the Bureau of Labor Statistics' Monthly Labor Review. The remaining CPIs and PPIs in the revised index can be obtained from the Bureau of Labor Statistics' CPI Detailed Report or Producer Price Indexes.

[5] Derived from a HCFA survey of several major insurers (the latest available historical percent change data are for calendar year 1997). This is consistent with prior computations of the professional liability insurance component of the MEI.

n/a Productivity is factored into the MEI compensation categories as an adjustment to the price variables; therefore, no explicit weight exists for productivity in the MEI.

Medicare Performance Relative to the SGR

Medicare Sustainable Growth Rate

Section 1848(f) of the Act, as amended by section 4503 of the BBA 1997, replaces the volume performance standard with a sustainable growth (SGR) standard. It specifies the formula for establishing yearly SGR targets for physicians' services under Medicare. The use of SGR targets is intended to control the actual growth in Medicare expenditures for physicians' services.

The SGR targets are not limits on expenditures. Payments for services are not withheld if the SGR target is exceeded. Rather, the appropriate fee schedule update, as specified in section 1848(d)(3)(A) of the Act, is adjusted to reflect the success or failure in meeting the SGR target.

As provided in section 4502 of the BBA 1997, the update to the conversion factor is established to match spending under the SGR. The law refers to this update as the update adjustment factor. The amended section 1848(d)(3)of the Act now states that:

> the 'update adjustment factor' for a year is equal (as estimated by the Secretary) to—
> (i) the difference between (I) the sum of the allowed expenditures for physicians' services (as determined under subparagraph (C)) for the period beginning April 1, 1997, and ending on March 31 of the year involved, and (II) the amount of the actual expenditures for physicians' services furnished during the period beginning April 1, 1997, and ending on March 31 of the preceding year; divided by—
> (ii) the actual expenditures for physicians' services for the 12-month period ending on March 31 of the preceding year, increased by the sustainable growth rate under subsection (f) for the fiscal year which begins during such 12-month period.

The result is a 0.0 percent adjustment for 1999. The allowed expenditures for physicians' services are calculated based upon the 1998 and 1999 SGR derivations as detailed in the October 31, 1997 final rule and the Notice announcing the Sustainable Growth Rate found in this edition of the Federal Register, respectively.

VI. Provisions of the Final Rule

The provisions of this final rule restate the provisions of the June 5, 1998, proposed rule except as noted elsewhere in this preamble. Following is a highlight of the changes made:

For our proposal relating to the medical direction of anesthesia services (§ 415.110), we have decided to retain the current requirements (that is, requirements (i) and (ii), and (iv) through (vii)) and make only one technical revision in requirement (iii). The technical revision pertains to the requirement that the physician participate in the most demanding procedures in the anesthesia plan, including induction and emergence.

For our proposal relating to nonphysician practitioners, following is a highlight of the changes to the proposed rule:

- Proposed §§ 410.75(c) and 410.76(c) are revised to remove the alternate proposed definition of collaboration. For purposes of Medicare coverage, the collaboration requirement will state that these nonphysician practitioners must meet the standards for a collaborative relationship, as established by the State in which they are practicing. In the absence of State law or regulations governing collaborative relationships, these nonphysician practitioners must document their scope of practice and indicate the relationships that they have with physicians to deal with issues outside their expertise.
- In proposed §§ 410.74(d) and 410.75(e) we deleted the proposed listing of examples of services that can be provided by physician assistants, nurse practitioners and clinical nurse specialists.
- Proposed § 410.76(b) is revised to implement the qualifications for clinical nurse specialist as established by the BBA without the proposed exception for those clinical nurse specialist that do not possess a master's degree.
- Proposed § 410.77(a) is revised to state that a nurse-midwife must—
  + Be a registered nurse who is currently licensed to practice as a nurse-midwife in the State where services are performed;
  + Have successfully completed an accredited program of study and clinical experience for nurse-midwives as specified by the State; or
  + Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American College of Nurse-Midwives Certification Council.
- Proposed § 410.74(c) is revised to state that a physician assistant is an individual who—
  + Has graduated from a physician assistant educational program that is accredited by the National Commission on Accreditation on Allied Health Education Programs;
  + Has passed the national certification examination that is certified by the National Commission on Certification of Physician Assistants; and
  + Is licensed by the State to practice as a physician assistant.

This final rule also restates the provisions of teleconsultations in rural health professional shortage areas proposed rule published on June 22, 1998, at 63 FR 33890, that provided for payment for consultations via telecommunications systems in rural HPSAs, with changes. The changes listed below have been discussed elsewhere in this preamble. Following is a highlight of the changes to the proposed rule:

- Proposed § 410.75(a)(1) is revised to omit clinical psychologists, clinical social workers, certified nurse

anesthetists, and anesthesiologist assistants from the list of practitioners who may be consulting practitioners and the section is redesignated as § 410.78(a)(1).

- The definition of referring practitioners at proposed § 410.75(a)(2) is revised to omit certified registered nurse anesthetists and anesthesiologist assistants, and is redesignated as § 410.78(a)(2).
- Proposed § 410.75(a)(5) is redesignated as § 410.78(a)(5) and specifies that as a condition of payment, the teleconsultation involves the participation of the referring practitioner or a practitioner described in section 1842(b)(18)(C) of the Act (other than a certified registered nurse anesthetist or anesthesiologist assistant) who is an employee of the referring practitioner, as appropriate to the medical needs of the beneficiary and to provide information to and at the direction of the consulting practitioner.
- The definition at proposed § 410.75(b) is revised to reflect the above changes and is redesignated as § 410.78(b).
- For clarification purposes, we are referencing different definition citations for non-physician practitioners than those provided in the proposed rule. The definitions of physician assistants, nurse practitioners, clinical nurse specialists, nurse-midwives, clinical social workers, and clinical psychologists have been reassigned to § 410.74(a)(2), § 410.75(b), § 410.76(b), § 410.77(a), § 410.73(a), and § 410.71(d), respectively.

VII. 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; and

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Based on a public comment, this rule modifies a regulatory requirement creating an additional information collection requirement (ICR) which was not reflected in the proposed rule that was published on June 5, 1998, at 63 FR 30818. (The PRA package associated with the proposed rule is: OMB No. 0938–0730, HCFA–R–0234, with an expiration date of August 31, 2001.) Therefore, to ensure that all of the requirements in this rule can be implemented concurrently, we are requesting emergency OMB review of the additional ICR referenced in this final rule. In compliance with section 3506(c)(2)(A) of the PRA of 1995, we are submitting to OMB the following requirement for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits specified by OMB's regulations at 5 CFR 1320. This ensures compliance with the Balanced Budget Act of 1997 (BBA) which requires us to revise our payment policy for nonphysician practitioners, for outpatient rehabilitation services, and for drugs and biologicals not paid on a cost or prospective payment basis.

We cannot reasonably comply with normal clearance procedures in order to implement the renewal and early termination of the opt-out requirement described below. Physicians and practitioners must notify carriers of their intent to terminate opt-out in accordance with the BBA.

We are requesting OMB review and approval of this collection within 11 working days from the date of publication of this regulation, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 10 working days from the date of publication of this regulation.

During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on this requirement. We will submit the requirement for OMB review and an extension of this emergency approval.

Therefore, we are soliciting public comment on this issue for the information collection requirement discussed below.

§ 405.445 Renewal and early termination of opt-out

Section 405.445(d) states that a physician or practitioner who has completed opt-out on or before January 1, 1999 may terminate opt-out during the 90 days following January 1, 1999 if he or she notifies all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out and complies with paragraphs (b)(3) and (4) of this section. Paragraph (c) of this section applies in those cases.

The burden associated with this requirement is time and effort for the physician or practitioner to notify all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out. There is a one-time opportunity for physicians and practitioners who opted-out in 1998 to re-enter the program. Afterwards, physicians and practitioners may re-enter the program annually. It is estimated that it will take 30 physicians or practitioners 15 minutes each to notify their carriers for a total of 8 hours. We estimate the average annualized three year burden estimate to be 11 hours. (Year 1—1998 and 1999 16 hours, Year 2—2000 8 hours, Year 3—2001 8 hours for a total of 32 hours/ 3 years = 11 hours per year)

We have submitted a copy of this final rule with comment to OMB for its review of the ICR described above. This requirement is not effective until they have been approved by OMB.

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

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn.: Louis Blank, HCFA–1006–FC.

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

VIII. Regulatory Impact Analysis

We have examined the impacts of this final rule as required by Executive Order 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 final rule is expected to have varying effects on the distribution of Medicare physicians' payments and services. With few exceptions, we expect that the impact will 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 final 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 final 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.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the Regulatory Flexibility Act. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

For purposes of the RFA, all physicians are considered to be small entities. There are about 700,000 physicians and other practitioners who receive Medicare payment under the physician fee schedule. 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 alternatives, and presents the measures we propose to minimize the burden on small entities.

B. Resource-Based Practice Expense Relative Value Units

Our methodology for implementing resource-based practice expense RVUs for each physician's service considers the staff, equipment, and supplies used in the provision of various medical and surgical services in various settings, including those that cannot be attributed to specific procedures. We are required to begin the transition to the new practice expense RVUs on January 1, 1999.

By law, the conversion to a resource-based determination for the payment of physicians' practice expenses must be budget neutral. In other words, the total Medicare expenditures for calendar year 1999 must be the same as the amount that would have been paid under the prior method of paying practice expenses.

As we indicated in the proposed rule, each year since the fee schedule has been implemented, our actuaries have determined any adjustments needed to meet this requirement. A key component of the actuarial determination of budget neutrality involves estimating any impact of changes in the volume and intensity of physicians' services provided to Medicare beneficiaries as a result of the proposed changes.

We indicated in the proposed rule that, in estimating the impacts of proposed changes under the physician fee schedule on the volume and intensity of services, the actuaries have historically used a model that assumes that 50 percent of the change in net revenue for a practice would be recouped. This does not mean that payments are reduced by 50 percent. In fact, payments have typically been reduced only a few percent or less. The actuaries also assume that there is no offsetting reduction in volume and intensity for physicians whose Medicare revenue increases.

As we indicated in the proposed rule, our actuaries have reviewed the literature and conducted data analysis of the volume-and-intensity response. In the proposed rule, we indicated that for the purpose of establishing budget neutrality for the physicians' practice expense determination, the actuaries will use a model that assumes a 30 percent volume-and-intensity response to price reductions but no reduction in volume and intensity in response to a price increase. There were some inadvertent delays in making our actuary's analysis of the volume-and-intensity response available on our homepage (www.hcfa.gov), but it is now available there.

Comment: Most commenters were pleased that the volume-and-intensity response was lowered, but opposed use of any volume-and-intensity offset. Many groups recommended that to the extent that any adjustments are necessary, they could be made within the framework of the SGR system. Some groups stated that their specialty or particular services should be exempt from the application of a volume-and-intensity adjustment.

Response: Our actuaries have reviewed the issue but believe that their review of the literature and their own analysis presents a convincing case as to the need for them to utilize a model that incorporates a volume-and-intensity response to price reductions. We cannot apply a volume-and-intensity adjustment that exempts certain procedures because the response could occur for other procedures furnished by a physician. Similarly, we cannot exempt certain specialties from application of the adjustment because physicians of all specialties have some discretion as to the nature and extent of services furnished. We do not believe that we can use the SGR mechanism alone, without the adjustment for volume and intensity for 1999, because any SGR adjustment would be in the future and the actuaries would not determine us to be in compliance with the statutory budget-neutrality requirement for 1999. To the extent that the volume-and-intensity response does not occur, the SGR system enacted as part of the BBA 1997 will return the volume-and-intensity adjustment in the form of higher future updates to the Medicare physician fee schedule conversion factor.

Using the revised actuarial model, achieving budget neutrality for the practice expense per hour method would require lowering physicians' payments in calendar year 1999 by 0.28 percent (1.12 percent cumulative from 1999 to 2002). The 0.28 percent volume-and-intensity adjustment results in a reduction in the 1999 physician fee schedule CF of $0.10.

Table 7, ''Impact on Total Allowed Charges by Specialty of the Resource-Based Practice Expense Relative Value Units under the Practice Expense per Hour'' shows the change in Medicare physician fees resulting from the practice expense per hour methodology discussed earlier in this final rule. In order to isolate the change in fees resulting from the resource-based methodology, this analysis assumes the same mix of services is furnished under the new and old practice expense payment systems and does not include the effects of the annual updates to the Medicare physician fee schedule conversion factor. The impact of the changes on the total revenue (Medicare and non-Medicare) for a given specialty is less than the impact displayed in

Table 7 since physicians furnish services to both Medicare and non-Medicare patients.

For example, Table 7 shows that when the resource-based system is fully phased-in, general surgery will experience a 7 percent decrease in Medicare revenues relative to the current practice expense system and family practice will experience a 7 percent increase.

The magnitude of the Medicare impact depends generally on the mix of services the specialty provides and the sites where the services are performed. In general, those specialties that furnish more office-based services are expected to experience larger increases in Medicare payments than specialties that provide fewer office-based services. Table 7 also includes the impact of the volume-and-intensity adjustments to the conversion factor discussed above, but does not include the impact of the volume response on revenues.

TABLE 7.—IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY OF THE RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNITS UNDER THE PRACTICE EXPENSE PER HOUR METHOD (PERCENT CHANGE)

Specialty	Allowed charges (in billions)	Impact per year	Cumulative 4-year impact
M.D./D.O. Physicians:			
Anesthesiology	1.6	0	0
Cardiac Surgery	0.3	−3	−12
Cardiology	3.8	−2	−9
Clinics	1.6	−1	−3
Dermatology	1.0	5	20
Emergency Medicine	0.9	−3	−10
Family Practice	2.7	2	7
Gastroenterology	1.2	−4	−15
General Practice	1.0	1	4
General Surgery	2.0	−2	−7
Hematology/Oncology	0.5	2	6
Internal Medicine	6.0	0	2
Nephrology	0.9	−2	−7
Neurology	0.7	0	−1
Neurosurgery	0.3	−3	−11
Obstetrics/Gynecology	0.4	1	4
Ophthalmology	3.3	1	4
Orthopedic Surgery	2.0	0	−1
Other Physician*	1.1	0	1
Otolaryngology	0.5	2	9
Pathology	0.5	−3	−13
Plastic Surgery	0.2	1	2
Psychiatry	1.1	0	1
Pulmonary	1.0	−1	−4
Radiation Oncology	0.6	−2	−6
Radiology	2.9	−3	−10
Rheumatology	0.2	4	16
Thoracic Surgery	0.6	−3	−12
Urology	1.1	1	5
Vascular Surgery	0.3	−3	−11
Others:			
Chiropractic	0.4	−2	−8
Nonphysician Practitioner	0.8	0	2
Optometry	0.3	6	27
Podiatry	0.9	2	9
Suppliers	0.5	−2	−6

*Other physician includes allergy/immunology, oral surgery, physical medicine and rehabilitation, pediatrics, critical care, and hematology.

Table 8 below compares the impact of the resource-based practice expense methodology described in this final rule with the impacts published in the June 5, 1998 proposed rule. Differences reflect the net effect of the changes described earlier in the section ''Results of the Evaluation of Comments.'' In general, the changes with the greatest impact were the creation of a separate pool for services with work relative value units equal to zero and the use of the Medicare conversion factor in the indirect cost pool allocation.

TABLE 8.—COMPARISON OF THE IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY OF THE RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNITS UNDER THE PRACTICE EXPENSE PER HOUR METHODOLOGY WITH THE IMPACTS FROM THE JUNE 5, 1998 PROPOSED RULE

Specialty	Proposed rule cumulative 4-year impact	Current cumulative 4-year impact
M.D./D.O. Physicians:		
Anesthesiology	2	0
Cardiac Surgery	−14	−12
Cardiology	−13	−9
Clinics	−3	−3
Dermatology	27	20
Emergency Medicine	−13	−10
Family Practice	6	7
Gastroenterology	−14	−15
General Practice	3	4
General Surgery	−6	−7
Hematology/Oncology	2	6
Internal Medicine	1	2
Nephrology	−5	−7
Neurology	0	−1
Neurosurgery	−10	−11
Obstetrics/Gynecology	5	4
Ophthalmology	11	4
Orthopedic Surgery	−1	−1
Other Physician*	0	1
Otolaryngology	6	9
Pathology	−10	−13
Plastic Surgery	5	2
Psychiatry	4	1
Pulmonary	−3	−4
Radiation Oncology	−13	−6
Radiology	−13	−10
Rheumatology	15	16
Thoracic Surgery	−13	−12
Urology	7	5
Vascular Surgery	−12	−11
Others:		
Chiropractic	−2	−8
Nonphysician Practitioner	−1	2
Optometry	36	27
Podiatry	5	9
Suppliers	−18	−6

*Other physician includes allergy/immunology, oral surgery, physical medicine and rehabilitation, pediatrics, critical care, and hematology.

For certain high volume procedures, Table 9, ''Total Payment for Selected Procedures,'' shows the percentage change between the current 1998 payments (calculated using the 1998 relative value units, 1998 site-of-service policy, and the 1998 conversion factor) and the fully phased-in resource-based practice expense payments (calculated using the full resource-based practice expense relative value units, the 1999 work and malpractice relative value units, and the 1999 Medicare conversion factor).

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TABLE 9. - TOTAL PAYMENT FOR SELECTED PROCEDURES

Code	Mod	Description	Current Non-Facility	Resource Based Non-Facility	Non-Facility Percent Change	Current Facility	Resource Based Facility	Facility Percent Change
11721		Debride nail, 6 or more	$39.81	$37.16	-7%	$29.91	$32.65	9%
17000		Destroy benign/premal lesion	$36.69	$46.89	28%	$28.99	$30.56	5%
27130		Total hip replacement	NA	NA	NA	$1,656.80	$1,360.78	-18%
27236		Repair of thigh fracture	NA	NA	NA	$1,244.62	$1,060.70	-15%
27244		Repair of thigh fracture	NA	NA	NA	$1,230.38	$1,074.59	-13%
27447		Total knee replacement	NA	NA	NA	$1,771.16	$1,422.60	-20%
33533		CABG, arterial, single	NA	NA	NA	$2,107.91	$1,839.38	-13%
35301		Rechanneling of artery	NA	NA	NA	$1,262.70	$1,065.91	-16%
43239		Upper GI endoscopy, biopsy	$228.81	$258.40	13%	$211.20	$139.97	-34%
45385		Colonoscopy, lesion removal	$443.89	$391.77	-12%	$414.17	$277.50	-33%
66821		After cataract laser surgery	$187.65	$191.37	2%	$187.65	$181.65	-3%
66984		Remove cataract, insert lens	NA	NA	NA	$795.26	$663.72	-17%
67210		Treatment of retinal lesion	$686.27	$563.34	-18%	$520.81	$516.80	-1%
71010	26	Chest x-ray	$9.36	$8.34	-11%	$9.36	$8.34	-11%
71020		Chest x-ray	$34.55	$33.34	-3%	$34.55	$33.34	-3%
71020	26	Chest x-ray	$11.44	$10.07	-12%	$11.44	$10.07	-12%
77430		Weekly radiation therapy	$188.62	$170.88	-9%	$188.62	$170.88	-9%
78465		Heart image (3D) multiple	$514.68	$514.37	0%	$514.68	$514.37	0%
88305		Tissue exam by pathologist	$65.95	$58.35	-12%	$65.95	$58.35	-12%
88305	26	Tissue exam by pathologist	$46.14	$38.20	-17%	$46.14	$38.20	-17%
90801		Psy dx interview	$122.08	$136.15	12%	$122.08	$135.45	11%
90806		Psytx, office (45-50)	$80.95	$92.73	15%	$80.95	$91.00	12%
90807		Psytx, office (45-50) w/e&m	$90.03	$96.55	7%	$90.03	$97.60	8%
90862		Medication management	$47.37	$47.23	0%	$47.37	$46.54	-2%
90921		ESRD related services, month	$235.86	$232.70	-1%	$235.86	$232.70	-1%
90935		Hemodialysis, one evaluation	NA	NA	NA	$93.87	$66.34	-29%
92004		Eye exam, new patient	$77.83	$114.61	47%	$67.37	$82.31	22%
92012		Eye exam established pt	$39.42	$71.89	82%	$31.35	$34.38	10%
92014		Eye exam & treatment	$57.55	$83.36	45%	$47.65	$55.92	17%
92980		Insert intra coronary stent	NA	NA	NA	$1,142.75	$899.89	-21%
92982		Coronary artery dilation	NA	NA	NA	$857.33	$679.00	-21%
93000		Electrocardiogram, complete	$28.83	$25.01	-13%	$28.83	$25.01	-13%
93010		Electrocardiogram report	$11.96	$8.34	-30%	$11.96	$8.34	-30%
93015		Cardiovascular stress test	$116.95	$101.07	-14%	$116.95	$101.07	-14%
93307		Echo exam of heart	$215.85	$193.80	-10%	$215.85	$193.80	-10%
93307	26	Echo exam of heart	$70.94	$47.23	-33%	$70.94	$47.23	-33%
93510	26	Left heart catheterization	$266.37	$219.16	-18%	$266.37	$219.16	-18%
98941		Chiropractic manipulation	$32.87	$32.99	0%	$27.55	$28.83	5%
99202		Office/outpatient visit, new	$50.15	$64.95	30%	$39.69	$50.71	28%
99203		Office/outpatient visit, new	$68.93	$92.04	34%	$56.82	$73.98	30%
99204		Office/outpatient visit, new	$102.50	$129.90	27%	$84.53	$106.28	26%
99205		Office/outpatient visit, new	$128.35	$161.15	26%	$108.72	$137.88	27%
99211		Office/outpatient visit, est	$14.16	$21.88	55%	$9.94	$13.55	36%
99212		Office/outpatient visit, est	$27.61	$34.73	26%	$21.01	$26.74	27%
99213		Office/outpatient visit, est	$39.42	$45.85	16%	$30.61	$36.47	19%
99214		Office/outpatient visit, est	$59.39	$72.24	22%	$47.65	$59.04	24%
99215		Office/outpatient visit, est	$93.67	$105.24	12%	$76.06	$91.69	21%
99221		Initial hospital care	NA	NA	NA	$69.84	$68.77	-2%

TABLE 9. - TOTAL PAYMENT FOR SELECTED PROCEDURES

Code	Mod	Description	Current Non-Facility	Resource Based Non-Facility	Non-Facility Percent Change	Current Facility	Resource Based Facility	Facility Percent Change
99222		Initial hospital care	NA	NA	NA	$113.45	$109.06	-4%
99223		Initial hospital care	NA	NA	NA	$144.98	$149.35	3%
99231		Subsequent hospital care	NA	NA	NA	$36.57	$32.30	-12%
99232		Subsequent hospital care	NA	NA	NA	$53.64	$52.10	-3%
99233		Subsequent hospital care	NA	NA	NA	$74.65	$74.33	0%
99236		Observ/hosp same date	NA	NA	NA	$188.78	$209.08	11%
99238		Hospital discharge day	NA	NA	NA	$63.24	$65.30	3%
99239		Hospital discharge day	NA	NA	NA	$79.05	$86.83	10%
99241		Office consultation	$47.95	$54.18	13%	$36.21	$38.55	6%
99242		Office consultation	$74.95	$91.00	21%	$60.82	$70.50	16%
99243		Office consultation	$97.12	$115.66	19%	$79.33	$93.43	18%
99244		Office consultation	$135.96	$159.42	17%	$113.40	$134.76	19%
99245		Office consultation	$183.26	$202.14	10%	$152.26	$176.44	16%
99251		Initial inpatient consult	NA	NA	NA	$49.72	$39.94	-20%
99252		Initial inpatient consult	NA	NA	NA	$75.59	$73.28	-3%
99253		Initial inpatient consult	NA	NA	NA	$99.75	$98.98	-1%
99254		Initial inpatient consult	NA	NA	NA	$136.88	$138.58	1%
99255		Initial inpatient consult	NA	NA	NA	$185.53	$187.90	1%
99261		Follow-up inpatient consult	NA	NA	NA	$27.34	$26.74	-2%
99262		Follow-up inpatient consult	NA	NA	NA	$46.94	$48.28	3%
99263		Follow-up inpatient consult	NA	NA	NA	$68.77	$68.42	-1%
99282		Emergency dept visit	NA	NA	NA	$33.55	$26.40	-21%
99283		Emergency dept visit	NA	NA	NA	$61.16	$56.27	-8%
99284		Emergency dept visit	NA	NA	NA	$93.48	$87.52	-6%
99285		Emergency dept visit	NA	NA	NA	$147.34	$135.11	-8%
99291		Critical care, first hour	$191.07	$191.37	0%	$191.07	$189.98	-1%
99292		Critical care, addl 30 min	$91.86	$96.55	5%	$91.86	$95.51	4%
99301		Nursing facility care	NA	NA	NA	$57.98	$62.17	7%
99302		Nursing facility care	NA	NA	NA	$73.98	$81.97	11%
99303		Nursing facility care	NA	NA	NA	$105.04	$102.11	-3%
99311		Nursing facility care,subseq	NA	NA	NA	$33.76	$31.95	-5%
99312		Nursing facility care,subseq	NA	NA	NA	$49.78	$50.36	1%
99313		Nursing facility care,subseq	NA	NA	NA	$66.12	$70.85	7%
99348		Home visit, estab patient	$63.30	$66.68	5%	$63.30	$67.03	6%
99350		Home visit, estab patient	$132.39	$150.04	13%	$132.39	$146.91	11%

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Table 10 below displays the impact of the practice expense per hour methodology by Medicare payment locality, including the volume-and-intensity increase and corresponding conversion factor adjustment discussed earlier. This analysis does not include the effects of the annual updates to the Medicare physician fee schedule conversion factor.

TABLE 10.—IMPACT OF PRACTICE EXPENSE PER HOUR METHODOLOGY ON TOTAL ALLOWED CHARGES BY MEDICARE LOCALITY (PERCENT CHANGE)

Locality	State	Impact per year	Cumulative four year impact
All	Alaska	0.1	0.5
All	Alabama	−0.2	−0.8
All	Arkansas	−0.2	−0.9
All	Arizona	0.2	1.0
Anaheim/Santa Ana	California	0.6	2.5
Los Angeles	California	0.5	2.1
Marin/Napa/Solano	California	0.6	2.4
Oakland/Berkley	California	0.3	1.1
Rest of California	California	0.3	1.4
San Francisco	California	0.6	2.3
San Mateo	California	0.4	1.5
Santa Clara	California	0.2	0.8
Ventura	California	0.4	1.5
All	Colorado	0.1	0.4
All	Connecticut	0.1	0.6
All	District of Columbia	0.1	0.3
All	Delaware	0.0	0.1
Ft Lauderdale	Florida	0.6	2.6
Miami	Florida	0.1	0.5
Rest of Florida	Florida	0.1	0.5
Atlanta	Georgia	−0.1	−0.3
Rest of Georgia	Georgia	−0.1	0.5
All	Hawaii	0.6	2.4
All	Iowa	−0.2	−0.8
All	Idaho	0.0	0.1
Chicago	Illinois	−0.2	−1.0
East St Louis	Illinois	−0.1	−0.5
Rest of Illinois	Illinois	−0.2	−0.7
Suburban Chicago	Illinois	−0.1	−0.4
All	Indiana	−0.4	−1.5
All	Kansas	−0.2	−0.8
All	Kentucky	−0.3	−1.1
New Orleans	Louisiana	−0.3	−1.2
Rest of Louisiana	Louisiana	−0.3	−1.3
Boston	Massachusetts	−0.3	−1.1
Rest of Massachusetts	Massachusetts	0.1	0.6
Balto/Surr Ctys	Maryland	−0.3	−1.2
Rest of Maryland	Maryland	−0.2	−0.6
Rest of Maine	Maine	−0.1	−0.4
Southern Maine	Maine	−0.1	−0.2
Detroit	Michigan	−0.2	−0.8
Rest of Michigan	Michigan	−0.2	−0.9
All	Minnesota	−0.1	−0.4
Metro Kansas City	Missouri	−0.7	−2.7
Rest of Missouri	Missouri	−0.2	−0.8
Rest of Missouri	Missouri	0.1	0.2
St Louis	Missouri	−0.4	−1.6
All	Mississippi	−0.5	−1.8
All	Montana	0.1	0.3
All	North Carolina	−0.1	−0.3
All	North Dakota	−0.3	−1.1
All	Nebraska	−0.2	−0.8
All	New Hampshire	0.0	−0.2
Northern New Jersey	New Jersey	0.0	0.0
Rest of New Jersey	New Jersey	0.1	0.5
All	New Mexico	0.2	0.8
All	Nevada	0.0	−0.1
Manhattan	New York	0.4	1.5
NYC Suburbs/LI	New York	0.3	1.3
NYC Suburbs/Poughk.	New York	0.3	1.2
Queens	New York	0.7	2.8
Rest of New York	New York	−0.1	−0.2
All	Ohio	−0.3	−1.2
All	Oklahoma	−0.2	−0.7

TABLE 10.—IMPACT OF PRACTICE EXPENSE PER HOUR METHODOLOGY ON TOTAL ALLOWED CHARGES BY MEDICARE LOCALITY (PERCENT CHANGE)—Continued

Locality	State	Impact per year	Cumulative four year impact
Portland	Oregon	0.1	0.2
Rest of Oregon	Oregon	0.4	1.5
Philadelphia	Pennsylvania	−0.1	−0.4
Rest of Pennsylvania	Pennsylvania	−0.1	−0.3
All	Puerto Rico	1.0	3.9
All	Rhode Island	0.2	0.6
All	South Carolina	0.0	−0.2
All	South Dakota	−0.4	−1.5
All	Tennessee	−0.3	−1.3
Austin	Texas	−0.3	−1.0
Beaumont	Texas	−0.6	−2.5
Brazoria	Texas	0.4	1.7
Dallas	Texas	−0.2	−0.8
Fort Worth	Texas	0.0	0.0
Galveston	Texas	−0.4	−1.5
Houston	Texas	−0.4	−1.8
Rest of Texas	Texas	−0.1	−0.4
All	Utah	0.0	0.2
All	Virginia	0.0	−0.1
All	Virgin Islands	0.6	2.5
All	Vermont	0.2	0.9
Rest of Washington	Washington	0.3	1.2
Seattle (King Co)	Washington	0.0	0.0
All	Wisconsin	−0.2	−1.0
All	West Virginia	−0.2	−0.8
All	Wyoming	0.3	1.0

C. Medical Direction for Anesthesia Services

For our proposal relating to the medical direction of anesthesia services (§ 415.110), we have decided to retain the current requirements (that is, requirements (i) and (ii), and (iv)) and make only one technical revision in requirement (iii). The technical revision pertains to the requirement that the physician participate in the most demanding procedures in the anesthesia plan, including, induction and emergence.

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

We are allowing separate payment for a physician's interpretation of a Pap smear to any patient (that is, hospital or nonhospital patient) as long as—(1) The laboratory's screening personnel suspect an abnormality; and (2) the physician reviews and interprets the pap smear. Currently, separate payment to a physician is limited to a Pap smear interpretation that is abnormal and is furnished to a hospital inpatient. We estimate that there would be a $10 million increase in payments under the physician fee schedule for this change in payment for Pap smear interpretations for FY 1999.

E. Rebasing and Revising the Medicare Economic Index

There is negligible impact on Medicare expenditures as a result of this change.

F. Payment for Nurse Midwives' Services

The provision for nurse midwives' services will place into regulations text a provision of OBRA 1993 that eliminates the limitation on coverage of services furnished outside the maternity cycle by nurse midwives. This provision has been implemented previously through program instructions; therefore, this change in the regulations text will have no impact.

G. BBA Provisions Included in This Final Rule

The following five provisions of BBA 1997 are implemented in this final rule. This final rule conforms the regulations text to BBA 1997 provisions. Table 11 below provides the cost and savings estimates (in millions of dollars) for the Medicare program for these provisions for the fiscal years shown:

TABLE 11.—COST AND SAVINGS ESTIMATES FOR BBA 1997 PROVISIONS

[In millions]

Provision section	Subject	1999	2000	2001	2002	2003
4206	Teleconsultations	20	40	55	70	90
4511	Nurse practitioners and Clinical Nurse Specialists	290	330	370	440	490
4512	Physician Assistants	60	60	70	90	100
4541	Outpatient Rehabilitation	−130	−190	−200	−230	−250
4556	Drugs	−60	−70	−70	−80	−80

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

Sections 4511 and 4512 of BBA 1997 provide for the expanded coverage of nurse practitioner, clinical nurse specialist, and physician assistant services. This provision is self-implementing. This final rule changes the regulations text to conform to the BBA 1997 provisions. We are clarifying the following two existing issues unrelated to the BBA 1997 provisions for nonphysician practitioners:

- Definition of physician collaboration for nurse practitioners.
- The impact of the BBA 1997 provisions is shown in Table 11 (a combination of sections 4511 and 4512 of BBA 1997). The proposals being made final in this rule will have negligible budgetary impact.

Payment for Outpatient Rehabilitation Services

Sections 4541(a)(2) and 4541(a)(3) of BBA 1997 change the payment of outpatient rehabilitation services from cost-based to a payment system based on the physician fee schedule. The regulatory changes are to conform our regulations to the provisions of the BBA 1997.

In addition to the changes directed by the statute, the following changes are being made in this rule to furnish information for identification of the outpatient rehabilitation services and for administrative purposes:

- Specifying HCPCS as the coding system for rehabilitation services since it is used by the fee schedule in section 1848 of the Act.
- Providing for discipline-specific modifiers to be used in coding services.
- Providing for a code for nursing services performed in CORFs.

These administrative changes will have a negligible impact.

Section 4541(c) of BBA 1997 applies an annual per beneficiary limit of $1,500 to all outpatient physical therapy services (including speech-language pathology services) except for services furnished by a hospital outpatient department. A separate $1,500 limit also applies to all outpatient occupational therapy services except for services furnished by hospital outpatient departments. Therapy services furnished incident to a physician's professional services are also subject to these limits. The changes in this rule conform the regulations to the BBA 1997 provisions. The delay in full implementation, however, is discussed below.

There are several different types of providers that will be affected by this BBA 1997 provision. The largest providers are SNFs, outpatient rehabilitation facilities, and hospital outpatient departments. There are about 15,000 SNFs, 2,500 outpatient rehabilitation facilities, and about 5,600 outpatient hospital facilities. We determined that the services that would be affected by these changes account for about 15 percent of Medicare Part B payments to facilities.

We estimate that these providers as well as other providers and practitioners of outpatient therapy services will experience a reduction in revenue both because of the movement from cost reimbursement to fee schedule payments and because of the $1,500 limits. The impact of the provisions on individual providers, however, cannot be estimated for a variety of reasons. First, since reimbursement has historically been based on cost for most providers, we do not have coded information on individual services per beneficiary at individual providers. Second, with respect to the impact of the $1,500 limit, the extent to which a provider will receive a payment from another source to substitute for Medicare's payment is unknown. For example, if a beneficiary reaches the $1,500 limit, Medicare will no longer pay, but payment may be received from another source, such as a Medigap insurer, a retiree health plan, or the beneficiary.

The $1,500 limits will reduce the amount of therapy services paid for by Medicare. The patients most affected are likely to be those with diagnoses such as stroke, certain fractures, and amputation, where the number of therapy visits needed by a patient may exceed those that can be reimbursed by Medicare under the statutory limits. Services not paid for by Medicare, however, may be paid for by other payers.

As explained in the preamble, the $1,500 limits will not be fully implemented until sometime in 2000 due to the necessity to devote resources to Y2K compliance activities. Until that time, the limits will be implemented partially on a per-provider basis whereby each provider will be held accountable for tracking expenses for each beneficiary and not billing Medicare for beneficiaries that have met the limit at their facility. Implementing the provision in this fashion should lessen the impact on both beneficiaries and providers until full implementation occurs.

Impact on Small Rural Hospitals

We realize that the provision to move from cost reimbursement to a fee schedule may have an impact on small rural hospitals; however, we have been unable to assess this impact because we do not have the data to make this analysis. Also, data that would identify the extent to which these services are currently being furnished in small rural hospitals to serve as the baseline for comparing the impact of the legislative changes are not available. In addition, we do not maintain data that identify services furnished under the physician fee schedule in areas where rural hospitals are located. Although there are localities designated for payment purposes, there is very little correlation between the payment localities (most of which are state-wide) and areas where small rural hospitals are located.

Payment for Drugs and Biologicals

The impact of this BBA 1997 provision is shown in Table 5. This final rule modifies the current regulatory language regarding drug payment to conform to the BBA 1997 changes. Revising the regulation on multi-source drugs to include the brand name version of the drug is not related to the BBA 1997 drug provision but will have a slight program savings.

Private Contracting with Medicare Beneficiaries

We anticipate that there would be a negligible impact on Medicare trust fund payments as a result of the regulation that implements the law. The program impact of the provision when it was assessed in the legislative process was negligible. The impact on beneficiaries, physicians, and practitioners is impossible to assess in any quantitative way.

Specifically, beneficiaries who have had difficulty in finding physicians or practitioners to furnish services because the physicians or practitioners were dissatisfied with the Medicare payment rates may find it easier to acquire care. On the other hand, beneficiaries who cannot afford to privately contract with physicians or practitioners who opt out of Medicare may have more limited access to care as they try to seek care from reduced numbers of physicians and practitioners who will accept Medicare payment rules.

Physicians and practitioners who opt out of Medicare may see increased incomes as a result of their ability to charge without regard to the Medicare limiting charge. However, to the extent that beneficiaries cease to seek treatment from them because they have

opted out of Medicare, their incomes may decline. Moreover, organizations to which physicians and practitioners had reassigned Medicare benefits may cease their contracts with them if they opt out since the organizations could no longer be paid by Medicare for the physician's or practitioner's service. Managed care plans that have a contract with Medicare may cease their contractual arrangement with physicians and practitioners who opt out of Medicare since the plan cannot pay for any of their services to Medicare beneficiaries and, hence, their services no longer offer access to care under the plan. Similarly, insurance plans other than Medicare can choose to not pay for the services provided to any of their enrollees by physicians and practitioners who opt out of Medicare, causing the physicians and practitioners who opt out further loss of income.

Teleconsultations

We estimate that the cost of providing consultation services in accordance with section 4206 of BBA 1997 will be approximately $20 million in FY 1999 and approximately $90 million by FY 2003. Note that the FY 1999 estimate reflects only a partial year estimate, given the January 1, 1999 effective date for teleconsultation coverage. We estimate that teleconsultation will cost approximately $275 million for the first 5 years of coverage, as indicated below:

MEDICARE COSTS

[In millions]

FY 1999	FY 2000	FY 2001	FY 2002	FY 2003
$20	$40	$55	$70	$90

This rule would provide for payment exclusively for professional consultation with a physician and certain other practitioners via interactive telecommunication systems. Section 4206 of BBA 1997 does not provide for payment for telephone line fees or any facility fees associated with teleconsultation that may be incurred by hospitals included in the telemedicine network.

Further, this rule does not mandate that entities provide consultation services via telecommunications. Thus, this final rule does not require entities to purchase telemedicine equipment or to acquire the telecommunications infrastructure necessary to deliver consultation services via telecommunication systems. Therefore, this rule does not impose costs associated with starting and operating a telemedicine network.

The benefit changes in this final rule resulting from payment for teleconsultation services do not result in additional Medicare expenditures of $100 million or more for any single FY through FY 2003. We have determined, and we certify, that teleconsultation provisions do not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

H. Impact on Beneficiaries

Although changes in physicians' payments when the physician fee schedule was implemented in 1992 were large, we detected no problems with beneficiary access to care. Because there is a 4-year transition to the resource-based practice expense system, we anticipate a minimal impact on beneficiaries.

The benefit changes in this final rule resulting from payment for teleconsultation services do not result in additional Medicare expenditures of $100 million or more for any single FY through FY 2003. We have determined, and we certify, that teleconsultation provisions do not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Statutory effects that are being implemented by this regulation result in specialty impacts exceeding $100 million per year. Therefore, this rule is an economically significant rule under Executive Order 12866, and a major rule under Title 5, United States Code, section 804(2).

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 415

Health facilities, Health professions, Medicare and Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as set forth below:

1. A new subpart D, consisting of §§ 405.400, 405.405, 405.410, 405.415, 405.420, 405.425, 405.430, 405.435, 405.440, 405.445, 405.450, and 405.455 is added to read as follows:

Subpart D—Private Contracts

Secs.

Authority: Secs. 1102, 1802, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395a, and 1395hh).

Subpart D—Private Contracts

§ 405.400 Definitions.

For purposes of this subpart, the following definitions apply:

Beneficiary means an individual who is enrolled in Part B of Medicare.

Emergency care services means services furnished to an individual for treatment of an ''emergency medical condition'' as that term is defined in § 422.2 of this chapter.

Legal representative means one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.

Opt-out means the status of meeting the conditions specified in § 405.410.

Opt-out period means the 2-year period beginning on the effective date of the affidavit as specified by § 405.410(c)(1) or § 405.410(c)(2), as applicable.

Participating physician means a ''physician'' as defined in this section who has signed an agreement to participate in Part B of Medicare.

Physician means a doctor of medicine or a doctor of osteopathy who is currently licensed as that type of doctor in each State in which he or she furnishes services to patients.

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, or clinical social worker, who is currently legally authorized to practice in that capacity by each State in which he or she furnishes services to patients or clients.

Private contract means a document that meets the criteria specified in § 405.415.

Properly opt-out means to complete, without defect, the requirements for opt-out as specified in § 405.410.

Properly terminate opt-out means to complete, without defect, the requirements for terminating opt-out as specified in § 405.445.

Urgent care services means services furnished to an individual who requires services to be furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

§ 405.405 General rules.

(a) 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, provided the conditions of this subpart are met.

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opts-out of Medicare for a 2-year period unless the opt-out is terminated early according to § 405.445. The physician's or practitioner's opt-out may be renewed for subsequent 2-year periods.

(c) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void if the physician or practitioner fails to properly opt-out in accordance with the conditions of this subpart.

(d) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void for the remainder of the opt-out period if the physician or practitioner fails to remain in compliance with the conditions of this subpart during the opt-out period.

(e) Services furnished under private contracts meeting the requirements of this subpart are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly, except as permitted in accordance with § 405.435(c).

§ 405.410 Conditions for properly opting-out of Medicare.

The following conditions must be met for a physician or practitioner to properly opt-out of Medicare:

(a) Each private contract between a physician or a practitioner and a Medicare beneficiary that is entered into prior to the submission of the affidavit described in paragraph (b) of this section must meet the specifications of § 405.415.

(b) The physician or practitioner must submit an affidavit that meets the specifications of § 405.420 to each Medicare carrier with which he or she would file claims absent completion of opt-out.

(c) A nonparticipating physician or a practitioner may opt-out of Medicare at any time in accordance with the following:

(1) The 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 is signed, provided the affidavit is filed within 10 days after he or she signs his or her first private contract with a Medicare beneficiary.

(2) If the physician or practitioner does not timely file any required affidavit, the 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in § 405.420 is submitted to the participating physician's Medicare carriers at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter and the furnishing of any items or services to a Medicare beneficiary under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

§ 405.415 Requirements of the private contract.

A private contract under this subpart must:

(a) Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract.

(b) Clearly state whether the physician or practitioner is excluded from Medicare under sections 1128, 1156, or 1892 or any other section of the Social Security Act.

(c) State that the beneficiary or his or her legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician or practitioner.

(d) State that the beneficiary or his or her legal representative understands that Medicare limits do not apply to what the physician or practitioner may charge for items or services furnished by the physician or practitioner.

(e) State that the beneficiary or his or her legal representative agrees not to submit a claim to Medicare or to ask the physician or practitioner to submit a claim to Medicare.

(f) State that the beneficiary or his or her legal representative understands

that Medicare payment will not be made for any items or services furnished by the physician or practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted.

(g) State that the beneficiary or his or her 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, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted-out.

(h) State the expected or known effective date and expected or known expiration date of the opt-out period.

(i) State that the beneficiary or his or her legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare.

(j) Be signed by the beneficiary or his or her legal representative and by the physician or practitioner.

(k) Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician or practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with § 405.440.)

(l) Be provided (a photocopy is permissible) to the beneficiary or to his or her legal representative before items or services are furnished to the beneficiary under the terms of the contract.

(m) Be retained (original signatures of both parties required) by the physician or practitioner for the duration of the opt-out period.

(n) Be made available to HCFA upon request.

(o) Be entered into for each opt-out period.

§ 405.420 Requirements of the opt-out affidavit.

An affidavit under this subpart must:

(a) Be in writing and be signed by the physician or practitioner.

(b) Contain the physician's 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 an NPI nor a UPIN has been assigned, the physician's or practitioner's tax identification number (TIN).

(c) State that, except for emergency or urgent care services (as specified in § 405.440), during the opt-out period the physician or practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of paragraph § 405.415 for services that, but for their provision under a private contract, would have been Medicare-covered services.

(d) State that the physician or practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician or practitioner permit any entity acting on his or her behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 405.440.

(e) State that, during the opt-out period, the physician or practitioner understands that he or she may receive no direct or indirect Medicare payment for services that he or she furnishes to Medicare beneficiaries with whom he or she has privately contracted, whether as an individual, 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 Medicare+Choice plan.

(f) State that a physician or practitioner who opts-out of Medicare acknowledges that, during the opt-out period, his or her services are not covered under Medicare and that no Medicare payment may be made to any entity for his or her services, directly or on a capitated basis.

(g) State a promise by the physician or practitioner to the effect that, during the opt-out period, the physician or practitioner agrees to be bound by the terms of both the affidavit and the private contracts that he or she has entered into.

(h) Acknowledge that the physician or practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician or practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom he or she has not previously privately contracted) without regard to any payment arrangements the physician or practitioner may make.

(i) With respect to a physician who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit.

(j) Acknowledge that the physician or practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of § 405.440 apply if the physician furnishes such services.

§ 405.425 Effects of opting-out of Medicare.

If a physician or practitioner opts-out of Medicare in accordance with this subpart for the 2-year period for which the opt-out is effective, the following results obtain:

(a) Except as provided in § 405.440, no payment may be made directly by Medicare or by any Medicare+Choice plan to the physician or practitioner or to any entity to which the physician or practitioner reassigns his right to receive payment for services.

(b) 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 this subpart.

(c) 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) of this chapter, except as provided in § 405.440.

(d) 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.

(e) In the case of a physician, he or she is not subject to the limiting charge provisions of § 414.48 of this chapter, except for services provided under § 405.440.

(f) The physician or practitioner is not subject to the prohibition-on-reassignment provisions of § 414.80 of this chapter, except for services provided under § 405.440.

(g) In the case of a practitioner, he or she is not prohibited from billing or collecting amounts from beneficiaries (as provided in 42 U.S.C. 1395u(b)(18)(B)).

(h) The death of a beneficiary who has entered into a private contract (or whose legal representative has done so) does not invoke § 424.62 or § 424.64 of this chapter with respect to the physician or practitioner with whom the beneficiary (or legal representative) has privately contracted.

(i) The physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act may order, certify the need for, or refer a beneficiary for Medicare-covered items and services, provided

the physician or practitioner is not paid, directly or indirectly, for such services (except as provided in § 405.440).

(j) The physician or practitioner who is excluded under sections 1128, 1156, or 1892 of the Social Security Act may not order, prescribe, or certify the need for Medicare-covered items and services except as provided in § 1001.1901 of this title, and must otherwise comply with the terms of the exclusion in accordance with § 1001.1901 effective with the date of the exclusion.

§ 405.430 Failure to properly opt-out.

(a) A physician or practitioner fails to properly opt-out if—

(1) Any private contract between the physician or practitioner and a Medicare beneficiary, that was entered into before the affidavit described in § 405.420 was filed, does not meet the specifications of § 405.415; or

(2) He or she fails to submit the affidavit(s) in accordance with § 405.420.

(b) If a physician or practitioner fails to properly opt-out in accordance with paragraph (a) of this section, the following results obtain:

(1) The physician's or practitioner's attempt to opt-out of Medicare is nullified, and all of the private contracts between the physician or practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt-out are deemed null and void.

(2) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician is subject to the limiting charge provisions of § 414.48 of this chapter. A participating physician is subject to the limitations on charges of the participation agreement he or she signed.

(3) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(4) The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts.

(5) The physician or practitioner may make another attempt to properly opt-out at any time.

§ 405.435 Failure to maintain opt-out.

(a) A physician or practitioner fails to maintain opt-out under this subpart if, during the opt-out period—

(1) He or she knowingly and willfully—

(i) Submits a claim for Medicare payment (except as provided in § 405.440); or

(ii) Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in § 405.440).

(2) He or she fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into contracts that fail to meet the specifications of § 405.415; or

(3) He or she fails to comply with the provisions of § 405.440 regarding billing for emergency care services or urgent care services; or

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit HCFA to inspect them upon request.

(b) If a physician or practitioner fails to maintain opt-out in accordance with paragraph (a) of this section, and fails to demonstrate, within 45 days of a notice from the carrier of a violation of paragraph (a) of this section, that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract), the following results obtain, effective 46 days after the date of the notice, but only for the remainder of the opt-out period:

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

(2) The physician's or practitioner's opt-out of Medicare is nullified.

(3) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

(4) The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as provided in paragraph (c) of this section.

(5) The physician is subject to the limiting charge provisions of § 414.48 of this chapter.

(6) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(7) The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

(8) The physician or practitioner may not attempt to once more meet the criteria for properly opting-out until the 2-year opt-out period expires.

(c) Medicare payment may be made for the claims submitted by a beneficiary for the services of an opt-out physician or practitioner when the physician or practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the carrier that the physician or practitioner has opted-out of Medicare.

§ 405.440 Emergency and urgent care services.

(a) A physician or practitioner who has opted-out of Medicare under this subpart need not enter into a private contract 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 previously entered into a private contract, provided the physician or practitioner complies with the billing requirements specified in paragraph (b) of this section.

(b) When a physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, he or she:

(1) Must submit a claim to Medicare in accordance with both 42 CFR part 424 and Medicare instructions (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).

(2) May collect no more than—

(i) The Medicare limiting charge, in the case of a physician; or

(ii) The deductible and coinsurance, in the case of a practitioner.

(c) 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.

(d) Medicare may make payment for emergency care services or urgent care services furnished by a physician or practitioner who has properly opted-out when the services are furnished and the claim for services is made in accordance with this section. A physician or practitioner who has been excluded

must comply with the regulations at § 1001.1901 (Scope and effect of exclusion) of this title when he or she furnishes emergency services to beneficiaries and may not bill and be paid for urgent care services.

§ 405.445 Renewal and early termination of opt-out.

(a) A physician or practitioner may renew opt-out by filing an affidavit with each carrier with which he or she would file claims absent completion of opt-out, provided the affidavits are filed within 30 days after the current opt-out period expires.

(b) To properly terminate opt-out a physician or practitioner must:

(1) Not have previously opted out of Medicare.

(2) 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.

(3) Refund to each beneficiary with whom he or she has privately contracted all payment collected in excess of:

(i) The Medicare limiting charge (in the case of physicians); or

(ii) The deductible and coinsurance (in the case of practitioners).

(4) Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner'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.

(c) 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 provision of § 405.425 shall not apply unless the physician or practitioner subsequently properly opts out.

(d) A physician or practitioner who has completed opt-out on or before January 1, 1999 may terminate opt-out during the 90 days following January 1, 1999 if he or she notifies all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out and complies with paragraphs (b)(3) and (4) of this section. Paragraph (c) of this section applies in these cases.

§ 405.450 Appeals.

(a) A determination by HCFA 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 is an initial determination for purposes of § 405.803.

(b) A determination by HCFA that no payment can be made to a beneficiary for the services of a physician who has opted-out is an initial determination for purposes of § 405.803.

§ 405.455 Application to Medicare+Choice contracts.

An organization that has a contract with HCFA to provide one or more Medicare+Choice (M+C) plans to beneficiaries (part 422 of this chapter):

(a) Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

(b) Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted-out of Medicare.

(c) May make payment to a physician or practitioner who furnishes emergency or urgent care services to a beneficiary who has not previously entered into a private contract with the physician or practitioner in accordance with § 405.440.

Subpart E—Criteria for Determining Reasonable Charges

2. The authority citation for part 405, subpart E, continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

3. Section 405.517 is revised to read as follows:

§ 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.

(a) *Applicability.* Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.

(b) *Methodology.* Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

(c) *Multiple-source drugs.* For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

4. A new § 405.520 is added to read as follows:

§ 405.520 Payment for a physician assistants, nurse practitioners, and clinical nurse specialists' services and services furnished incident to their professional services.

(a) *General rule.* A physician assistants, nurse practitioners, and clinical nurse specialists' services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistants' services may not exceed the limits at § 414.52 of this chapter. The payment for a nurse practitioners' and clinical nurse specialists' services may not exceed the limits at § 414.56 of this chapter.

(b) *Requirements.* Medicare payment is made only if all claims for payment are made on an assignment-related basis in accordance with § 424.55 of this chapter, that sets forth, respectively, the conditions for coverage of physician assistants' services, nurse practitioners' services and clinical nurse specialists' services, and services and supplies furnished incident to their professional services.

(c) *Civil money penalties.* Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty not to exceed $2,000 for each bill or request for payment.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. Part 410 is amended as set forth below:

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 410.1 [Amended]

2. Section 410.1, paragraph (a) is amended by adding the following sentence at the end: ''Section 4206 of the Balanced Budget Act of 1997 sets forth the conditions for payment for professional consultations that take place by means of telecommunications systems.''

§ 410.32 [Amended]

3. In § 410.32(a)(3), the last word, ''section,'' is removed and the word ''paragraph'' is added in its place.

4. A new section 410.59 is added to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) *Basic rule.* Medicare Part B pays for outpatient occupational therapy services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By or under the personal supervision of an occupational therapist in private practice as described in paragraph (c) of this section.

(b) *Outpatient occupational therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient occupational therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by occupational therapists in private practice.*

(1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient occupational therapy services, each individual occupational therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) A partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, a professional corporation or other incorporated occupational therapy practice. Private practice does not include any individual during the time he or she is working as an employee of a provider.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to 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. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, an CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of occupational therapy services.* Occupational therapy services are performed by, or under the personal supervision of, the occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, personally supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient occupational therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient occupational therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation is determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(2) For purposes of applying the limitation, outpatient occupational therapy includes:

(i) Except as provided in paragraph (e)(3) of this section, outpatient occupational therapy services furnished under this section;

(ii) Outpatient occupational therapy services furnished by a comprehensive outpatient rehabilitation facility;

(iii) Outpatient occupational therapy services furnished by a physician or incident to a physician's service;

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services.

(3) For purposes of applying the limitation, outpatient occupational therapy services excludes services furnished by a hospital directly or under arrangements.

5. Section 410.60 is revised to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Medicare Part B pays for outpatient physical therapy services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By or under the personal supervision of a physical therapist in private practice as described in paragraph (c) of this section.

(b) *Outpatient physical therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise +ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by physical therapists in private practice.* (1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) An unincorporated partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated physical therapy practice. Private practice does not include any individual during the time he or she is working as an employee of a provider.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to 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. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of physical therapy services.* Physical therapy services are performed by, or under the personal supervision of, the physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, personally supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient physical therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient physical therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation shall be determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(2) For purposes of applying the limitation, outpatient physical therapy includes:

(i) Except as provided in paragraph (e)(3) of this section, outpatient physical therapy services furnished under this section;

(ii) Except as provided in paragraph (e)(3) of this section outpatient speech-language pathology services furnished under § 410.62;

(iii) Outpatient physical therapy and speech-language pathology services furnished by a comprehensive outpatient rehabilitation facility;

(iv) Outpatient physical therapy and speech-language pathology services furnished by a physician or incident to a physician's service;

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services.

(3) For purposes of applying the limitation, outpatient physical therapy excludes services furnished by a hospital or CAH directly or under arrangements.

6. In § 410.61, the section heading and paragraphs (a) through (d) are revised to read as follows:

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

(a) *Basic requirement.* Outpatient rehabilitation services (including services furnished by a qualified physical or occupational therapist in private practice), must be furnished under a written plan of treatment that meets the requirements of paragraphs (b) through (e) of this section.

(b) *Establishment of the plan.* The plan is established before treatment is begun by one of the following:

(1) A physician.

(2) A physical therapist who furnishes the physical therapy services.

(3) A speech-language pathologist who furnishes the speech-language pathology services.

(4) An occupational therapist who furnishes the occupational therapy services.

(5) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan—

(1) Are made in writing and signed by one of the following:

(i) The physician.

(ii) The physical therapist who furnishes the physical therapy services.

(iii) The occupational therapist who furnishes the physical therapy services.

(iv) The speech-language pathologist who furnishes the speech-language pathology services.

(v) A registered professional nurse or a staff physician, in accordance with oral orders from the physician, physical therapist, occupational therapist, or speech-language pathologist who furnishes the services.

(vi) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(2) The changes are incorporated in the plan immediately.

* * * * *

7. In § 410.62, the section heading and paragraph (a)(3) are revised and a new paragraph (d) is added to read as follows:

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) * * *

(3) They are furnished by a provider as defined in § 489.2 of this chapter or by others under arrangements with, or under the supervision of, a provider.

* * * * *

(d) *Limitation.* After 1998, outpatient speech-language pathology services are subject to the limitation in § 410.60(e).

8. New §§ 410.74, 410.75, 410.76, 410.77, and 410.78 are added to subpart B to read as follows:

Subpart B—Medical and Other Health Services

§ 410.74 Physician assistants' services.

(a) *Basic rule.* Medicare Part B covers physician assistants' services only if the following conditions are met:

(1) The services would be covered as physicians' services if furnished by a physician (a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act).

(2) The physician assistant—

(i) Meets the qualifications set forth in paragraph (c) of this section;

(ii) Is legally authorized to perform the services in the State in which they are performed;

(iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;

(iv) Performs the services under the general supervision of a physician (The supervising physician need not be physically present when the physician assistant is performing the services unless required by State law; however, the supervising physician must be immediately available to the physician assistant for consultation.);

(v) Furnishes services that are billed by the employer of a physician assistant; and

(vi) Performs the services—

(A) In all settings in either rural and urban areas; or

(B) As an assistant at surgery.

(b) *Services and supplies furnished incident to a physician assistant's services.* Medicare covers services and supplies (including drugs and biologicals that cannot be self-administered) that are furnished incident to the physician assistant's services described in paragraph (a) of

this section. These services and supplies are covered only if they—

(1) Would be covered if furnished by a physician or as incident to the professional services of a physician;

(2) Are the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the physician assistants' services;

(3) Are, although incidental, an integral part of the professional service performed by the physician;

(4) Are performed under the direct supervision of the physician assistant (that is, the physician assistant is physically present and immediately available); and

(5) Are performed by the employee of a physician assistant or an entity that employs both the physician assistant and the person providing the services.

(c) *Qualifications.* For Medicare Part B coverage of his or her services, a physician assistant must meet all of the following conditions:

(1) Have graduated from a physician assistant educational program that is accredited by the National Commission on Accreditation of Allied Health Education Programs;

(2) Have passed the national certification examination of the National Commission on Certification of Physician Assistants; and

(3) Be licensed by the State to practice as a physician assistant.

(d) *Professional services.* Physician assistants can be paid for professional services only if the services have been professionally performed by them and no facility or other provider charges for the service or is paid any amount for the furnishing of those professional services.

(1) Supervision of other nonphysician staff by a physician assistant does not constitute personal performance of a professional service by the physician assistant.

(2) The services are provided on an assignment-related basis, and the physician assistant may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the physician assistant must make the appropriate refund to the beneficiary.

§ 410.75 Nurse practitioners' services.

(a) *Definition.* As used in this section, the term ''physician'' means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a nurse practitioner must—

(1) Possess a master's degree in nursing;

(2) Be a registered professional nurse who is authorized by the State in which the services are furnished, to practice as a nurse practitioner in accordance with State law; and,

(3) Be certified as a nurse practitioner by the American Nurses Credentialing Center or other recognized national certifying bodies that have established standards for nurse practitioners as defined in paragraphs (b)(1) and (2) of this section.

(c) *Services.* Medicare Part B covers nurse practitioners' services in all settings in both rural and urban areas, only if the services would be covered if furnished by a physician and the nurse practitioner—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage because of one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a nurse practitioner has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by nurse practitioners documenting the nurse practitioners' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Nurse practitioners must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the nurse practitioner when the services are furnished or to make an independent evaluation of each patient who is seen by the nurse practitioner.

(d) *Services and supplies incident to a nurse practitioners' services.* Medicare Part B covers services and supplies (including drugs and biologicals that cannot be self-administered) incident to a nurse practitioner's services that meet the requirements in paragraph (c) of this section. These services and supplies are covered only if they—

(1) Would be covered if furnished by a physician or as incident to the professional services of a physician;

(2) Are of the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the nurse practitioner's services;

(3) Although incidental, are an integral part of the professional service performed by the nurse practitioner; and

(4) Are performed under the direct supervision of the nurse practitioner (that is, the nurse practitioner must be physically present and immediately available).

(e) *Professional services.* Nurse practitioners can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by a nurse practitioner does not constitute personal performance of a professional service by a nurse practitioner.

(2) The services are provided on an assignment-related basis, and a nurse practitioner may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the nurse practitioner must make the appropriate refund to the beneficiary.

§ 410.76 Clinical nurse specialists' services.

(a) *Definition.* As used in this section, the term ''physician'' means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a clinical nurse specialist must—

(1) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(2) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and

(3) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(c) *Services.* Medicare Part B covers clinical nurse specialists' services in all settings in both rural and urban areas only if the services would be covered if furnished by a physician and the clinical nurse specialist—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage by one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a clinical nurse specialist works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a clinical nurse specialist has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by clinical nurse specialists documenting the clinical nurse specialists' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Clinical nurse specialists must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the clinical nurse specialist when the services are furnished, or to make an independent evaluation of each patient who is seen by the clinical nurse specialist.

(d) *Services and supplies furnished incident to clinical nurse specialists' services.* Medicare Part B covers services and supplies (including drugs and biologicals that cannot be self-administered) incident to a clinical nurse specialist's services that meet the requirements in paragraph (c) of this section. These services and supplies are covered only if they—

(1) Would be covered if furnished by a physician or as incident to the professional services of a physician;

(2) Are of the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the clinical nurse specialist's services;

(3) Although incidental, are an integral part of the professional service performed by the clinical nurse specialist; and

(4) Are performed under the direct supervision of the clinical nurse specialist (that is, the clinical nurse specialist must be physically present and immediately available).

(e) *Professional services.* Clinical nurse specialists can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by clinical nurse specialists does not constitute personal performance of a professional service by clinical nurse specialists.

(2) The services are provided on an assignment-related basis, and a clinical nurse specialist may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the clinical nurse specialist must make the appropriate refund to the beneficiary.

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

(a) *Qualifications.* For Medicare coverage of his or her services, a certified nurse-midwife must:

(1) Be a registered nurse who is legally authorized to practice as a nurse-midwife in the State where services are performed;

(2) Have successfully completed a program of study and clinical experience for nurse-midwives that is accredited by an accrediting body approved by the U.S. Department of Education; and

(3) Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American College of Nurse-Midwives Certification Council.

(b) *Services.* A certified nurse-midwife's services are services furnished by a certified nurse-midwife and services and supplies furnished as an incident to the certified nurse-midwife's services that—

(1) Are within the scope of practice authorized by the law of the State in which they are furnished and would otherwise be covered if furnished by a physician or as an incident to a physician's service; and

(2) Unless required by State law, are provided without regard to whether the certified nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

(c) *Incident to services: Basic rule.* Medicare covers services and supplies furnished incident to the services of a certified nurse-midwife, including drugs and biologicals that cannot be self-administered, if the services and supplies meet the following conditions:

(1) They would be covered if furnished by a physician or as incident to the professional services of a physician.

(2) They are of the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the certified nurse-midwife's services.

(3) Although incidental, they are an integral part of the professional service performed by the certified nurse-midwife.

(4) They are furnished under the direct supervision of a certified nurse-midwife (that is, the midwife is physically present and immediately available).

(d) *Professional services.* A nurse-midwife can be paid for professional services only when the services have been performed personally by the nurse-midwife.

(1) Supervision of other nonphysician staff by a nurse-midwife does not constitute personal performance of a professional service by the nurse-midwife.

(2) The service is provided on an assignment-related basis, and a nurse-midwife may not charge a beneficiary for a service not payable under this provision. If the beneficiary has made payment for a service, the nurse-midwife must make the appropriate refund to the beneficiary.

(3) A nurse-midwife may provide services that he or she is legally authorized to perform under State law as a nurse-midwife, if the services would otherwise be covered by the Medicare program when furnished by a physician or incident to a physicians' professional services.

§ 410.78 Consultations via telecommunications systems.

(a) *General rule.* Medicare Part B pays for professional consultations furnished by means of interactive telecommunications systems if the following conditions are met:

(1) The consulting practitioner is any of the following:

(i) A physician as described in § 410.20.

(ii) A physician assistant as defined in § 410.74.

(iii) A nurse practitioner as defined in § 410.75.

(iv) A clinical nurse specialist as described in § 410.76.

(v) A nurse-midwife as defined in § 410.77.

(2) The referring practitioner is any of the following:

(i) A physician as described in § 410.20.

(ii) A physician assistant as defined in § 410.74.

(iii) A nurse practitioner as defined in § 410.75.

(iv) A clinical nurse specialist as described in § 410.76.

(v) A nurse-midwife as defined in § 410.77.

(vi) A clinical psychologist as described at § 410.71.

(vii) A clinical social worker as defined in § 410.73.

(3) The services are furnished to a beneficiary residing in a rural area as defined in section 1886(d)(2)(D) of the Act, and the area is designated as a

health professional shortage area (HPSA) under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)). For purposes of this requirement, the beneficiary is deemed to be residing in such an area if the teleconsultation presentation takes place in such an area.

(4) The medical examination of the beneficiary is under the control of the consulting practitioner.

(5) As a condition of payment, the teleconsultation involves the participation of the referring practitioner, or a practitioner described in section 1842(b)(18)(C) of the Act (other than a certified registered nurse anesthetist or anesthesiologist assistant) who is an employee of the referring practitioner, as appropriate to the medical needs of the patient and as needed to provide information to and at the direction of the consultant.

(6) The consultation results in a written report that is furnished to the referring practitioner.

(b) *Definition.* For purposes of this section, *interactive telecommunications systems* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting real-time consultation among the patient, consultant, and referring practitioner, or a practitioner described in section 1842(b)(18)(C) of the Act (other than a certified registered nurse anesthetist or anesthesiologist assistant) who is an employee of the referring practitioner, as appropriate to the medical needs of the patient and as needed to provide information to and at the direction of the consulting practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of interactive telecommunications systems.

9. In § 410.150, the introductory text to paragraph (b) is republished, and new paragraphs (b)(15) and (b)(16) are added to read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

* * * * *

(15) To the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies furnished incident to his or her services. Payment is made to the employer of a physician assistant regardless of whether the physician assistant furnishes services under a W–2, employer-employee employment relationship, or whether the physician assistant is an independent contractor who receives a 1099 reflecting the relationship. Both types of relationships must conform to the appropriate guidelines provided by the Internal Revenue Service. A qualified employer is not a group of physician assistants that incorporate to bill for their services. Payment is made only if no facility or other provider charges or is paid any amount for services furnished by a physician assistant.

(16) To a nurse practitioner or clinical nurse specialist for professional services furnished by a nurse practitioner or clinical nurse specialist in all settings in both rural and nonrural areas and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges, or is paid, any amount for the furnishing of the professional services of the nurse practitioner or clinical nurse specialist.

* * * * *

10. In § 410.152, the headings to paragraphs (a) and (a)(1) are republished, and paragraph (a)(1)(v) is revised to read as follows:

§ 410.152 Amount of payment.

(a) *General provisions*—(1) *Exclusion from incurred expenses.* * * *

(v) In the case of expenses incurred for outpatient physical therapy services including speech-language pathology services, the expenses excluded are from the incurred expenses under § 410.60(e). In the case of expenses incurred for outpatient occupational therapy including speech-language pathology services, the expenses excluded are from the incurred expenses under § 410.59(e).

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

C. Part 413 is amended as set forth below.

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

2. Section 413.125 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

§ 413.125 Payment for home health agency services.

* * * * *

(b) The reasonable cost of outpatient rehabilitation services furnished by a home health agency to homebound patients who are not entitled to home health benefits may not exceed the amounts payable under the physician fee schedule for comparable services effective January 1, 1999.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

D. Part 414 is amended as set forth below:

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

2. In § 414.1, the introductory text is republished, and the following statutory authorities are added in numerical order to read as follows:

§ 414.1 Basis and scope.

This part implements the indicated provisions of the following sections of the Act:

1802—Rules for private contracts by Medicare beneficiaries.

1820—Rules for Medicare reimbursement for telehealth services.

* * * * *

3. Sections 414.20 through 414.62 are redesignated as Subpart B, and a new heading is added to read ''Subpart B—Physicians and Other Practitioners''.

4. In § 414.22, the introductory text to the section is revised and the heading to paragraph (b) is republished, and new paragraph (b)(5) is added to read as follows:

§ 414.22 Relative value units (RVUs).

HCFA establishes RVUs for physicians' work, practice expense, and malpractice insurance.

* * * * *

(b) *Practice expense RVUs.* * * *

(5) For services furnished beginning January 1, 1999, the practice expense RVUs are based on 75 percent of the practice expense RVUs applicable to services furnished in 1998 and 25 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2000, the practice expense RVUs are based on 50 percent of the practice expense RVUs applicable to services furnished in 1998 and 50 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2001, the practice expense RVUs are based on 25 percent of the practice expense RVUs applicable to services furnished in 1998 and 75 percent of the relative practice expense

resources involved in furnishing the service. For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) Usually one of two levels of practice expense RVUs per code can be applied to each service. The lower practice expense RVUs apply to services furnished to hospital, skilled nursing facility, or ambulatory surgical center patients. The higher practice expense RVUs apply to services performed in a physician's office; services, other than evaluation and management services, furnished to patients in a nursing facility, in a facility or institution other than a hospital, skilled nursing facility, or ambulatory surgical center, or in the home; and other services furnished to facility patients for which the facility payment does not include physicians' practice costs.

(ii) Only one practice expense RVU per code can be applied for each of the following services: services that have only technical component practice expense RVUs or only professional component practice expense RVUs; evaluation and management services, such as hospital or nursing facility visits, that are furnished exclusively in one setting; and major surgical services.

* * * * *

5. In § 414.32, the heading and paragraph (b) are revised to read as follows:

§ 414.32 Determining payments for certain physicians' services furnished in facility settings.

* * * * *

(b) *General rule.* If physicians' services of the type routinely furnished in physicians' offices are furnished in facility settings before January 1, 1999, the physician fee schedule amount for those services is determined by reducing the practice expense RVUs for the services by 50 percent. For services furnished on or after January 1, 1999, the practice expense RVUs are determined in accordance with § 414.22(b)(5).

* * * * *

6. In § 414.34, the section heading is revised, and a new paragraph (a)(2)(iii) is added to read as follows:

§ 414.34 Payment for services and supplies incident to a physician's service.

(a) *Medical supplies.* * * *

(2) * * *

(iii) It is furnished before January 1, 1999.

* * * * *

7. In § 414.52, the section heading and introductory text are revised, and a new paragraph (d) is added to read as follows:

§ 414.52 Payment for physician assistants' services.

Allowed amounts for the services of a physician assistant furnished beginning January 1, 1992 and ending December 31, 1997, may not exceed the limits specified in paragraphs (a) through (c) of this section. Allowed amounts for the services of a physician assistant furnished beginning January 1, 1998, may not exceed the limits specified in paragraph (d) of this section.

* * * * *

(d) For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

8. Section 414.56 is revised to read as follows:

§ 414.56 Payment for nurse practitioners' and clinical nurse specialists' services.

(a) *Rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a rural area (as described in section 1861(s)(2)(K)(iii) of the Act) may not exceed the following limits:

(1) For services furnished in a hospital (including assistant-at-surgery services), 75 percent of the physician fee schedule amount for the service.

(2) For all other services, 85 percent of the physician fee schedule amount for the service.

(b) *Non-rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a nursing facility may not exceed 85 percent of the physician fee schedule amount for the service.

(c) *Beginning January 1, 1998.* For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

9. Section 414.65 is added to subpart B, to read as follows:

§ 414.65 Payment for consultations via interactive telecommunications systems.

(a) *Limitations on payment.* Medicare payment for a professional consultation conducted via interactive telecommunications systems is subject to the following limitations:

(1) The payment may not exceed the current fee schedule amount applicable to the consulting practitioner for the health care service provided.

(2) The payment may not include reimbursement for any telephone line charges or any facility fees.

(3) The payment is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.

(4) The payment differential of section 1848(a)(3) of the Act applies to services furnished by nonparticipating physicians.

(b) *Prohibited billing.* The beneficiary may not be billed for any telephone line charges or any facility fees.

(c) *Assignment required for nonphysician practitioners.* Payment to nonphysician practitioners is made only on an assignment-related basis.

(d) *Who may bill for the consultation.* Only the consultant practitioner may bill for the consultation.

(e) *Sharing of payment.* The consultant practitioner must provide to the referring practitioner 25 percent of any payments he or she receives for the consultation, including any applicable deductible or coinsurance amounts.

(f) *Sanctions.* A practitioner may be subject to the applicable sanctions provided for in chapter V, parts 1001, 1002, and 1003 of this title if he or she—

(1) Knowingly and willfully bills or collects for services in violation of the limitations of this section on a repeated basis; or

(2) Fails to timely correct excess charges by reducing the actual charge billed for the service to an amount that does not exceed the limiting charge for the service or fails to timely refund excess collections.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

E. Part 415 is amended as set forth below:

1. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (41 U.S.C. 1302 and 1395hh).

2. Section 415.110 is revised to read as follows:

§ 415.110 Conditions for payment: Medically directed anesthesia services.

(a) *General payment rule.* Medicare pays for the physician's medical direction of anesthesia services for one service or two through four concurrent anesthesia services furnished after December 31, 1998, only if each of the services meets the condition in § 415.102(a) and the following additional conditions:

(1) For each patient, the physician—

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

(ii) Prescribes the anesthesia plan;

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

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

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

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

(vii) Provides indicated post-anesthesia care.

(2) The physician directs no more than four anesthesia services concurrently and does not perform any other services while he or she is directing the single or concurrent services so that one or more of the conditions in paragraph (a)(1) of this section are not violated.

(3) If the physician personally performs the anesthesia service, the payment rules in § 414.46(c) of this chapter apply (Physician personally performs the anesthesia procedure).

(b) *Medical documentation.* The physician alone 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 that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

F. Part 424 is amended as set forth below:

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (41 U.S.C. 1302 and 1395hh).

2. In § 424.24, paragraphs (c) introductory text, (c)(1)(ii), (c)(1)(iii), (c)(3)(i), (c)(3)(ii), (c)(4), (f)(2), and (f)(3) are revised to read as follows:

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

* * * * *

(c) *Outpatient physical therapy and speech-language pathology services*—(1) *Content of certification.* * * *

(ii) The services were furnished while the individual was under the care of a physician, nurse practitioner, clinical nurse specialist, or physician assistant.

(iii) The services were furnished under a plan of treatment that meets the requirements of § 410.61 of this chapter.

* * * * *

(3) *Signature.* * * *

(i) If the plan of treatment is established by a physician, nurse practitioner, clinical nurse specialist, or physician assistant, the certification must be signed by that physician or nonphysician practitioner.

(ii) If the plan of treatment is established by a physical therapist or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(4) *Recertification*—(i) *Timing.* Recertification statements are required at least every 30 days and must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

(ii) *Content.* 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.

(iii) *Signature.* Recertifications must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

* * * * *

(f) * * *

(2) *Signature.* The certificate must be signed by a physician, nurse practioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(3) *Timing.* The physician, nurse practioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

G. Part 485 is amended as set forth below:

1. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (41 U.S.C. 1302 and 1395hh).

2. Section 485.705 is revised to read as follows:

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.

(2) *For a speech-language pathologist,* the qualifications specified in section 1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

(1) An *administrator* is a person who has a bachelor's degree and:

(i) Has experience or specialized training in the administration of health institutions or agencies; or

(ii) Is qualified and has experience in one of the professional health disciplines.

(2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

(3) *An occupational therapy assistant* must meet the requirements in part 484 of this chapter.

(4) A *physical therapist* must meet the requirements in part 484 of this chapter.