

requirements prior to being eligible to bill the Medicare program.

While this change limits the retrospective payments that an IDTF may obtain from Medicare program, we believe that this approach is consistent with our existing requirements for those providers that require a State survey prior to being enrolled as specified in § 489.13 and the requirements followed by DMEPOS suppliers as established in section 1834(j)(1) of the Act and § 424.57(b)(2). Moreover, this change would ensure that we are able to verify that an IDTF meets all program requirements at the time of filing, including the performance standards outlined in § 410.33(g) before payment for service occurs.

We are also proposing a new performance standard at § 410.33(g)(15), which states, “Does not share space, equipment, or staff or sublease its operations to another individual or organization.” We believe that it is inappropriate for a fixed-base (physical site) IDTF to commingle office space, staff, and equipment, and that commingling office space, staff and equipment or subleases its fixed-base (physical site) operation to another individual or organization constitutes a significant risk to the Medicare program because it prohibits CMS or our contractors from ensuring that each fixed-base (physical site) IDTF establishes and maintains Medicare billing privileges consistent with the provisions at § 424.500 and each IDTF meets and maintains all performance standards and other requirements under § 410.33. While we believe that this new performance standard should only apply to fixed-base (physical site) IDTF locations, we are seeking public comments on establishing a similar requirement for mobile IDTFs. This proposed standard, in conjunction with the existing IDTF performance standard three (concerning appropriate sites for an IDTF), expands the interpretation of these standards to state that a motel, or hotel is not an appropriate site for an IDTF. While we initially believed that this new performance standard should apply to only fixed-based (physical site) locations, we also believe it should apply to mobile IDTFs, but we are seeking public comment on establishing this requirement.

We believe that allowing fixed-base (physical site) IDTFs to commingle office space (including waiting rooms), staff (including supervising physicians, nonphysician personnel, or receptionists), or equipment through subleasing agreements may allow an IDTF to circumvent Medicare enrollment and billing requirements.

These types of arrangements also raise concerns because they may implicate the physician self-referral prohibition and the anti-kickback prohibition.

#### *J. Expiration of MMA Section 413 Provisions for Physician Scarcity Areas (PSAs)*

[If you choose to comment on issues in this section, please include the caption “PHYSICIAN SCARCITY AREAS” at the beginning of your comments.]

Section 413(a) of the MMA added a new section 1833(u) to the Act. That section provided a 5 percent incentive payment to physicians furnishing services in physician scarcity areas (PSAs) for physicians’ services furnished on or after January 1, 2005, and before January 1, 2008. Specifically, section 1833(u) of the Act provided for payment of an additional 5 percent of the payment amount for services furnished by primary care physicians in a primary care scarcity area and by non-primary care physicians in a specialist care scarcity area.

Because the provisions of section 1833(u) of the Act do not apply to services furnished after January 1, 2008, we are providing notification that these 5 percent incentive payments will no longer be made for services furnished on or after January 1, 2008.

#### *K. Comprehensive Outpatient Rehabilitation Facility (CORF) Issues*

[If you choose to comment on issues in this section, please include the caption “CORF ISSUES” at the beginning of your comments.]

Section 4541(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA), related to prospective payment for outpatient rehabilitation services, established section 1832(a)(2)(E) of the Act for all comprehensive outpatient rehabilitation facility (CORF) services, not just rehabilitation services of outpatient physical therapy services (including outpatient speech-language pathology (SLP) services), and outpatient occupational therapy services. The BBA also amended sections 1833 and 1834 of the Act to provide that all CORF services (as defined under section 1861(cc)(1) of the Act) furnished on or after January 1, 1999 would no longer be paid on a “reasonable cost” basis but instead would be paid based on the applicable fee schedule amount (or if less, based on the actual charge for the services). Where there is no applicable fee schedule amount, payment would be based on a comparable service or, if less, the CORF’s actual charge for the service. Specifically, section 1834(k)(1)(B) of the

Act states that the payment basis for outpatient physical therapy services (including outpatient SLP services), outpatient occupational therapy services, and all other CORF services provided on or after January 1, 1999 will be 80 percent of the lesser of: (i) The actual charge for the services; or (ii) the applicable fee schedule amount. The term “applicable fee schedule amount” is defined under section 1834(k)(3) of the Act to mean, for services furnished in a year, the payment amount determined under the PFS established under section 1848 of the Act for such services for the year “or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.”

In the CY 1999 PFS final rule (63 FR 58860), we stated that we would base payment for a CORF service on the PFS amount for the service when the PFS established a payment amount for such service. We further explained that we would use the higher PFS amount applicable to services furnished in a nonfacility setting, rather than the facility payment amount, because no separate payment will be made for facility costs. The nonfacility payment rate includes, along with any physician work and MP RVUs, the PE RVUs representing nonfacility resources necessary for the physician to perform each service in the office setting, including both direct and indirect PE inputs, such as the costs of clinical labor, disposable supplies, personnel salaries, equipment, and overhead expenses. The facility payment rate is based primarily on the physician work and MP RVUs, although it contains RVUs for the indirect PE RVUs related to the primary providing specialties, but does not include the costs of the direct PE inputs (that is, clinical labor, disposable supplies, and equipment) that are utilized when the service is provided in the physician office or nonfacility setting. Payment at the higher nonfacility payment rate was already in place prior to CY 1999 for physical therapy, occupational therapy, and speech-language pathology (SLP) services provided in the physician’s office and for the services of physical therapists (PTs) and occupational therapists (OTs) in private practice. Effective with the CY 1999 PFS final rule, we used the PFS nonfacility amount to make payment for outpatient Part B physical therapy, occupational therapy, and SLP services furnished in provider settings, including outpatient hospitals, SNFs, providers of outpatient

physical therapy (OPT) and SLP services, also known as rehabilitation agencies, CORFs, and home health agencies (HHAs) (for non-homebound patients), as discussed in the CY 1999 PFS final rule (63 FR 58860). Similarly, we used the PFS nonfacility amount for all other CORF services when the PFS established a payment amount for such service.

In addition, in CY 1999, we established a fee schedule amount under the PFS for nursing services delivered within a CORF, and created a new HCPCS code (G0128) for such services. We defined this code as direct face-to-face skilled nursing services delivered to a CORF patient by a registered nurse (RN) as part of a rehabilitative therapy plan of treatment, billable in 10-minute intervals provided the initial interval is longer than 5 minutes. We stated that the HCPCS code G0128 could be used for RN services that are not included in the work or PE of another therapy or physician service. The CORF conditions of participation at § 485.58 provide that CORF services must be provided by personnel that meet the qualifications set forth in § 485.70. Sections 485.70(b) and (h) require, respectively, that as a condition of coverage of service a licensed practical nurse (LPN) be licensed as a LPN or vocational nurse by the State of practice, and that an RN be a graduate of an approved school of nursing and licensed as an RN by the State of practice. In creating the HCPCS code G0128 for CORF nursing services, we determined that a condition of coverage for the service is that it be furnished by an individual who meets the personnel requirements for an RN because we believe only an RN possesses the necessary training to provide the clinical nursing services that are medically necessary and appropriate for CORF patients as they relate to the therapy plan of treatment.

Finally, in the CY 1999 PFS final rule (63 FR 58860), we explained that we interpret section 1834(k)(3) of the Act, defining the term “applicable fee schedule amount,” as requiring us to use the payment amount established by an existing fee schedule other than the PFS when the PFS does not establish a payment amount for the CORF service. Specifically, we stated that we would use the existing fee schedules for prosthetic and orthotic devices, DME and supplies, and drugs and biologicals for covered prosthetics and orthotics devices, durable medical equipment (DME) and supplies, and drugs and biologicals, respectively, provided by CORFs. Covered DME, orthotic and prosthetic devices, and supplies

provided by a CORF are paid under the DMEPOS fee schedule.

Drugs and biologicals that are not considered to be self-administered are specified as CORF services at section 1861(cc)(1)(F) of the Act. However, as discussed in section II.K.7., we believe that drugs and biologicals provided to CORF patients are not appropriately provided as part of a rehabilitation plan of treatment and, as such, we propose to remove drugs and biologicals from the scope of CORF services as defined at § 410.100. In addition, because we believe it is appropriate for pneumococcal, influenza, and hepatitis B vaccines to be administered to CORF patients in the CORF setting, even though such vaccines fall outside the scope of CORF services, we propose to revise the conditions of participation at § 485.51(a) to permit CORFs to provide to their patients pneumococcal, influenza, and hepatitis B vaccines in addition to CORF services.

Because the regulations under 42 CFR parts 410 and 413 were never updated to reflect the change in CORF payment methodology from a “reasonable cost” basis to 80 percent if the lesser of a payment amount under an existing fee schedule or the CORF’s actual charge, we are proposing to add a new subpart M to 42 CFR Part 414 to reflect the change in CORF payment methodology. In addition, we propose to revise the following sections of the Medicare regulations to clarify the CORF benefit.

#### 1. Requirements for Coverage of CORF services—Plan of Treatment (§ 410.105(c))

In accordance with section 1861(cc)(1) of the Act, requiring that CORF services be furnished “under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician,” § 410.105(c) provides that CORF services as defined under § 410.100 are covered only if furnished under a written plan of treatment. Specifically, the plan of treatment must: (1) Be established and signed by a physician prior to the commencement of treatment in the CORF setting; and (2) Indicate the diagnosis and anticipated rehabilitation goals, and prescribe the type, amount, frequency, and duration of the services to be furnished. We interpret these provisions as requiring that the services furnished under the plan of treatment must relate directly to the rehabilitation of injured, disabled, or sick patients. Services provided in the CORF setting that do not relate directly to such rehabilitation goals are not covered as CORF services.

We propose to revise § 410.105(c) to clarify our policy that CORF services are covered only if they relate directly to the rehabilitation of injured, disabled, or sick patients. We believe our policy is consistent with the statutory requirements under section 1861(cc) of the Act. Section 1861(cc)(1) of the Act specifies that CORF services must be furnished under a plan of treatment. Section 1861(cc)(1)(H) of the Act further states that “other items and services” are considered CORF services only if “medically necessary for the rehabilitation of the patient.” We believe the implication of this limitation for “other items of services” is that all other CORF services (that is, those listed under sections 1861(cc)(1)(A) through (G) of the Act) also must be necessary for the rehabilitation of the patient. In addition, we note that section 1861(cc)(2)(A) of the Act specifies that a CORF facility is a facility “primarily engaged in providing \* \* \* diagnostic, therapeutic, and restorative services to outpatients *for the rehabilitation of injured, disabled, or sick persons*” (emphasis added). We believe this requirement further signals the Congress’s intent that the services provided in a CORF setting be covered as CORF services only if such services relate directly to the rehabilitation of the patient.

#### 2. Included Services (§ 410.100)

Section 410.100 establishes the services that are covered under the CORF services benefit, consistent with section 1861(cc)(1) of the Act. Because of the change in payment methodology from that based on cost to payment under the PFS and other existing fee schedules beginning in CY 1999, this section does not reflect our current payment policies. Therefore, we propose to clarify our payment policy in the introductory paragraph of this section by including a cross-reference to proposed § 414.1101, which sets forth the payment methodology for CORF services, including identifying the applicable fee schedule for each CORF service. In addition, we propose to revise our definitions of physician services to reflect the change in payment methodology for CORF services. We also propose to revise the definitions of physician services, respiratory therapy services, social and psychological services, and nursing services to ensure that these definitions include only those services appropriately provided by qualified nonphysician and physician personnel and related to the rehabilitation plan of treatment established under § 410.105(c). In addition, we propose

revisions to the definition of supplies, equipment, and appliances to conform to the statutory provision at section 1861(cc)(1)(G) of the Act. Finally, we propose to remove the provision for drugs and biologicals. Although vaccines are not included in the definition of CORF services at section 1861(cc)(1) and § 410.100, we propose to make revisions to the CORF conditions of participation at § 485.51 to reflect current coverage and payment policy for vaccines provided in the CORF setting.

### 3. Physician services (§ 410.100(a))

Section 410.100(a) defines the physician services included within the scope of CORF services. Specifically, those services of a CORF physician described as administrative in nature are considered CORF services, to the exclusion of diagnostic and therapeutic services, which are physician services under section 1861(q) of the Act and separately billable as physician services under 42 CFR part 414, subpart B. Section 1861(cc)(1) of the Act excludes from the definition of CORF services any item or service that, if furnished to an inpatient of a hospital, would be excluded under section 1861(b) of the Act. Section 1861(b)(4) of the Act excludes from the definition of "inpatient hospital services" the "medical or surgical services provided by a physician," which would include the diagnostic and therapeutic services of a physician. Consequently, diagnostic and therapeutic services provided in the CORF setting by a physician are not considered CORF services. In contrast, because those services of a CORF physician that are of an administrative nature are not "medical" services, such services are included in the definition of CORF services.

In accordance with section 1861(cc)(2)(B)(i) of the Act and § 485.70(a)(1), the CORF physician must be either a medical doctor (MD) or a Doctor of Osteopathy (DO); and the conditions of participation at § 485.70(a)(2) and (3) further require that the physician have training or experience in the medical management of patients requiring rehabilitation services. The conditions of participation at § 485.58(a)(1)(i) also require the CORF facility physician to provide, in accordance with accepted principles of medical practice, medical direction, medical supervision, medical care services and consultation. We are proposing to revise § 410.100(a) to clarify that only those physician services required and provided by the CORF facility physician that are administrative in nature are considered

CORF services, whereas diagnostic and therapeutic services provided by a physician to CORF patients are considered physician services under section 1861(q) of that Act. Specifically, we propose to define CORF physician services as those services provided by a CORF facility physician that are administrative in nature, such as consultation with and medical supervision of nonphysician staff, patient case review conferences, utilization review, and the review of the therapy plan of treatment, as appropriate.

Services provided to a CORF patient by the CORF facility physician or other physician that are not administrative in nature but that are diagnostic or therapeutic services are considered physician services under section 1861(q) of the Act. Where these services are covered, they are separately payable to the physician as physician services under the PFS at the nonfacility payment amount. The physician bills the carrier in the same manner as if the services were provided in the physician office setting and notes the CORF as the place of service.

In addition, § 410.100(a) currently provides that physician services included within the definition of CORF services are reimbursed on a reasonable cost basis under part 413, and that physician services to CORF patients not included within the definition of CORF services but billed as physician services are paid by the carrier on a reasonable charge basis subject to the provisions of subpart E of part 405 of this chapter. This description of the payment methodology for physician services provided in the CORF setting under § 410.100(a) is inconsistent with the payment methodology set forth under section 1834(k)(1) of the Act for CORF services and section 1848 of the Act for physician services, as well as the preamble discussion in the CY 1999 PFS final rule (63 FR 58860). In the CY 1999 PFS final rule, we stated that we would base payment for diagnostic and therapeutic physician services provided to individuals in the CORF setting on the PFS amount for the services. Therefore, we are proposing to revise § 410.100(a) to remove the reference to reasonable cost-based payments for CORF physician services and the reference to reasonable charge based payments for non-CORF physician services. In place of these references, we propose to revise § 410.100(a) to add a reference to 42 CFR part 414, subpart B, setting forth the payment methodology for non-CORF physician services.

### 4. Clarifications of CORF Respiratory Therapy Services

Section 1861(cc)(1)(B) of the Act states that CORF services include respiratory therapy services along with physical therapy, occupational therapy, and SLP services. Because respiratory therapists (RTs) are not recognized as independent practitioners in the Act or regulations, and respiratory therapy services do not have a statutory benefit category except as specified in the CORF services benefit at section 1861(cc)(1)(B) of the Act, separate payment is not made for services provided by RTs. Instead, RTs are most often employed in physician offices and in facility settings, such as hospitals and SNFs, where payment is made to the RT employer.

The description of CORF respiratory therapy services currently includes some services that should be provided by a physician, and not an RT, and thus are inappropriate to include in a respiratory therapy plan of care. Therefore, we are proposing to remove these services from the description of CORF respiratory therapy services under § 410.100(e), and to limit these services to those provided by RTs under a respiratory therapy plan of treatment. Section 410.105(c) requires a physician, and not the RT, to provide the clinical diagnosis; establish and sign the respiratory therapy plan of treatment for each patient that includes the type, amount, frequency and duration of the services to be furnished; and indicate the diagnosis and the patient's rehabilitation goals. The physician must also recertify this plan for medical necessity every 60 days or sooner if appropriate. However, the description of respiratory therapy services under § 410.100(e) includes these services, as well as other services that under current clinical standards should not be provided by RTs, but rather should be entrusted to the physician.

Therefore, we are proposing to revise § 410.100(e) to limit respiratory therapy services to those services appropriately provided to CORF patients by RTs under a physician-established respiratory therapy plan of treatment in accordance with current medical and clinical standards. Specifically, we propose to remove from the definition of CORF respiratory therapy services the services of establishing the medical and therapy-related diagnosis and the provision of E/M services because these services are provided by the physician, as necessary, to establish the respiratory therapy plan of treatment. These services may be provided by either the CORF facility physician, as CORF

physician services or as non-CORF physician services, or by the patient's referring physician, as appropriate. We also propose to remove diagnostic tests from the description of CORF respiratory therapy services since diagnostic tests are covered under the physician services benefit category at section 1861(s)(2)(C) of the Act when provided by the physician to a CORF patient, and accordingly are separately billable by the physician under the PFS as previously discussed.

In addition to RTs, we note that the conditions of participation also recognize respiratory therapy technicians as CORF personnel; however, during the CY 1999 PFS rulemaking to recognize the 1997 BBA payment requirements, we did not include services performed by respiratory therapy technicians because we believed that current medical standards for skilled respiratory therapy services provided to patients in the CORF setting required the educational requirements possessed by RTs. This determination to only recognize the services of RTs, and not those provided by respiratory therapy technicians in carrying out the therapy plan of treatment was further supported in the CY 2002 and CY 2003 rulemaking (66 FR 55311 and 67 FR 79999), when we developed and discussed G-codes for certain CORF respiratory therapy services and specifically recognized the RT as the appropriate level of personnel to provide these CORF services. These G-codes were created to differentiate between the CORF services provided under a respiratory therapy plan of treatment from those services provided under physical and occupational therapy plans of treatment by PTs and OTs, respectively, under benefit sections 1861(p) and (g) of the Act in the 97XXX CPT code series. Because physical and occupational therapy services are subject to the therapy caps, the services provided under a CORF respiratory therapy plan of treatment needed to be identified by procedure codes specific to these services so as not to be attributed to the therapy caps. The three HCPCS codes G0237, G0238, and G0239 are specific to services provided under the respiratory therapy treatment plan and, as such, are not designated as subject to the therapy caps. We are proposing to revise the description of respiratory therapy services to remove those services appropriately provided by the physician establishing the respiratory therapy plan of treatment. In addition, we have determined that a condition of coverage for the respiratory therapy service is that it be provided by

an individual meeting the educational and training level of the RT, rather than the RT technician. For these reasons, we will accept comments on the service description at § 410.100(e), and the personnel qualifications at § 485.70(j) and (k) for a respiratory therapist and a respiratory therapy technician, respectively.

##### 5. Social and Psychological Services

In accordance with section 1861(cc)(1)(D) of the Act, social and psychological services are included within the definition of CORF services under § 410.100(h) and (i), respectively. In addition, § 485.58 specifies that the CORF must provide a coordinated rehabilitation program that includes, at a minimum, social or psychological services, along with physical therapy services and physician services, and that these services must be consistent with the therapy plan of treatment.

Currently, the description of social work services considered CORF services under § 410.100(h) includes (1) Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility; (2) casework services to assist in resolving social and emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and (3) assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care. The current description of CORF psychological services under § 410.100(h) includes: (1) Assessment diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation; (2) Psychological evaluations of the individual's response to and rate of progression under the treatment plan; and (3) Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment. We believe the current definitions of CORF social and psychological services are too broad. As discussed above in this section, we propose to revise § 410.105 to clarify our policy that CORF services are covered only if they are provided under the rehabilitation plan of treatment and relate directly to the rehabilitation of the patient. As such, we are concerned that the current descriptions of CORF social and psychological services may be misconstrued to include social and psychological services for the treatment of mental illness, which we believe is

outside the scope of coverage for CORF social and psychological services because these services do not relate directly to a rehabilitation plan of treatment and the associated rehabilitation goals.

In addition, we believe it unnecessary to distinguish between CORF social services and CORF psychological services given their similarities, and therefore, we propose to merge the two definitions into a single definition of CORF social and psychological services. As noted at section 1861(cc)(2)(B) of the Act, we believe that CORFs are required to provide either social services or psychological services, and not both types of services. We believe that merging the regulations at § 410.100(h) and (i) into a single definition of CORF social and psychological services is warranted to clarify the similarities between them.

Therefore, we are proposing to clarify the description of social and psychological services at § 410.100(h) to include only those services that address the patient's response and adjustment to the treatment plan; rate of improvement and progress towards the rehabilitation goals, or other services as they directly relate to the physical therapy, occupational therapy, SLP, or respiratory therapy plan of treatment. In addition, we propose to change the heading at § 410.100(h) from "social services" to "social and psychological services," and to eliminate the separate definition for psychological services under § 410.100(i).

Because we are proposing to revise the description of social and psychological services in § 410.100(h), we are interested in receiving comments concerning the CORF personnel qualifications in the conditions of participation at § 485.70(l) and (g) for social workers and psychologists, respectively, and comments relating to the appropriate CPT codes to represent these CORF services.

Due to the specificity of the purpose of CORF social and psychological services requiring these covered services to directly relate to the patient's rehabilitation treatment plan, we are inviting comments on which CPT codes would be appropriate for CORF social and psychological services. We believe that the procedure codes for health and behavior assessment and treatment, represented by CPT codes 96150 through 96154, specific to the patient's physical health problems, best describe the social and psychological services required in the CORF setting.

## 6. Nursing Care Services

Because the PFS does not contain a CPT code for nursing services, we established in the CY 1999 PFS final rule a new HCPCS code (G0128) for direct face-to-face skilled nursing services delivered to a CORF patient by an RN as part of a rehabilitative therapy plan of treatment. In the CORF conditions of participation at § 485.70(b) and (h), qualified personnel for nursing services include an LPN or vocational nurse and an RN, respectively. However, when the HCPCS code G0128 was created for CORF nursing services we determined that a condition for coverage is that the nursing service be provided by an individual meeting the qualifications of an RN, rather than the LPN, for CORF clinical nursing services as they relate, or are part of, the therapy plan of treatment. Because we established coverage for CORF nursing services only when provided by an RN, we are proposing to revise new § 410.100(i) (that is, the current § 410.100(j) is redesignated as § 410.100(i)) to specifically reflect this coverage decision. Consequently, in addition to the above proposal, we are also asking for comments on the appropriateness of the personnel qualification standards at § 485.79(b) and (h) for the LPN and for the RN, respectively.

## 7. Drugs and Biologicals

Section 410.100(k) currently provides that drugs and biologicals included within the definition of CORF services includes drugs and biologicals that are prescribed by a physician and administered by a physician or a CORF RN and not otherwise excluded from Medicare Part B payment under section § 410.29 (relating to self-administered drugs). In addition, in accordance with § 410.105(c), drugs and biologicals administered to a CORF patient will be covered as CORF services only if included as part of the rehabilitation plan of treatment. However, we are unable to identify any physician prescribed drugs or biologicals that are not self-administered that would be appropriately provided under a patient's rehabilitation treatment plan.

In addition, we are concerned about duplicate payment for drugs and biologicals provided to CORF patients in the CORF setting. Drugs and biologicals provided to CORF patients by CORF physicians or RNs under the supervision of a physician are considered services and supplies furnished incident to a physician's professional services under section 1861(s)(2)(A) of the Act, and therefore,

may be paid to the physician in accordance with section 1847(A) of the Act. Physicians bill the carrier for such incident to services. If such drugs and biologicals also considered CORF services, the CORF could submit a claim for the same drugs and biologicals to the fiscal intermediary for payment. If physicians and CORFs each were able to bill for drugs and biologicals that are provided in the CORF setting, we believe there is a risk of duplicative payments for the same drugs and biologicals—one payment to the CORF and one payment to the physician by the carrier. Such duplicative billing would be difficult for us to detect given that CORFs bill the fiscal intermediary for CORF services while physicians bill the carrier for physician services.

While we recognize that drugs and biologicals are enumerated as CORF services at section 1861(cc)(1) of the Act, we do not believe that drugs and biologicals are appropriately provided under rehabilitation therapy plans of treatment. Therefore, we propose to remove § 410.100(k).

We invite comments on this proposal. We are especially interested in receiving comments on the appropriateness of including drugs and biologicals under a CORF patient's rehabilitation plan of treatment.

## 8. Supplies and DME

Payment for supplies and DME as part of CORF services is specified at § 410.100(l) as “[s]upplies, appliances and equipment” and includes nonreusable supplies, medical equipment and appliances, and DME as defined in § 410.38 (except for renal dialysis systems), is a CORF covered service when provided for the patient's use outside the CORF whether purchased or rented, and is paid under the DMEPOS fee schedule. We believe that the provision at § 410.100(l) is too broad, out of date, and inconsistent with current terminology used for covered services or items. The CORF provision at section 1861(cc)(1)(G) of the Act applies only to supplies and DME, yet the regulatory provision also encompasses medical equipment and appliances. Because we believe the requirements of § 410.100(l) are inconsistent with those of section 1861(cc)(1)(G) of the Act, we are proposing to revise both the title and description at new § 410.100(k) (that is, the current § 410.100(l) is redesignated as § 410.100(k)) by deleting reference to medical equipment and appliances to reflect the CORF statutory provision by including only the items specified under section 1861(cc)(1)(G) of the Act. We also note that DME, as well as

prosthetics, orthotics, and supplies, provided in the CORF setting requires the CORF's participation in the competitive bidding, where applicable, in accordance with 42 CFR part 414 subpart F.

## 9. Clarifications and Payment Updates for Other CORF Services

Section 4078 in the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) (OBRA) amended section 1861(cc)(1) of the Act to provide that there is no requirement that any item or service furnished by a CORF in connection with physical therapy, occupational therapy, and speech pathology services under the plan of treatment be furnished at a single fixed location; however, such items and services are covered as CORF services only if payment is not otherwise made under Medicare. We note that such items and services may be covered under the Medicare home health benefit established under sections 1861(g), (m), and (p) of the Act. Accordingly, physical therapy, occupational therapy, and SLP services provided in the home are not covered as CORF services if such services and related items are covered under the Medicare home health benefit. Because the CORF regulations were not revised to reflect these changes in coverage and payment methodology, we propose to do so now.

Therefore, we are proposing to clarify the regulations at new § 410.100(l) (that is, the current § 410.100(m) is redesignated as § 410.100(l)) and § 410.105(b)(3) to reflect these requirements.

In § 410.105(b)(3), we propose to clarify that physical therapy, occupational therapy and SLP services can be furnished in the patient's home when payment for these therapy services is not otherwise made under the Medicare home health benefit.

In addition, we propose to revise § 410.100(l) to clarify that the patient must be present during the home environment evaluation that is performed by the PT, OT or speech-language pathologist, as appropriate, because we believe that the patient's presence is necessary to fully evaluate the potential impact of the home situation on the patient's rehabilitation goals.

## 10. Cost-Based Payment (§ 413.1)

Section 413.1(a)(2)(iv) currently provides for cost-based payment for CORF services, which reflects the payment methodology provided for under section 1833(a) of the Act, requiring payment on the basis of the lesser of the provider's reasonable costs

or customary charges. As discussed above, this payment methodology is inconsistent with section 1834(k) of the Act, requiring that the payment basis for outpatient physical therapy services (including outpatient SLP services), outpatient occupational therapy services, and all other CORF services provided on or after January 1, 1999 be 80 percent of the lesser of: (i) The actual charge for the services; or (ii) the applicable fee schedule amount. Therefore, we are proposing to remove § 413.1(a)(2)(iv) to clarify that cost-based payment is not applicable to services provided in the CORF setting. We are also proposing to remove § 413.1(a)(2)(vi) for OPTs or rehabilitation agencies as referenced at section 1861(p) of the Act, because these providers were also affected by the same payment changes required by the 1997 BBA for physical therapy, occupational therapy, and SLP services effective for CY 1999.

#### 11. Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

We are proposing to establish a new regulatory subpart M at 42 CFR Part 414 to specify the payment methodology for comprehensive outpatient rehabilitation services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act. Specifically, this proposed subpart would identify and describe how payment is determined for services included as CORF services under § 410.100.

Proposed § 414.1100 sets forth the basis and scope for payment for CORF services. Proposed § 414.1101 sets forth the payment methodology for CORF services, including identifying the applicable fee schedule for each type of CORF service identified in § 410.100.

Section 1834(k)(1)(B) of the Act provides that the payment basis for CORF services is 80 percent of the lesser of: (i) The actual charge for the services; or (ii) the applicable fee schedule amount. The term "applicable fee schedule amount" is defined under section 1834(k)(3) of the Act to mean, for services furnished in a year, the payment amount determined under the PFS established under section 1848 of the Act for such services for the year "or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies." Accordingly, we propose at new § 414.1101(a) to base payment for a CORF service on 80 percent of the lesser of the actual charge or the PFS amount

for the service when the PFS establishes a payment amount for such service. Payment for CORF services under the PFS is made for physical therapy, occupational therapy, SLP, and respiratory therapy services, as well as the related nursing and social and psychological services. In the CY 1999 PFS final rule (63 FR 58860), we explained that we interpret section 1834(k)(3) of the Act, defining the term "applicable fee schedule amount," as requiring us to use the payment amount established by an existing fee schedule other than the PFS when the PFS does not establish a payment amount for the CORF service. Therefore, we propose at new § 414.1101(c) that we use the existing fee schedules for prosthetic and orthotic devices, DME and supplies for covered DMEPOS provided by CORFs. Specifically, we propose that payment for covered DME, orthotic and prosthetic devices and supplies provided by a CORF be based on the lesser of 80 percent of actual charges or the payment amount established under the DMEPOS fee schedule under sections 1834 and 1847 of the Act and in 42 CFR part 414, subparts D and F. Finally, we propose at new § 414.1101(d) that if there is no fee schedule amount established for a CORF service, payment shall be based on the lesser of 80 percent of actual charges or the amount determined under the fee schedule established for a comparable service, as specified by the Secretary.

As discussed in sections II.K.7. and II.K.12., we propose to remove drugs and biologicals from the scope of CORF services as defined under § 410.100. Therefore, we propose not to include payment for drugs and biologicals under § 414.1101.

As discussed in section II.K.3., physician services included within the definition of CORF services under § 410.100(a) are limited to those services of a CORF physician described as administrative in nature, to the exclusion of diagnostic and therapeutic services which are considered separately billable physician services. Medicare generally does not permit providers to separately bill for their administrative costs; rather, such costs typically are subsumed in the payment amounts for covered medical services and items furnished to Medicare beneficiaries. Under the PFS these costs are included in the payment amount as part of the indirect practice expenses that are reflected in the PE RVUs for each service and also captured as part of the post-visit work RVU component. Similarly, we believe payment to CORFs for the administrative duties of a CORF physician, required as a condition of

participation at § 485.58(a), such as participating in patient case review conferences is subsumed within PFS payments to CORFs for physical therapy, occupational therapy, SLP, and respiratory therapy services, and the related nursing, and social and psychological services. Generally, administrative costs associated with the provision of such services is incorporated into payment amounts established under the PFS through the PE RVUs representing the resources necessary to perform each service in the physician office or nonfacility setting. Therefore, we believe it unnecessary to separately compensate CORFs for CORF physician services given that such services are administrative in nature, and propose at § 414.1001(b) not to separately pay CORFs for CORF physician services.

To ensure that CORFs are not paid twice for CORF services, we propose at new § 414.1101 to base payment for a CORF service on the applicable fee schedule amount only to the extent that payment for such service is not included in the payment amount for other CORF services. For example, under the PFS, disposable supplies generally are included in the PE RVUs representing the resources necessary to perform the service in the nonfacility setting, and thus are included in the payment amount for each service and cannot be billed separately. Accordingly, under proposed § 414.1001(c) a CORF could not bill separately for supplies included in the PE RVU component of the payment amount established for a service under the PFS. However, we note that CORFs could bill separately for certain splint and cast supplies for the application of casts and strapping because these supplies have been removed from the payment amounts established under the PFS. These splint and cast supplies are currently paid using the HCPCS code series Q4001 through Q4051 which were established to make separate payment under section 1861(s)(5) of the Act for surgical dressings, and splint and cast materials. In the CORF setting, the splint and cast supplies may be applicable for certain cast/strapping application procedures in the CPT code series 29000 through 29750. We would note that Medicare makes separate payment for surgical dressings, which are also referenced at section 1861(s)(5) of the Act, only when used by the beneficiary in his or her home. No separate payment is made when these surgical dressings are used in the CORF setting; rather the dressings costs are bundled into the payment amount

established under the PFS for the provided services.

For CORF services based on the payment amount determined under the PFS, we propose at new § 414.1101(a)(2) to use the PFS amount applicable to services furnished in a nonfacility setting, with no separate payment made for facility costs. The nonfacility payment rate includes, along with any physician work and malpractice RVUs, the PE RVUs representing the resources necessary to perform each service in the nonfacility setting, such as overhead expenses and personnel salaries and the direct costs of clinical labor, disposable supplies, and equipment. In contrast, the facility payment rate is based primarily on the physician work and malpractice RVUs, as well as RVUs for indirect PE incurred by the physician, and does not include the cost of the direct PE associated with providing each service in the physician office or nonfacility setting. We propose to use the PFS nonfacility amount for CORF services in order to offset any costs of providing such services in the CORF setting.

## 12. Vaccines

Section 485.51(a) defines a CORF as a nonresidential facility that “is established and operated exclusively for the purpose of providing” rehabilitation services by or under the supervision of a physician. Because vaccines administered in the CORF setting are not rehabilitation services furnished under a plan of treatment relating directly to the rehabilitation of the patient (or, presumably, even medically necessary for the rehabilitation of the patient), in accordance with § 485.51(a), a CORF may not administer vaccines to its patients. However, we note that nothing in the Medicare statute would prohibit a CORF from providing pneumococcal, influenza, and hepatitis B vaccines to its patients provided the facility is “primarily engaged in providing \* \* \* diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons” (section 1861(cc)(2)(A) of the Act). Accordingly, under the statute, such vaccines may be covered separately from the CORF services benefit under section 1861(s)(10) of the Act—defining the term “medical and other health services” to include the pneumococcal, influenza, and hepatitis B vaccines—provided the applicable conditions of coverage under § 410.58 and § 410.63 are met. In order to include coverage and payment for these vaccines when provided to CORF patients in the CORF setting, we propose to amend the CORF

conditions of participation at § 485.51 to permit CORFs to provide vaccines to their patients in addition to rehabilitation services. Such vaccines would be covered in the CORF setting provided the conditions of coverage under § 410.58 and § 410.63 are met. In accordance with sections 1833(a)(1) and 1842(o)(1) of the Act, payment for covered pneumococcal, influenza, and hepatitis B vaccines provided in the CORF setting is based on 95 percent of the average wholesale price (AWP).

We are interested in receiving comments on this proposal.

### *L. Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen (§ 414.930)*

[If you choose to comment on issues in this section, please include the caption “DRUG COMPENDIA” at the beginning of your comments.]

#### 1. Background

##### a. Statutory Requirements

Section 1861(t)(2)(B)(ii)(I) of the Act lists three drug compendia that may be used in determining the medically-accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen. The three drug compendia listed are:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- American Medical Association Drug Evaluations (AMA-DE)
- United States Pharmacopoeia-Drug Information (USP-DI)

Section 1861(t)(2) of the Act provides the Secretary the authority to revise the list of compendia for determining medically-accepted indications for drugs. Due to changes in the pharmaceutical reference industry, fewer of the statutorily named compendia are available for our reference. (That is, AMA-DE is no longer in publication; USP-DI has been purchased by Thomson Micromedex and it is our understanding that the name “USP-DI” may not be used after 2007.)

Section 6001(f)(1) of the DRA amends both “sections 1927(g)(1)(B)(i)(II) and 1861(t)(2)(B)(ii)(I) of the Act by inserting ‘(or its successor publications)’ after ‘United States Pharmacopoeia-Drug Information.’” We interpret this DRA provision as explicitly authorizing the Secretary to continue recognition of the compendium currently known as USP-DI after its name change if the Secretary determines that it is in fact a successor publication rather than a substitute publication.

##### b. Requests To Amend the Compendia Listings

We received requests from the stakeholder community for recognition of additional compendia under the following authorities:

- Section 1861(t)(2)(B) of the Act which allows the Secretary to identify additional authoritative compendia; and
- Section 1873 of the Act which allows the Secretary to recognize a successor publication if one of the statutorily named compendia changes its name.

In contrast, others have suggested that the Secretary consider elimination of certain listed compendia. However, there is no established regulatory process by which the agency can currently accept and act definitively on such requests. In addition, there is currently no transparency about the criteria upon which we could base a decision. Therefore, we are seeking public input on this topic.

##### c. Technology Assessment of Drug Compendia Used to Determine Medically-Accepted Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen

We commissioned a technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ) on the currently listed compendia (AHFS and USP-DI), as well as other compendia (that is, National Comprehensive Cancer Network (NCCN), ClinPharm, DrugDex, Facts & Comparisons (F&C)) which might provide comparable information. AHRQ contracted the TA to the New England Medical Center (NEMC) and Duke Evidence-based Practice Centers (EPCs) and found little agreement in the evidence cited among drug compendia. In addition, the TA found little agreement between the EPC’s independent identification of evidence on 14 example off-label indications and evidence cited in the drug compendia. The TA can be found at <http://www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=46>.

##### d. Medicare Evidence Development and Coverage Advisory Committee (MedCAC)

On March 30, 2006, the MedCAC (formerly the Medicare Coverage Advisory Committee (MCAC)) met in public session to advise CMS on the evidence about the desirable characteristics of compendia to determine medically-accepted indications of drugs and biologicals in anti-cancer therapy and the degree to which the currently listed and other

available compendia display those characteristics. All information on this MedCAC meeting can be found on the CMS Web site at <http://www.cms.hhs.gov/mcd/viewmccac.asp?where=index&mid=33>. The agenda included a presentation of the TA performed for AHRQ by staff of the NEMC and Duke EPCs, scheduled stakeholder presentations, as well as an opportunity to hear testimony from members of the audience. As is customary, the MedCAC panelists elicited additional information from the presenters and discussed the evidence in preparation for a formal vote.

The MedCAC identified the following desirable characteristics:

- Extensive breadth of listings.
- Quick throughput from application for inclusion to listing.
- Detailed description of the evidence reviewed for every individual listing.
- Use of pre-specified published criteria for weighing evidence.
- Use of prescribed published process for making recommendations.
- Publicly transparent process for evaluating therapies.
- Explicit “Not recommended” listing when validated evidence is appropriate.
- Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies.
- Explicit “Equivocal” listing when validated evidence is equivocal.
- Process for public identification and notification of potential conflicts of interest of the compendia’s parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

The MedCAC concluded that none of the compendia fully display the desirable characteristics. The voting results can be viewed at the same Web site provided previously for the MedCAC meeting. In addition the MedCAC noted significant variability among the compendia. There was no agreement among the panel members that any particular predetermined number of compendia was desirable.

Participants in the meeting also discussed the clinical usefulness of drug compendia in the treatment of cancer. It was reported that oncologists do not rely on compendia when making treatment decisions, relying instead on published treatment guidelines, clinical trial protocols, or consultation with peers.

Prior to this proposed rule, we received and reviewed unsolicited comments from professional societies regarding additions and deletions to the listing of compendia for purposes of

section 1861(t) of the Act. We believe that the notice and comment period of this proposed rule will provide the opportunity for the public to present its concerns regarding this process. We encourage all interested parties to submit their comments via the process mentioned in the **SUPPLEMENTARY INFORMATION** section of this proposed rule.

## 2. Process for Determining Changes to the Compendia List

A compendium for the purpose of this section is defined as a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example, a compendium of anti-cancer treatment. A compendium: (1) Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; (2) is indexed by drug or biological; (3) differs from a disease treatment guideline, which is indexed by disease. We believe that the use of compendia to determine medically-accepted indications of drugs and biologicals in the manner specified in section 1861(t)(2)(B)(ii)(I) of the Act is more efficiently accomplished if the information contained is organized by the drug or biological and if the listings are comprehensive.

We propose to create a process incorporating public notice and comment to receive and make determinations regarding requests for changes to the list of compendia used to determine medically-accepted indications for drugs and biologicals used in anti-cancer treatment as described in section 1861(t)(2)(B)(ii)(I) of the Act. Requests may be for addition or deletion of a compendium from the list.

We will use the following process to receive and make determinations regarding requests for changes to the list of compendia:

- For the purposes of this section, the notice may be accomplished by posting the information on the CMS Web site. This does not preclude us from using other reasonable means at our discretion. We believe this will facilitate a timely and efficient consideration of requests.

- We will issue annually a notice for requests to revise the list of compendia. This notice will be published and will specify a 30-day time period within which we will accept any external requests that are complete, as defined in this section. To allow sufficient time for

the public to be notified, we will begin the acceptance process for external requests no sooner than 45 days after publication of the notice. We believe that this will enhance the administrative efficiency of this process without placing a significant burden on the public.

- We will publish a listing of the timely complete request(s) received and allow the public 30 days to submit comments on the request(s). The listing will identify the requestor and the requested addition or deletion to the list of compendia.

- A complete request must include the following:

- + The full name and contact information (including the mailing address, e-mail address, and telephone number) of the requestor. If the requestor is not an individual person, the information shall identify the officer or other representative who is authorized to act for the requestor on all matters related to the request.

- + Full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

- + A complete written copy of the compendium that is the subject of the request. If the complete compendium is available electronically, it may be submitted electronically in place of hard copy. If the compendium is available online, the requestor may provide us with electronic access by furnishing at no cost to the Federal government sufficient accounts for the purposes and duration of the review of the application in place of hard copy.

- + The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium.

- + Detailed, specific documentation that the compendium that is the subject of the request does or does not comply with the conditions of this rule. Broad, nonspecific claims without supporting documentation cannot be efficiently reviewed; therefore, they will not be accepted.

- + A request may have only a single compendium as its subject. This will provide greater clarity on the scope of the agency’s review of a given request. A requestor may submit multiple requests, each requesting a different action.

- + Requests must be in writing as opposed to verbal.

- Requests may be submitted in two ways (no duplicates please). Electronic

submissions are encouraged to facilitate administrative efficiency. We will, in our solicitation of requests, identify the electronic address to be used for submissions. Hard copy requests can be sent to the Centers for Medicare & Medicaid Services, Coverage and Analysis Group, Mailstop C1-09-06, 7500 Security Boulevard, Baltimore, MD, 21244. Please allow sufficient time for hard copies to be received prior to the close of the solicitation period. We may internally generate a request to change the list of compendia at any time. We believe that this preserves the agency's ability to act quickly if we determine that urgent action is needed to protect the interests of the Medicare program and its beneficiaries.

- We will consider a compendium's attainment of the MedCAC-recommended desirable characteristics of compendia, listed above in this section, in reviewing requests. We may consider additional reasonable factors in making a determination. (For example, we may consider factors that are likely to impact the compendium's suitability for this use, such as a change in ownership or affiliation, the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest. We may consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians or both in choosing among treatment options.)

- We will also consider a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

- We may, at our discretion, combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions. This facilitates administrative efficiency in our review of requests.

- We will publish our decision within 120 days after the close of the public comment period.

- For each compendium that we determine should be included on the list, the publisher or its designee must notify CMS, within 45 days from the publication date of each new edition or revision of the compendium, that a new edition or version is available. This will ensure that we have the most current information for each compendium. This may be provided electronically or via online access. We believe that this is necessary to permit us to efficiently ensure that the listed compendia continue to meet the conditions set forth in this rule.

- In addition to the annual process, we may generate a request for changes to the list of compendia at any time.

#### *M. Physician Self-Referral Provisions*

[If you choose to comment on issues in this section, please include the caption "PHYSICIAN SELF-REFERRAL PROVISIONS" at the beginning of your comments.]

#### 1. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

Medicare rules currently prohibit the markup of the technical component of certain diagnostic tests that are performed by outside suppliers and billed to Medicare by a different individual or entity (§ 414.50). In addition, Medicare program instructions restrict who may bill for the professional component (the interpretation) of diagnostic tests (CMS Pub. 100-04, Chapter 1, 30.2.9.1).

In the CY 2007 PFS proposed rule (71 FR 48982), we stated that recent changes to our rules on reassignment concerning the right to receive Medicare payment may have led to some confusion as to whether the anti-markup and purchased interpretation requirements apply to certain situations where a reassignment has occurred under a contractual arrangement. In addition, we expressed concern about the existence of certain arrangements that we believe are not within the intended purpose of the physician self-referral rules, which permit physician group practices to bill for certain services furnished by a contractor physician in a "centralized building." We also expressed concern that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare program (71 FR 49054).

In the CY 2007 PFS proposed rule (71 FR 48982), we proposed to amend § 424.80 to provide that if the TC of a diagnostic test (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act) is billed by a physician or medical group (the "billing entity") under a reassignment involving a contractual arrangement with a physician or other supplier who performs the service, the amount billed to Medicare by the billing entity, less the applicable deductibles

and coinsurance, may not exceed the lowest of the following amounts:

- The physician or other supplier's net charge to the billing physician or medical group.
- The billing physician's or medical group's actual charge.
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

We also proposed that, to bill for the TC, the billing entity would be required to perform the interpretation. In addition, we considered imposing certain conditions on when a physician or medical group can bill for a reassigned PC of a diagnostic test. We stated that we were considering the following conditions (which currently appear in manual provisions and are known as the purchased interpretation rules):

- The test must be ordered by a physician who is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation.
- The physician or medical group performing the interpretation does not see the patient.
- The physician or medical group billing for the interpretation must have performed the TC of the test.

We stated that, although we welcomed comments on all aspects of our proposals, we were particularly interested in receiving comments on whether: diagnostic imaging tests should be excepted from any of our proposed provisions; the proposal in whole or in part should apply only to pathology services; any of the proposed provisions should apply to services performed on the premises of the billing entity and if so, how to define the premises appropriately. We also requested comments as to whether an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement, and if so, how to determine the correct amount that should be billed to the Medicare program.

For our physician self-referral rules, we proposed to modify the definition of "centralized building" at § 411.351 to require a centralized building to consist of at least 350 square feet. We further proposed that the proposed minimum square footage requirement would not apply to space owned or rented in a building in which no more than three group practices own or lease space in the "same building," as defined at § 411.351 (that is, in a building with the same street address) and share the same

“physician in the group practice” (as defined at § 411.351). We also proposed that a centralized building must contain, on a permanent basis, the necessary equipment to perform substantially all of the designated health services (DHS) that are performed in the space in order to meet the definition of a centralized building. We solicited comments as to whether a centralized building should have a minimum square foot requirement, and if so, whether the minimum should be 350 square feet or an amount more or less than that. In addition, we sought comments regarding whether there should be an exception to any minimum square foot requirement, and if so, the circumstances under which an exception should apply.

For our proposal that the centralized building permanently contain the necessary equipment to perform substantially all of the DHS that is furnished in the centralized building, we sought comments on whether this test should be imposed, and whether at least 90 percent or some other minimum percentage or measurement would be appropriate. We stated that we were also considering whether to require that, for space to qualify as a centralized building, the group practice must employ, in that space, a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. Finally, we sought comments on whether a group practice should be allowed to maintain a centralized building in a State different from the State(s) in which it has an office that meets the criteria in § 411.355(b)(2)(i), and if so, whether space that is located in a different State must be within a certain number of miles from an office of the group practice that meets the criteria in § 411.355(b)(2)(i) in order to qualify as a centralized building.

We received numerous comments on these proposals. As a result, we did not finalize our proposals in the CY 2007 PFS final rule with comment period. Based on the comments received and other information that we considered, we are proposing to impose an anti-markup provision on the TC and PC of diagnostic tests. We would apply the anti-markup provision irrespective of whether the billing physician or medical group outright purchases the PC or the TC, or whether the physician or other supplier performing the TC or PC reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity). To prevent gaming, whereby the performing physician's or other

supplier's net charge to the billing entity is inflated to cover the cost of equipment or space that is leased to the performing physician or other supplier, we would define “net charge” as exclusive of any amount that takes into consideration such charges. For example, consider the following hypothetical:

- The fee schedule amount for the PC of a particular diagnostic test is \$100.
- Performing Physician A rents office space and equipment from Group B for \$50 per test interpretation performed.
- Physician A charges Group B \$100 per test. In this example, pursuant to our proposal, Physician A's charge of \$100 would be deemed to take into account the \$50 rental fee imposed by Group B (simply by virtue of the rental arrangement). Therefore, Group B would not be allowed to bill the full fee schedule amount of \$100, but rather, would be limited to the lesser of Physician A's net charge determined exclusive of the amount that is deemed to have taken into consideration the lease expense, that is \$50, or Group B's actual charge for the PC. We are also concerned that overutilization of diagnostic tests could continue despite our proposal to apply an anti-markup provision to TCs that are reassigned to, or outright purchased by, group practices. That is, our proposal in the CY 2007 PFS proposed rule to impose an anti-markup provision would not have addressed the situation in which the TC is performed by a part-time or leased employee of the group practice in a centralized building, and the group neither receives a reassignment from the employee technician (if the technician is not able to bill for the TC in his or her own right), nor purchases the TC outright from the technician. Therefore, we are proposing to apply an anti-markup provision to TCs that are performed in a centralized building, and are seeking comments on whether we should have such a provision and, if so, how we should effect such a provision (for example, through amending the definition of “centralized building” or through some other means. We would except the anti-markup provision for PCs ordered by independent laboratories because we do not believe that PCs ordered by independent laboratories pose a significant risk of program abuse because the independent lab is not ordering the TC. In States where the corporate practice of medicine doctrine is in effect, independent labs that are organized as corporations are prevented from hiring physicians as employees to perform PCs of diagnostic tests.

In addition, we are proposing in § 414.50 that—(1) The PC of a purchased test be subject to an anti-markup provision; (2) the anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity; (3) the performing physician's or other supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or other supplier by the billing entity; and (4) the anti-markup provision not apply to independent labs that have not ordered the TC.

At this time, we are not proposing to make changes to the definition of “centralized building” (with the one possible exception noted below in this section). We believe that changes to the definition may be unnecessary in light of our proposals for an anti-markup provision on the TC and PC of diagnostic tests (although if we decide to impose an anti-markup for TCs performed by technicians in a centralized building, we may accomplish that through amending the definition of “centralized building”). If an anti-markup provision is finalized, we may evaluate at a later time whether to make any revisions to the definition of “centralized building.” We also are not proposing to adopt the purchased test interpretation rules in the context of reassignments because this provision may be unnecessary if we impose an anti-markup provision and because the purchased test interpretation rules may be problematic for multi-specialty group practices. Finally, in the CY 2007 PFS proposed rule, we proposed that, in order to bill for the TC of the diagnostic test, the billing physician or medical group must directly perform the PC. However, we believe this provision may be unnecessary if we impose an anti-markup provision and also would be problematic for independent labs that cannot employ physicians due to corporate practice of medicine restrictions.

## 2. Burden of Proof

We are proposing to add § 411.353(g) to clarify that, consistent with our policy with respect to claims denials, in any appeal of a denial of payment for a DHS that was made on the basis that the service was furnished pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral. That is, the burden of proof is not on CMS or our contractors to establish that the service was furnished pursuant to a prohibited referral.

### 3. In-Office Ancillary Services Exception

One of the most important exceptions to the physician self-referral prohibition, applicable to services furnished by group practices and sole practitioners, is the in-office ancillary services exception. Section 1877(b)(2) of the Act sets forth an exception for certain services (other than durable medical equipment and parenteral and enteral nutrients) that are provided ancillary to medical services provided by a physician or group practice and that meet certain conditions. The in-office ancillary services exception is codified in § 411.355(b).

Among other things, the exception allows patients of a sole practitioner or physician in a group practice to receive ancillary services in the same building in which the referring physician or his or her group practice furnishes medical services, including some services unrelated to the furnishing of DHS. The exception provides additional flexibility for patients seen by a physician in a group practice by allowing these patients to receive a test or procedure in another building in space owned or leased on a full-time, exclusive basis by a group practice (that is, a "centralized building" as defined at § 411.351).

The in-office ancillary services exception does not contain certain requirements that are found in other compensation exceptions. For example, the exception for personal service arrangements in § 411.357(d), like many of the compensation exceptions, requires that compensation be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. These requirements are not present in the in-office ancillary services exception. Also, under the "special rule for productivity bonuses and profit shares" in § 411.352(i), a physician in a group practice may receive a share of profits or a productivity bonus for referred ancillary services, provided that the payment is not directly related to the volume or value of referrals.

We believe that the Congress included an exception for in-office ancillary services to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office. At the time of enactment, a typical in-office ancillary services arrangement might have involved a clinical laboratory owned by physicians located on one floor of a small medical office building. Under

such an arrangement, a staff member would take a urine or blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited.

However, services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice. For example, pathology services may be furnished in a building that is not physically close to any of the group practice's other offices, and the professional component of the pathology services may be furnished by contractor pathologists who have virtually no relationship with the group practice (in some cases, the technical component of the pathology services is furnished by laboratory technologists who are employed by an entity unrelated to the group practice). In other words, the core members of the group practice and their staff are never physically present in the contractor pathologist's office. Similarly, the contractor pathologists do not participate in any group practice activities; they attend no meetings (except for phone calls about individual patients), and do not obtain retirement or health benefits from the group practice. In sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS.

Even in the case of ancillary services furnished in the same building, there may be very little interaction between the physicians who treat patients and the staff that provide the ancillary services. For example, an entity with its own staff located in a large medical office building next to a hospital may furnish an array of diagnostic services, including clinical laboratory services and radiology services, to patients of physicians who practice in the building and own either the equipment or the entity.

Comments received on the Phase I and Phase II physician self-referral rules (66 FR 856 and 69 FR 16055, respectively) stated that the in-office ancillary services exception is susceptible to abuse. For example, in response to the 1998 physician self-referral proposed rule (66 FR 892), a commenter asserted that the Congress did not intend for a group practice to have multiple centralized office locations, except for the provision of clinical laboratory services. This sentiment was reiterated in response to the Phase I final rule when several commenters objected to the decision to allow group practices to have more than one centralized facility (69 FR 16075).

In response to Phase II, we received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices. In addition, we have been informed by a number of physician specialists that the in-office ancillary services exception enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist.

In the CY 2007 PFS proposed rule (71 FR 48982), we stated our intent to address certain types of potentially abusive arrangements in which group practice physicians make a referral for a DHS to a specialist who is an independent contractor of the group practice. The specialist then performs the service for the group practice in a "centralized building" and reassigns his or her right to Medicare payment to the group (which then bills Medicare at a profit).

Comments received on the CY 2007 PFS proposed rule stated that, although our proposal addressed potential abuses arising from referrals to independent contractors who perform services in a centralized building, it failed to address abusive arrangements within the physician's office. Our review of industry trade articles and discussions with trade associations has heightened our awareness of the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment to physician offices. "Turn-key" operations, such as the arrangements described in this section for in-office laboratories and other ventures, are being marketed to physicians over the internet.

At this time, we decline to issue a specific proposal for amending the in-office ancillary services exception. Rather, we are soliciting comments as to whether changes are necessary and, if so, what changes should be made. We are interested in receiving comments on: (1) Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services); (2) whether and, if so, how we should make changes to our definitions of same building and centralized building; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists;

and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

#### 4. Obstetrical Malpractice Insurance Subsidies

We are concerned that our exception for obstetrical malpractice insurance subsidies is unnecessarily restrictive; that is, that our exception does not allow for certain obstetrical malpractice insurance subsidies that may be provided without a risk of program or patient abuse. The exception in § 411.357(r) incorporates by reference the conditions in the anti-kickback safe harbor in § 1001.952(o). We have received accounts, through advisory opinion requests and anecdotally, of patient difficulty obtaining obstetrical care in some communities in States in which obstetrical malpractice insurance premiums are relatively high. We have also been informed that obstetricians have left these States for other practice locations where obstetrical malpractice insurance premiums are less expensive, requiring patients to drive long distances to receive obstetrical care. We are seeking comments describing such problems and recommendations for how the exception should be changed without creating a risk of program or patient abuse. For example, the exception requires that the physician practice in a primary care HPSA and that 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will either reside in a HPSA or a medically-underserved area or be part of a medically-underserved population. We are interested in whether the exception would more effectively ensure beneficiary access to obstetrical care without risking program abuse if any of the requirements were changed. In addition, to the extent possible, we would like to establish bright-line requirements in the exception.

We are proposing to revise the exception in § 411.357(r) to specifically list the conditions that we believe are appropriate to safeguard against program or patient abuse when remuneration is provided by a hospital to a physician in the form of an obstetrical malpractice insurance subsidy. As noted previously, the current exception incorporates the conditions in the anti-kickback safe harbor in § 1001.952(o). We are seeking comments with respect to requirements, such as the following, that would be appropriate to include in the exception for obstetrical malpractice insurance subsidies:

- A requirement for a written agreement between the parties.
  - Physician certification (or, in subsequent years, actual data indicating) that a specified percent of the physician's obstetrical patients treated under the coverage of the subsidized malpractice insurance will either reside in a HPSA or medically-underserved area or be part of a medically-underserved population.
  - Location of the entity making the malpractice insurance premium subsidy payment.
  - Location of the medical practice of the physician receiving the malpractice insurance subsidy payment.
  - A requirement that the payment not be conditioned on the physician making referrals to, or otherwise generating business for, the entity.
  - No restriction on the physician establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity.
  - A requirement that the amount of the payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the physician.
  - A requirement that the physician must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.
  - A requirement that the insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance.
- In addition, we would include the requirement that the arrangement not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission (which is a requirement of our other compensation exceptions issued under our authority under section 1877(b)(4) of the Act).

#### 5. Unit-of-Service (Per-Click) Payments in Space and Equipment Leases

Section 1877(e)(1) of the Act provides an exception to the prohibition of physician referrals for space and equipment leases, provided that certain requirements are met. Among the requirements, which are incorporated in our regulations in § 411.357(a) and (b), are that the lease be commercially reasonable even if no referrals were made between the parties, and that the rental charges be set in advance, be consistent with market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated

between the parties. The statute also requires that the lease arrangement meet such other requirements as the Secretary may impose by regulation as needed to safeguard against program or patient abuse. We are concerned with lease arrangements that are structured so that a physician is rewarded for each referral he or she makes for DHS. Such arrangements could take the form of a physician leasing equipment that he or she owns to a hospital, and receiving a per-use (per-click) fee each time a patient is referred by the physician-owner to the hospital for the use of the equipment. We are also concerned about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. For example, if a physician rents an MRI machine from a hospital only when the physician refers a patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital, the physician benefits financially and the arrangement could provide an incentive for overutilization or other program abuse.

In the 1998 proposed rule (63 FR 1714), we noted that we had been asked about situations in which a physician rents equipment (such as a magnetic resonance imaging (MRI) machine) to an entity that furnishes a DHS, such as a hospital, with the physician receiving rental payments on a per-click basis (that is, total rental payments increase each time the machine is used). We stated that we believed that this arrangement would not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements were typical and complied with the fair market value and other requirements included under the rental exception. However, we added that, because a physician's compensation under this exception may not reflect the volume or value of the physician's own referrals, the rental payments may not reflect per-click payments for patients who are referred for the service by the lessor physician.

In the Phase I rulemaking, we stated that we were substantially revising the proposed rule with respect to "the volume or value standard." We stated:

Most importantly, we are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at

inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. (66 FR 876)

After reconsidering the issue, we are proposing that space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity. We believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee, and we would disallow such per-click payments, using our authority under section 1877(e)(1) of the Act, even if the statute does not expressly forbid per-click payments to a lessor for patient referred to the lessee.

Finally, we are soliciting comments on whether, using our authority under section 1877(e)(1) of the Act, we should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.

#### 6. Period of Disallowance for Noncompliant Financial Relationships

In response to the Phase II interim final rule with comment period (69 FR 16054), we received several comments that questioned what the period would be for which the physician could not refer DHS to the entity and the entity could not bill Medicare for the situation in which a financial arrangement between a referring physician and an entity failed to satisfy the requirements of an exception to the general prohibition on self-referrals.

At this time, we are not making proposals for prescribing the period of disallowance for various types of noncompliance, but rather are seeking comments on how we might, to the extent practicable, set forth the period of disallowance for arrangements that implicate, but fail to satisfy the requirements of, one or more of the various exceptions. As a general matter, we believe that the statute contemplates that the period of disallowance should begin with the date that a financial arrangement failed to comply with the statute and the regulations and end with the date that the arrangement came into compliance or ended. However, in some instances it may not be clear when a financial arrangement has ended. For example, where an entity leases space to a physician at a rental price that is substantially below fair market value, it may raise the inference that the below market rent was in exchange for future referrals, including referrals made

beyond the expiration of the lease. We are seeking comment whether, with respect to types of noncompliance for which it is not clear when a financial relationship ended, we should always employ a case-by-case approach, or deem certain types of financial relationships to continue for a prescribed period of time.

We are also soliciting comment as to whether we should allow the period of disallowance to terminate where the parties have returned, or paid back the value of, the consideration. For example, if we were to impose a period of disallowance for a prescribed period of time because it would not be clear when a noncompliant compensation arrangement ended, we might allow the parties to terminate the period of disqualification sooner than the prescribed period if the prohibited compensation were returned. We caution that we do not envision allowing such an option where the parties knew or, in our judgment, reasonably should have known that the arrangement did not satisfy the requirements of an exception.

We are also seeking comment as to whether we should impose a period of disqualification from using an exception where an arrangement has failed to satisfy the requirements of that exception. For example, suppose non-monetary compensation is given by an entity to a physician that greatly exceeds the permissible limit prescribed in § 411.357(k). In addition to whatever period of disallowance that would apply, we are considering whether the parties should be disqualified, for a period of time, from relying on this exception. For example, if an entity gives a piece of equipment to a physician that has a fair market value of \$900, we may—

- Prohibit one or both of the parties from relying on this exception for a period of time;
- Require the parties to “spend down” in order to use the exception again (for example, if the permissible year limit is \$300 (not taking into account adjustment for inflation) and the parties exceeded this limit by \$600, the parties would be precluded from using the exception during the next 2 years (not taking into account adjustment for inflation); or
- Require the physician to return or pay back the value of the excess compensation in order for one or both of the parties to use the exception again.

#### 7. Ownership or Investment Interest in Retirement Plans

In the 1998 proposed rule (63 FR 1708), we noted that we had received

questions concerning whether stock options and other nonvested interests (such as an interest in retirement funds that vests after a certain number of years worked) in an entity constitutes ownership in that entity. We replied that it was our view that options and nonvested interests are inchoate or partial ownership interests that qualify as “ownership” for purposes of the physician self-referral law. In response to a comment to the 1998 proposed rule, however, we stated in the Phase I final rule with comment period that we were withdrawing the statement in the 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest for purposes of section 1877 of the Act and that, instead, we would consider contributions (including employer contributions) to retirement plans to be part of an employee’s overall compensation arrangement with his or her employer (66 FR 870). As part of the Phase I rule, we promulgated § 411.354(b)(3)(i), which excludes “[a]n interest in a retirement plan” from the definition of ownership and investment interests. We made no changes to this provision in Phase II (69 FR 16054).

We received a comment in response to the Phase II interim final rule (69 FR 16054) concerning the exclusion from an ownership or investment interest for retirement plans as specified in § 411.354(b)(3)(i). The commenter stated that, contrary to our intent, some physicians are using retirement plans to purchase DHS entities to which they refer patients for DHS. We agree with the commenter that it was not our intent to exclude from the definition of an ownership or investment interest an interest in a DHS entity that results from a physician’s (or family member’s) participation in a retirement plan that purchases an interest in that DHS entity. That is, where a physician has an interest in a retirement plan offered by Entity A, through the physician’s (or an immediate family member’s) employment with Entity A, we intended to except from the definition of ownership or investment interests any interest the physician would have in Entity A by virtue of his or her interest in the retirement plan; we did not intend to exclude from the definition of ownership or investment interests any interest the physician may have in Entity B through the retirement plan’s purchase of an interest in Entity B.

Accordingly we are proposing to revise § 411.354(b)(3)(i) to provide that ownership and investment interests do not include an interest in a retirement plan offered by the entity to the physician or immediate family member

as a result of the physician's or immediate family member's employment with the entity.

#### 8. "Set in Advance" and Percentage-Based Compensation Arrangements

Several of the compensation exceptions in section 1877 of the Act require that the compensation be "set in advance" (or "fixed in advance"). This requirement has been carried over in our regulations implementing those statutory exceptions, and we have also included a "set in advance" requirement in some of our regulatory exceptions (that is, exceptions promulgated pursuant to our authority in section 1877(b)(4) of the Act to create additional exceptions that pose no risk of program or patient abuse). In § 411.354(d), Special Rules on Compensation, we state that compensation will be considered "set in advance" if the aggregate compensation, a time-based or per unit-of-service-based amount, or a specific formula for calculating the compensation, is set forth in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. Under Phase I (66 FR 959), the last sentence of § 411.354(d)(1) read,

Percentage compensation arrangements do not constitute compensation that is 'set in advance' in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

We had explained in that rule, in response to a public comment, that "[p]ercentage compensation that is determined by calculating a percentage of a fluctuating or indeterminate amount, such as revenues, collections or expenses, is not fixed in advance" (66 FR 878). Following publication of the Phase I rule, however, we received anecdotal accounts about contracts for physician services under which payment was calculated based on a percentage of the revenue raised by a physician's own professional services. Therefore, we delayed the effective date of the final sentence of § 411.354(d)(1) through four **Federal Register** notices, to allow us to revise the provision "to avoid unnecessarily disrupting existing contractual arrangements for physician services" (68 FR 74491, December 24, 2003; 68 FR 20347, April 25, 2003; 67 FR 70322, November 22, 2002; 66 FR 60154 and 60155, December 3, 2001).

In the Phase II interim final rule with comment period, in the section on physician compensation, we explained that percentage compensation arrangements were of particular concern

to academic medical centers and to hospitals "which argued that percentage compensation is commonplace in their physician compensation arrangements" (69 FR 16068). We were persuaded that our original position was overly restrictive, and accordingly, we deleted the last sentence in § 411.354(d)(1) and clarified that the specific formula must be set forth in sufficient detail before the furnishing of the items or services and the formula may not be modified within the time period in any manner that reflects the volume or value of referrals or any other business generated between the parties.

Despite our intent that percentage compensation arrangements could be used only for compensating physicians for the physician services they perform, it has come to our attention that percentage compensation arrangements are being used for the provision of other services and items, such as equipment and office space that is leased on the basis of a percentage of the revenues raised by the equipment or in the medical office space. We are concerned that percentage compensation arrangements in the context of equipment and office space rentals are potentially abusive. We note that section 1877(e)(1)(A)(vi) of the Act, with respect to office space rentals, and section 1877(e)(1)(B)(vi) of the Act, with respect to equipment rentals, allow us to impose requirements on office space and equipment rental arrangements as needed to protect against program or patient abuse. Although we are concerned primarily with percentage compensation arrangements in the context of equipment and office space rentals, we believe there is the potential for percentage compensation to be utilized in other areas as well. Therefore, relying on our authority in sections 1877(e)(1)(A)(vi), 1877(e)(1)(B)(vi), and 1877(b)(4) of the Act, we are proposing to clarify that percentage compensation arrangements: (1) May be used only for paying for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided).

#### 9. Stand in the Shoes

Commenters to the Phase I final rule with comment period proposed that we permit physicians to stand in the shoes of their group practices, thereby requiring analysis of certain indirect compensation arrangements as direct

compensation arrangements. In the Phase II interim final rule, we solicited comments on this issue, and we may be addressing this issue in an upcoming final rule. In this proposed rule, we are focusing on the DHS entity side of physician-DHS entity financial relationships. We propose to amend § 411.354(c) to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls. For example, a hospital would stand in the shoes of a medical foundation that it owns or controls (such as where the hospital is the sole member of a non-profit corporation). Thus, if a hospital owns or controls a medical foundation that contracts with a physician to provide physician services at a clinic owned by the medical foundation, the hospital would stand in the shoes of the medical foundation, and would be deemed to have a direct compensation relationship with the contractor physician.

We believe that it is necessary to collapse the type of relationship discussed above to safeguard against program abuse by parties who endeavor to avoid the application of the physician self-referral requirements by simply inserting an entity or contract into a chain of financial relationships linking a DHS entity and a referring physician. We are soliciting comments as to whether and how we would employ a stand in the shoes approach for the type of relationship discussed above, as well as for other types of financial relationships. In submitting comments, commenters should be mindful that we finalize (or may already have finalized) a provision that treats physicians as standing on the shoes of their group practices or other physician practices.

#### 10. Alternative Criteria for Satisfying Certain Exceptions

We received several comments in response to the Phase II rulemaking that asserted that even innocent and trivial violations of the physician self-referral statute may result in huge penalties to an entity that submits claims to Medicare. For example, the failure of a hospital to obtain a signature on a lease or a personal services arrangement with a physician could result in the hospital being required to make repayment for all services for which it billed Medicare as a result of prohibited referrals from the physician. One commenter stated that we should exercise our discretion

in pursuing minor violations and the failure to meet the procedural requirements of an exception (such as obtaining all required signatures prior to commencement of the agreement for personal services) and technical violations. Another commenter stated that we should consider adding an exception that would permit physicians to refer for DHS, and entities to submit and receive payment for DHS, if, in our sole discretion, we determined that there was no abuse. The commenter suggested that such an exception be available only after (1) receipt by the entity of a favorable advisory opinion, or (2) a voluntary disclosure by the entity or upon audit or investigation by the government.

Although we do not have discretion to waive violations of the physician self-referral statute, we are considering whether to amend certain of the exceptions that appear in § 411.355 through § 411.357 to provide an alternate method for satisfying the exception. We caution that our proposal is intended to address only inadvertent, violations in which an agreement fails to satisfy the procedural of "form" requirements of an exception of the statute or regulations. We do not intend to apply the alternative method for compliance to other requirements such as compensation that is fair market value, not related to volume or value of referrals, or set in advance. What we have in mind, for example, is a situation in which parties are missing a signature but every other requirement of the exception for personal service arrangements is satisfied. In such a case, provided that there is full disclosure, the missing signature is inadvertent, and other conditions for alternative compliance described here are satisfied, the alternative method for compliance would be met and the parties would comply with the exception.

The alternative method for compliance with the physician self-referral prohibition would provide that, if an arrangement does not meet all of the existing prescribed criteria of an exception, the arrangement nevertheless would meet the exception if: (1) The facts and circumstances of the arrangement are self-disclosed by the parties to us; (2) we determine that the arrangement satisfied all but the prescribed procedural or "form" requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS; (3) the failure to meet all the prescribed criteria of the exception was inadvertent; (4) the referral for DHS and the claim for DHS were not made with knowledge that one or more of the

prescribed criteria of the exception were not met (consistent with other exceptions, we would apply the same knowledge standard as that applicable under the False Claims Act; (5) the parties have brought (or will bring as soon as possible) the arrangement into complete compliance with the prescribed criteria of the exception or have terminated (or will terminate as soon as possible) the financial relationship between or among them; (6) the arrangement did not pose a risk of program or patient abuse; (7) no more than a set amount of time had passed since the time of the original noncompliance with the prescribed criteria; and (8) the arrangement at issue is not the subject of an ongoing Federal investigation or other proceeding (including, but not limited to, an enforcement matter). We would consider there to be an "inadvertent" failure to meet all of the prescribed criteria in an exception only where there was an innocent or unintentional mistake. We would rely on our authority under section 1877(b)(4) of the Act to implement an alternative compliance policy, and we would include requirements that are contained in all exceptions that we promulgate under that authority (including, but not limited to, the requirement that the arrangement not violate the anti-kickback statute).

We believe that if we were to adopt an alternative compliance method policy for certain exceptions, with the criteria specified above, the determination of whether an arrangement meets the terms of an exception despite not meeting all of the prescribed criteria of an exception should be at our sole discretion and not subject to further administrative or judicial review. We caution that we would retain the discretion as to *whether* to make such a determination; parties would have no right to receive such a determination and no time period by which we would be required to issue a determination. We further caution that, because we would retain sole authority to determine that an arrangement that failed to satisfy all of the prescribed procedural or "form" criteria of an exception that meets the conditions for the alternative method of compliance, and because of the proposed requirements that: (1) The failure to meet all of the prescribed criteria of the exception was inadvertent; and (2) the referral for DHS and the claim for DHS were not made with knowledge that one or more of the prescribed criteria of the exception were not met, parties to an arrangement

would not be able to refer or bill for DHS with the knowledge that the arrangement did not comply with all of the prescribed criteria of an exception and then later claim in response to an enforcement action that they believed that their conduct was proper because, in their view, the arrangement would have met the criteria for the alternative method for compliance with the prescribed criteria of an exception. In fact, if our proposal were to be adopted and a DHS entity were to submit a claim for Medicare payment with the knowledge that its financial relationship with the referring physician (or his or her immediate family member) did not meet the prescribed criteria of any exception, and did so in advance of any determination from us that the arrangement met the alternative method of compliance, it could be found liable under the False Claims Act.

We are especially interested in comments regarding: whether we should adopt an alternative compliance method policy, and if so, the exceptions for which the policy should be applicable; the conditions that must be met in order to obtain a favorable determination that an arrangement that does not meet all of the prescribed criteria of an exception nevertheless satisfies the alternative method of compliance with the exception; the manner (for example, advisory opinion) for making such a determination; the length of time during which the alternative method option would be available (that is, the length of time that a party would have to discover that an arrangement was out of compliance with the prescribed criteria of an exception and seek protection under the alternative compliance method policy); and, whether, having received a favorable determination that an arrangement satisfied the alternative method of compliance (essentially, that the arrangement was deemed to have met the prescribed criteria of an exception), an entity should be precluded for a period of time from receiving another favorable determination with respect to an arrangement that (1) failed to meet the prescribed criteria of the same exception (or similar criteria of another exception) and (2) that was entered into after the date the arrangement that received the favorable determination was entered into by the entity. We are also interested in comments as to whether each eligible exception should specify which criterion or criteria an arrangement can fail to meet and nevertheless still qualify under the alternative method criteria as satisfying the exception (for

example, specifying in several exceptions that an arrangement that is missing a signature can nevertheless qualify for the alternative compliance method), or whether, in addition to or in lieu thereof, we should provide that an arrangement may qualify for the alternative compliance method if we make a determination that the arrangement substantially complied with the prescribed criteria and met all of the other alternative criteria. We are specifically seeking comment on what, if any, additional requirements or standards should be met where an arrangement fails to satisfy a procedural of "form" requirement of an exception. For example, we would like comments on whether we should require other documentary proof of the parties' intent to contract (through memoranda, electronic mail, or otherwise) in the case where the parties failed to obtain a necessary signature to effect the contractual arrangement.

We reiterate that we do not have the authority to waive violations of the physician self-referral statute or regulations. We do not mean to suggest that, for financial relationships that implicate the general prohibition, anything less than full compliance with one or more of the exceptions is sufficient; rather, we are proposing to provide additional and alternative criteria for some of the exceptions themselves so that some arrangements that otherwise would be noncompliant as a result of an inadvertent mistake might satisfy an exception. In effect, we are merely proposing to expand the scope of some exceptions to provide more flexibility.

Finally, we note that our proposal for an alternative compliance method policy is intended to complement, and not replace, the provisions in § 411.353(f) for certain arrangements involving temporary noncompliance. Among other requirements, in order to qualify for protection under § 411.353(f), the financial relationship between the entity and the referring physician must have been in compliance with an exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant, and the financial relationship must have fallen out of compliance due to reasons beyond the control of the entity. In addition, claims are payable only for DHS rendered during a maximum of 90 consecutive calendar days following the date on which the financial relationship became noncompliant; the exception may be used by an entity only once every 3 years for the same referring physician; and the exception may not be

used for temporary noncompliance with the exception for nonmonetary compensation or medical staff incidental benefits.

#### 11. Services Furnished "Under Arrangements"

Our physician self-referral rules prohibit a physician from making referrals for DHS to an entity with which the physician (or an immediate family member) has a financial relationship, and prohibits the entity from billing Medicare for the DHS, unless an exception applies. In the 1998 proposed rule, we stated that we had received questions about which entities are the relevant ones for purposes of the prohibition on referrals, given that some entities only bill for services, whereas others actually directly "furnish" the services. We noted that, for example, in an "under arrangements" situation, a hospital, rural primary care hospital, SNF, HHA, or hospice program contracts with a separate provider to furnish services to the hospital's, SNF's, or other contracting entity's patients, for which the hospital, SNF or other contracting entity ultimately bills. Sections 1832, 1835(b)(1), 1861(e), and 1861(w)(1) of the Act and § 413.65(i) provide for Medicare payment to providers for services furnished "under arrangements." The Internet-Only Manual (IOM) manual 100-01, Medicare General Information, Eligibility and Entitlement Manual, Pub. 100-01, at Chapter 5, section 10.3 requires that the provider must exercise professional responsibility over an arranged-for service, using the same quality controls as applied to services furnished by the provider's salaried employees. Under § 413.65(i), a provider-based hospital department may not provide all of its services under arrangements. Therefore, a hospital department may not contract out all of its patient care services.

We stated in the 1998 proposed rule that, absent an exception, the referral prohibition applies to a physician's DHS referrals to any entity that directly furnishes DHS to Medicare or Medicaid patients. We stated that a physician can have an incentive to overutilize services if he or she has a financial relationship with the entity that directly furnishes DHS, even if this is not the entity ultimately billing for the services. In these situations, the physician can potentially recognize a profit from each referral based on the fact that the DHS will, in essence, be sold to the entity that bills (63 FR 1707). Notwithstanding our statements in the 1998 proposed rule, we have interpreted the definition of "entity" at § 411.351 as including only the person or entity that bills

Medicare for the DHS, and not the person or entity that performs the DHS (where the person or entity performing the DHS is not the person or entity billing for it).

We continue to have concerns with services provided under arrangements to hospitals and other providers. We believe that the risk of overutilization that we identified in the 1998 proposed rule has continued, particularly with hospital outpatient services for which Medicare pays on a per-service basis. That is, we pay a hospital separately for each clinical laboratory test, for each therapy service, and for the vast majority of radiology and other imaging services. We have received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly. There appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. Many of the services furnished by the joint venture were previously furnished directly by the hospitals, and in most cases, could continue to be furnished directly by hospitals.

We are also concerned that the services furnished under arrangements to a hospital are furnished in a less medically-intensive setting than the hospital, but billed at higher outpatient hospital PPS rates, which not only costs the Medicare program more, but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance. Often, physician specialists who order services for their hospital patients set up joint ventures, frequently including as an owner a hospital to which the physicians refer patients. The joint venture often owns an entity that furnishes medically less intensive services than a hospital, such as an ASC, an IDTF, or a physician office. The entity may even be located in a hospital building in space leased by the hospital to the joint venture, whether owned by physicians alone or with the hospital. It appears that the use of these arrangements may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries.

We believe that more and more procedures are being performed as arranged for hospital services. The provider community is well aware that, effective for services furnished on or after January 1, 2008, Medicare may pay more for all hospital outpatient surgical procedures than for the same procedures billed by ASCs under the

revised ASC payment system required by section 626(b) of the MMA. (In the CY 2007 OPPTS/ASC proposed rule (71 FR 49635), we proposed that payment for an ASC surgical procedure would be made at 62 percent of the payment for the same procedure under the OPPTS (71 FR 49656).)

After the close of the Phase II comment period, the Medicare Payment Advisory Commission (MedPAC), in its March 2005 Report to Congress, recommended that the Secretary “should expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services.” Specifically, MedPAC wrote:

Physician ownership of entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers, which could lead to higher use of services. Prohibiting these arrangements should help ensure that referrals are based on clinical, rather than financial, considerations. It would also help ensure that competition among health care facilities is based on quality and cost, rather than financial arrangements with entities owned by physicians who refer patients to the facility.

(See [http://www.medpac.gov/publications/congressional\\_reports/Mar05\\_EntireReport.pdf](http://www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf), at page 170.)

We agree with the concerns of MedPAC and a commenter to the Phase II interim final rule that arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items and services to entities furnishing DHS but do not submit claims, raise significant concerns under the fraud and abuse laws. We believe such arrangements to be contrary to the plain intent of the physician self-referral law. Arrangements so structured are particularly problematic because referrals by physician-owners of leasing, staffing, and similar entities to a contracting DHS entity can significantly increase the physician-owned entity's profits and investor returns, creating incentives for overutilization and corrupting medical decision-making.

We are attempting to determine the best approach to prohibit certain arrangements under which physicians supply items and services to DHS entities. We note that some of the arrangements described by MedPAC are subject to the physician self-referral prohibition and more may become subject to the physician self-referral prohibition through provisions we may implement in the upcoming Phase III final rule.

Although MedPAC recommended that the definition of physician ownership subject to the physician self-referral prohibition be expanded to include any entity that derives a substantial proportion of its revenue from a provider of DHS, we are proposing what we believe is a more straightforward approach to addressing the issue. That is, we propose to revise our definition of entity at § 411.351 so that a DHS entity includes both the person or entity that performs the DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. Our proposal is not meant to exclude any persons or entities that presently are considered to be DHS entities. (In this regard, we note that we propose to reorganize and delete some of the material in the current definition and are seeking comment on our proposed changes to the regulatory text.) Although we believe our proposed approach is sufficient to address abusive arrangements, we solicit comments on whether we should implement the MedPAC approach, either in some combination with our proposed approach or instead of our proposed approach. We would be particularly interested in comments related to what should constitute a “substantial” proportion of revenue derived from providing DHS.

#### *N. Beneficiary Signature for Ambulance Transport Services*

[If you choose to comment on issues in this section, please include the caption “BENEFICIARY SIGNATURE” at the beginning of your comments.]

Section 424.36 requires that a beneficiary's signature must appear on all claims submitted for Medicare services, unless the beneficiary has died, or another exception applies. For example, if a beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on the beneficiary's behalf by another individual listed in § 424.36(b). Ambulance suppliers and providers have stated that, in emergency situations, it is impossible or impractical for ambulance providers or suppliers to obtain a beneficiary's or other authorized person's signature on a claim to properly bill Medicare for ambulance transport services because: (1) Many beneficiaries are incapable of signing claims due to their medical condition at the time of transport; and (2) another person authorized to sign the claim under § 424.36(b) is not available, or is unwilling to sign the claim at the time of transport; and (3) if an individual listed in § 424.36(b) is not available or willing to sign a claim on

behalf of the beneficiary at the time of transport, it is impractical later to locate the beneficiary (or the beneficiary's authorized representative) to obtain a signature on the claim form before submitting it to Medicare for payment.

We are sympathetic to the concerns of ambulance providers and suppliers insofar as emergency transport services are involved. Therefore, at § 424.36, we are proposing that, for emergency ambulance transport services, where the ambulance provider or supplier documents that the beneficiary was physically or mentally incapable of signing a claim form at the time the service was provided and that none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign a claim on behalf of the beneficiary, the ambulance provider or supplier may submit the claim without a beneficiary signature. Such claim submission would be permitted only if: (1) The beneficiary was physically or mentally incapable of signing the claim form at the time the service was provided; (2) none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign the claim form on behalf of the beneficiary at the time the service was provided; and (3) the ambulance provider or supplier maintains in its files for a period of at least 4 years from the date of service certain documentation. Required documentation would include: (1) A signed contemporaneous statement, made by an ambulance employee present during the trip to the receiving facility, that the beneficiary was physically or mentally incapable of signing a claim form and that none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign the claim form on behalf of the beneficiary at the time the service was provided; (2) the date and time the beneficiary was transported, and the name and location of the facility where the beneficiary was received; and (3) a signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the time and date that the beneficiary was received by that facility.

For non-emergency ambulance transport services, the ambulance provider or supplier would continue to be required to obtain a beneficiary's signature on a claim form (or the signature of someone who is authorized to sign on behalf of the beneficiary under § 424.36(b)(1) through (5) prior to submitting claims to Medicare.

*O. Update to Fee Schedules for Class III DME for CYs 2007 and 2008*

[If you choose to comment on issues in this section, please include the caption "DME UPDATE" at the beginning of your comments.]

1. Background

a. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Classifications

Under § 414.210, for Medicare payment purposes, fee schedules are determined for the following classes of equipment and devices:

- Inexpensive or routinely purchased items as specified in § 414.220.
- Items requiring frequent and substantial servicing, as specified in § 414.222.
- Certain customized items, as specified in § 414.224.
- Oxygen and oxygen equipment, as specified in § 414.226.
- Prosthetic and orthotic devices, as specified in § 414.228.
- Other DME (capped rental items), as specified in § 414.229.
- Transcutaneous electric nerve stimulators (TENS), as specified in § 414.232.

We designate the items in each class of equipment or device through our program instructions.

Under section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c), the Food and Drug Administration (FDA) must classify devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness; class III devices typically posing the greatest risk. Devices are to be classified into class I if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness. General controls apply to all medical devices and include provisions that relate to adulteration, misbranding, device registration and listing, notification, including repair, replacement, or refund, records and reports, and good manufacturing practices. Examples of class I devices are canes and crutches.

Class II devices are those for which general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, development and dissemination of

guidelines, recommendations, and any other appropriate action the FDA deems necessary (section 513(a)(1)(B) of the act). Examples of class II devices are blood glucose test systems and infusion pumps.

Class III devices are those for which there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. Class III devices paid in accordance with the DME fee schedule payment methodology include osteogenesis or bone growth stimulators, implantable infusion pumps, and stair-climbing wheelchairs (standard power wheelchair function only). This is not an inclusive list of class III devices. The Medicare DMEPOS suppliers should specify on the Medicare claim form whether the device furnished to a beneficiary is a class III device as described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)(C)).

b. DMEPOS Payment

Section 302(b)(1) of the MMA amended section 1847 of the Act to require the Secretary to establish and implement competitive acquisition programs for the furnishing under Medicare Part B of certain types of DMEPOS. Section 1847(a)(2)(A) of the Act provides that devices determined by the FDA to be class III devices under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) cannot be included in the competitive acquisition programs. As part of the transition to competitive acquisition, the Congress mandated in sections 1847(a)(14)(G) through (I) of the Act that the fee schedule amounts for DME, other than class III devices, be frozen at 2003 levels through 2008.

For class III devices, section 1834(a)(14)(G)(i) of the Act mandates that an annual update factor based on the percentage change in the consumer price index for urban customers (CPI-U) be applied to the fee schedule amounts for CYs 2004 through 2006. Section 1834(a)(14)(H)(i) of the Act, as added by section 302 of the MMA, gives the Secretary discretion in determining the appropriate fee schedule update percentage for CY 2007 for DME which are class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)(C)).<sup>1</sup> Specifically, for

<sup>1</sup> Section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act has been codified as 21 U.S.C.

2007, the 2006 fee schedule amounts for class III devices are to be updated by the percentage change determined to be appropriate by the Secretary, taking into account recommendations contained in a report of the Comptroller General of the United States under section 302(c)(1)(B) of the MMA. Also mandated by section 1834(a)(14)(I)(i) of the Act, for 2008, the 2007 fee schedule amounts for class III devices are to be increased by an annual factor based on the percentage change in the CPI-U, as applied to the 2007 payment amount determined after application of the percentage change under section 1834(a)(14)(H)(i) of the Act.

As stated above, section 1834(a)(14)(H)(i) of the Act mandated that the Secretary take into account recommendations by the Comptroller General of the United States, who is the head of the Government Accountability Office (GAO), when determining the appropriate update percentage for class III devices for 2007. On March 1, 2006, the GAO published a report, "Class III Devices do not Warrant a Distinct Annual Payment Update" (GAO-06-62). The GAO concluded in that report, "because the initial payment rates for all classes of devices on the Medicare DME fee schedule are based on retail prices or an equivalent measure, they account for the costs of class III and similar class II devices in a consistent manner. Distinct updates for two different classes of devices are unwarranted." The GAO recommended that the Secretary establish a uniform payment update to the DME fee schedule for 2007 for class II and class III devices.

In the May 1, 2006 **Federal Register**, we published the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues proposed rule (71 FR 25660). We solicited comments on how to determine the appropriate fee schedule percentage change for class III devices for 2007 and 2008. We stated that we would consider the comments received in conjunction with the recommendations in the GAO report in determining the appropriate update percentage for these devices for 2007 and 2008.

A majority of the submitted public comments indicated that the GAO report was flawed since it did not recommend a specific update factor or take into account changes over time in the costs of producing, supplying and

360c(a)(1)(C). Accordingly, we believe that the reference to 21 U.S.C. 360(c)(1)(C) in sections 1834(a)(14)(G)(i), (H)(i), and (I)(i) of the Act is a scrivener's error.

servicing class III devices. Several commenters recommended that we continue to use the CPI-U to adjust fee schedule amounts for class III devices, but offered no substantive information that would otherwise support a distinct update factor for class III devices. Another commenter recommended that the class III proposal be included in a separate rulemaking procedure because it is not related to competitive acquisition.

## 2. Proposed Update to Fee Schedule

We believe that the GAO has done a thorough job in reviewing Medicare payment rules and methods and issues associated with the costs of furnishing class III devices. Accordingly, we agree with the finding in the report that the costs of furnishing class II and class III DME devices have been factored into the fee schedule amounts calculated for these devices. We also agree with the GAO recommendation that a uniform payment update be established to the DME fee schedule for 2007 for class II and class III devices. For class II devices, the MMA provided for a zero percent payment update from 2004 through 2008. Accordingly, for 2007, we are proposing a zero percent update for class III devices. Also, in accordance with the MMA, we are proposing to use the percent change in the CPI-U to update the class III device 2007 fee schedule amounts for 2008.

### *P. Discussion of Chiropractic Services Demonstration*

[If you choose to comment on issues in this section, please include the caption "CHIROPRACTIC SERVICES DEMONSTRATION" at the beginning of your comments.]

In the CY 2006 PFS final rule with comment period (70 FR 70266) and the CY 2007 PFS final rule with comment period (71 FR 69707), we included a discussion of the 2-year chiropractic services demonstration that ended on March 31, 2007. This demonstration was authorized by section 651 of the MMA to evaluate the feasibility and advisability of covering chiropractic services under Medicare. These services extended beyond the current coverage for manipulation to care for neuromusculoskeletal conditions typical among eligible beneficiaries, and covered diagnostic and other services that a chiropractor was legally authorized to perform by the State or jurisdiction in which the treatment was provided. The demonstration was conducted in four sites, two rural and two urban. The demonstration was required to be budget neutral as the statute requires the Secretary to ensure

that the aggregate payment made under the Medicare program does not exceed the amount which would be paid in the absence of the demonstration.

Ensuring budget neutrality requires that the Secretary develop a strategy for recouping funds should the demonstration result in costs higher than those that would occur in the absence of the demonstration. As we stated in the CY 2006 and CY 2007 PFS final rules with comment period, we would make adjustments to the chiropractor fees under the Medicare PFS to recover aggregate payments under the demonstration in excess of the amount estimated to yield budget neutrality. We will assess budget neutrality by determining the change in costs based on a pre- and post-comparison of aggregate payments and the rate of change for specific diagnoses that were treated by chiropractors and physicians in the demonstration sites and control sites. Because the aggregate payments under the expanded chiropractor services may have an impact on other Medicare expenditures, we will not limit our analysis to reviewing only chiropractor claims.

Any needed reduction to chiropractor fees under the PFS would be made in the CY 2010 and CY 2011 physician fee schedules as it will take approximately 2 years after the demonstration ends to complete the claims analysis. If we determine that the adjustment for BN is greater than 2 percent of spending for the chiropractor fee schedule codes (comprised of the 3 currently covered CPT codes 98940, 98941, and 98942), we would implement the adjustment over a 2-year period. However, if the adjustment is less than 2 percent of spending under the chiropractor fee schedule codes, we would implement the adjustment over a 1-year period. We will include the detailed analysis of budget neutrality and the proposed offset during the CY 2009 PFS rulemaking process.

### *Q. Technical Corrections*

[If you choose to comment on issues in this section, please include the caption "TECHNICAL CORRECTIONS" at the beginning of your comments.]

#### 1. Particular Services Excluded From Coverage (§ 411.15(a))

Prior to January 1, 2005, Medicare did not pay for routine physical examinations or checkups. Section 1862(a)(7) of the Act states that routine physical checkups are excluded services. This exclusion is described in § 411.15(a), Particular services excluded from coverage. In addition, we had interpreted section 1862(a)(1)(A) of the

Act to exclude coverage for cardiovascular disease screening tests and diabetes screening tests. This section provides that items or services must be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member as stated in § 411.15(k). Since preventative services are not provided for diagnosis or treatment of illness, injury, or malformation, we determined that these services are not reasonable and necessary within the meaning of the statute.

Effective January 1, 2005, Part B coverage was expanded to include an initial preventative physical examination (IPPE) for certain individuals. Our regulations governing the IPPEs are primarily set forth in § 410.16. Additional conforming changes were made at that time to § 411.15 to reflect this expansion in coverage.

Sections 612 and 613 of the MMA added coverage under Part B for cardiovascular disease screening tests and diabetes screening tests, effective for services furnished on or after January 1, 2005, subject to certain eligibility and other limitations. These provisions were implemented in the CY 2005 PFS final rule with comment period (69 FR 66236). Those rules are codified in § 410.17 and § 410.18, respectively. However, at the time we neglected to make additional conforming changes to § 411.15 to reflect this expansion in coverage.

To conform the regulations to the MMA provisions, we are proposing a technical correction to the provisions in § 411.15 by specifying additional exceptions to provide payment for cardiovascular disease screening tests and diabetes screening tests that meet the eligibility limitation and the conditions for coverage that we specified under § 410.17, Cardiovascular Disease Screening Tests, and § 410.18, Diabetes Screening Tests.

#### 2. Medical Nutrition Therapy (MNT) (§ 410.132)

In the CY 2006 PFS final rule with comment period (70 FR 70160), we added individual medical nutrition therapy, as represented by HCPCS codes G0270, 97802 and 97803, to the list of telehealth services. We are making a technical correction to § 410.132(a) to conform the regulations to include an exception for services provided at § 410.78. This revised paragraph reads as follows:

“(a) *Conditions for coverage of MNT services.* Medicare Part B pays for MNT services provided by a registered

dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the treating physician. Except as provided at § 410.78, services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally-accepted dietary or nutritional protocols.”

3. Payment Exception: Pediatric Patient Mix (§ 413.184)

In the CY 2006 PFS final rule with comment period (70 FR 70214), we revised § 413.180 through § 413.192 regarding criteria and the application procedures for requesting an exception to the ESRD composite rate payment. As part of the revisions we intended to amend the section heading of § 413.184 to reflect that, as specified in the statute, this exception only pertains to a pediatric ESRD facility. However, this change was not made. Therefore, we are proposing to revise the section heading of § 413.184 to read as follows: “Payment exception: Pediatric patient mix.”

4. Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (§ 410.32(a)(1))

Section 1861(r)(5) of the Act was amended by section 4513(a) of the BBA to allow Medicare payment for a chiropractor’s manual manipulation of the spine to correct subluxation, without requiring the subluxation to be demonstrated by an x-ray. The BBA provision was effective for services furnished on or after January 1, 2000. Prior to this statutory change, the subluxation was required to be demonstrated by an x-ray. Because chiropractors are limited by statute with respect to the services they can provide under Medicare, it had been necessary to create an exception to the requirement that diagnostic services (including x-rays) must be ordered by the treating physician as provided in § 410.32(a). This exception, which permits a physician who is not a treating physician to order and receive payment for an x-ray that is used by a chiropractor, is specified in § 410.32(a)(1).

We revised § 410.22 to reflect the BBA change in the CY 2000 PFS final rule (64 FR 59439). (Note: § 410.22 was redesignated as § 410.21 in the CY 2001 PFS final rule.) However, we neglected to remove the chiropractic exception at § 410.32 (a)(1). Because of the BBA change, which removed the requirement that subluxation must be demonstrated by an x-ray, the chiropractic exception is no longer warranted. We do not believe it would be necessary or

appropriate to continue to permit payment for an x-ray ordered by a non-treating physician when a chiropractor, not the ordering physician, will use that x-ray. Therefore, we are proposing to revise § 410.32 by removing paragraph (a)(1) and by redesignating paragraphs (a)(2) and (a)(3) as (a)(1) and (a)(2), respectively.

R. The Percentage Change in the Medicare Economic Index (MEI)

[If you choose to comment on issues in this section, please include the caption “MEI” at the beginning of your comments.]

The Medicare Economic Index (MEI) is authorized by section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes.

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 multifactor productivity. This index, which has CY 2000 base year weights, is comprised of two broad categories: (1) Physician’s own time; and (2) physician’s PE.

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: (1) Wages and salaries; and (2) fringe benefits.

The physician’s PE category represents nonphysician inputs used in the production of services in physicians’ offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. The physician’s PE component also includes the following categories of nonlabor inputs: office expense; medical materials and supplies; professional liability insurance; medical equipment; prescription drugs; and other expenses. The components are adjusted to reflect productivity growth in physicians’ offices by the 10-year moving average of productivity in the private nonfarm business sector. Table 14 presents a listing of the MEI cost categories with the associated weights.

TABLE 14.—MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES AND WEIGHTS

Expenditure category	2000 Expense weight
Physician Compensation .....	52.466
Wages and Salaries .....	42.730
Benefits .....	9.735
Practice Expense .....	47.534
Nonphysician Compensation	18.653
Nonphysician wages ....	13.808
Prof/Tech Wages ..	5.887
Manager Wages .....	3.333
Clerical Wages .....	3.892
Services Wages .....	0.696
Employee Benefits	4.845
Other Practice Expense	18.129
Office Expenses ....	12.209
Prof. Liability Insurance .....	3.865
Medical equipment	2.055
Drugs and Supplies .....	4.319
Medical material and supplies .....	2.011
Prescription Drugs	2.308
Other Expenses .....	6.433
All Other .....	6.433

Beginning in April 2007, with their March 2007 publication, the Bureau of Labor Statistics (BLS) will discontinue production and publication of the white collar occupation employment cost index (ECI) series.

The white collar benefit ECI for private workers has been used as the price proxy for nonphysician benefits in the MEI. There is no other comparable, published series that is a suitable replacement for the white collar benefit ECI. Consequently, Global Insight, Inc. (GII) and CMS jointly developed a composite series which is composed of four published ECI series and weighted by November 2004 National Industry—Specific Occupational Employment and Wage Estimates for NAICS 6211, Office of Physicians. Global Insight Inc. is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Table 15 lists the four ECI series and corresponding weights used to construct the new composite benefit index. We are proposing to replace the ECI white collar benefit series with this composite benefit index effective for the CY 2008 MEI update.

TABLE 15.—CMS COMPOSITE PRICE INDEX FOR NON-PHYSICIAN EMPLOYEE BENEFITS

ECI series	Weight
Benefits, Private, Professional, Scientific, Technical .....	59.0

TABLE 15.—CMS COMPOSITE PRICE INDEX FOR NON-PHYSICIAN EMPLOYEE BENEFITS

ECI series	Weight
Benefits, Private, Management, Business, Financial .....	6.3
Benefits, Private, Office & Administrative Support .....	32.6
Benefits, Private, Service Occupations .....	2.1

We compared the historical 4-quarter moving average percent changes of the MEI using the ECI white collar benefit index and the proposed ECI composite benefit series and in the 5 most recent calendar years, the difference in the overall MEI update is no greater than 0.1 percentage point. This analysis shows that the new composite benefit index would be expected to have little material impact on the aggregate MEI updates; and therefore, we believe the use of this composite benefit index is the most technically accurate index for capturing nonphysician benefits price pressures.

Although we have not done so in the past, we believe it would be beneficial to publish a preliminary estimate of the expected MEI update. For CY 2008, the forecasted increase in the MEI is 1.9 percent, which includes a forecasted 1.5 percent productivity offset based on the 10-year moving average of multifactor productivity. This forecast is based on GII's 1st quarter 2007 forecast of the MEI market basket. The final update will be based on historical data through 2nd quarter 2007.

#### S. Other Issues

##### 1. Recalls and Replacement Devices

[If you choose to comment on issues in this section, please include the caption "RECALLS AND REPLACEMENT DEVICES" at the beginning of your comments.]

Recently, there has been a recall of 73,000 implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) because of a faulty capacitor that can cause the batteries to deplete sooner than expected. (See the FDA Web site at [www.fda.gov/cdrh/news](http://www.fda.gov/cdrh/news) for Questions and Answers posted April 20, 2007 on this recall). This follows upon the recall of thousands of ICDs and pacemakers in CY 2004 and CY 2005. These recalls raise issues both with regard to the additional costs of replacement devices and with regard to the additional physicians' services and diagnostic tests that beneficiaries who have these devices often need.

For outpatient hospital costs of the replacement devices, effective for services furnished on or after January 1, 2007, we reduce the ambulatory payment classification (APC) payment we make to hospitals when the hospital receives a replacement device without cost or with full credit for the device.

We also proposed a reduction to Medicare payment for inpatient hospital services in the FY 2008 IPPS proposed rule (72 FR 26479). This proposed rule would reduce payments for hospital inpatients when hospitals use a recalled or replacement device at no cost or with partial credit.

While these regulations address hospital payment for the devices involved, there are also costs associated with physician monitoring of patients treated with recalled devices. Specifically, the manufacturer of the devices that have been most recently recalled recommends that patients with the recalled device consult with their physicians in each case and, in some cases, begin a routine of monthly evaluations. We would expect that not only could extra visits to physicians' offices or hospital outpatient departments be necessary, but additional diagnostic tests may also be needed to care for the beneficiaries who have the recalled devices. Thus, even when immediate replacement of the device is not required, we are concerned that the potential greater costs to Medicare and to the beneficiary for these unforeseen extra services may be substantial and burdensome.

We will be actively assessing ways to identify the additional health care costs and Medicare expenditures associated with device recall actions and exploring what actions would be appropriate in the case of these additional monitoring and related expenses as they relate to both the hospital outpatient and physician payment systems. We welcome public comments on this issue to inform our future review and analyses.

##### 2. Therapy Standards and Requirements

[If you choose to comment on issues in this section, please include the caption "THERAPY STANDARDS AND REQUIREMENTS" at the beginning of your comments.]

###### a. Revisions to Personnel Qualification Standards for Therapy Services

In the CY 2005 PFS final rule with comment period (69 FR 66354), we amended § 410.59, § 410.60, and § 410.62 to refer to the qualifications for physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists at § 484.4, which sets the

personnel qualifications required under the HHA Conditions of Participation.

Section 484.4 contains requirements for persons furnishing services in HHAs that include physical therapists (PTs), physical therapist assistants (PTAs), occupational therapists (OTs), occupational therapy assistants (OTAs) and speech-language pathologists (SLPs). The CY 2005 PFS final rule with comment period clarified that the personnel qualifications in § 484.4 are applicable to all outpatient PT, OT, and SLP services "in order to create consistent requirements for therapists and therapy assistants" (69 FR 66345).

We propose to update the personnel qualifications in § 484.4 for PTs, PTAs, OTs, and OTAs. We also propose to revise the qualifications for SLPs to remove a reference to audiologists in the definition for speech-language pathologists because a speech-language pathologist would not have a Certificate of Clinical Competence in audiology, as implied by the regulation, unless that person was dually qualified as an audiologist. Otherwise, we are not proposing to update the qualifications for SLPs because we believe the qualifications in § 484.4 are currently appropriate and address the issues of continuing education and internationally trained SLPs.

We are proposing these changes for the following several reasons.

- The current regulations at § 484.4 contain outdated terminology relating to several of the relevant professional organizations.
- The standards that now exist in the fields of physical therapy and occupational therapy have changed since a substantial portion of these qualification requirements were developed.
- Some of the current qualification requirements do not address individuals who have been trained outside of the United States, or refer to outdated requirements.
- These revisions would have the benefit of establishing consistent standards across provider/supplier lines.

Although all States license PTs, some States have no licensing provisions for PTAs, OTs, OTAs, and SLPs. In particular, the qualifications for PTAs vary widely among States. According to the Federation of State Boards of Physical Therapy Web site (accessed on March 29, 2007), the "Number of states that grandfathered PTAs prior to regulation = 41." Under the title "What method does your state use to regulate PTAs?" the field contains the word "Licensed," or "Certified", or is blank. Therefore, we believe PTAs who have

been licensed and practicing for many years may not meet the current education requirements in § 484.4. We believe the same is true of occupational therapy assistants who obtained their training prior to application of the requirements of the certification examination for Certified Occupational Therapy Assistant (COTA) developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). Additionally, we believe some States permitted licensure or certification of PTs and OTs without successful completion of a curriculum in physical therapy or occupational therapy after 1977 (the date currently specified under the “grandfather clause” in § 484.4 before which a practicing PT or OT need not have completed a curriculum in physical therapy or occupational therapy). We believe there may also be licensed or certified PTAs and OTAs who do not meet the educational requirements in § 484.4.

Therefore, we believe it would be appropriate to broaden the current grandfathering clauses for practicing PTs, OTs, PTAs, and OTAs. We propose to revise our requirements to recognize PTs, OTs, PTAs, or OTAs who meet their respective State qualifications (or have received State recognition as PTs, OTs, PTAs or OTAs) before January 1, 2008. Individuals who furnish physical or occupational therapy services but have not met State qualifications (or received State recognition as PTs, OTs, PTAs and OTAs) before January 1, 2008, would be required to meet the updated qualifications in § 484.4.

We are not proposing to change the current grandfathering provisions relating to the qualifications for PTs, OTs, PTAs, and OTAs furnishing services under the Home Health PPS or the Hospice PPS because the current regulations in § 484.4 (that is, occupational therapist (paragraph (c)), OTA (paragraph (b)), physical therapist (paragraph (c) or (d)), or PTA (paragraph (2)) have applied to those settings consistently for almost 20 years. We do not expect that there are therapists furnishing services in a HHA or hospice that do not meet either the current or proposed revised qualifications. Therefore, we will retain the current grandfathering clauses for personnel providing services in those settings before 1977. We would not apply to Home Health and Hospice settings the proposed new grandfathering clause that would permit those qualified professionals who are licensed, certified, registered or otherwise regulated by a State and are furnishing services in other settings before January

1, 2008 to continue providing services without updating their education to meet the new requirements.

We are seeking comment on appropriate grandfathering provisions relating to qualifications of therapists and assistants to assure that skilled therapists and assistants with comparable and appropriate education and training treat Medicare beneficiaries in all settings. We propose these grandfathering provisions to § 409.16, § 409.23, § 410.43, § 410.59, § 410.60, § 482.56, § 485.70, § 485.705, § 491.9.

The proposed revised personnel qualifications in § 484.4 for therapists and assistants must address minimum requirements for the provision of therapy services by qualified personnel who have attained the skills of therapists with education and training in the specific discipline in which they are practicing, but who are not licensed. Also, for therapists and assistants trained outside the United States or trained by the United States military, we want to consider developing standards comparable to those applied to therapists and assistants trained in the United States. By “comparable” we mean that we would refer to and base our standard on a process whereby it is determined (either by the State or by another credentialing authority such as the NBCOT) that the education, training, or testing standards obtained outside the United States or in the military are so similar as to be substantially indistinguishable from standards applied to those who meet the qualifications for therapists and assistants trained in the United States. However, we note that we intend to establish standards comparable to those we establish for PTs, OTs, PTAs, OTAs, and speech-language pathologists, and not to recognize as qualified therapists or therapy assistants individuals trained in other disciplines for purposes of furnishing PT, OT, or SLP services to Medicare beneficiaries. It is not our intention to modify the policy that requires physical therapy, occupational therapy, and SLP services furnished incident to a physician's service to meet all the standards and conditions (except licensure) that apply to therapists, as this policy is based on the section 1862(a)(20) of the Act. Rather, it is our intention to assure that Medicare payment is made only for physical therapy, occupational therapy, and SLP services provided by personnel who meet qualifications, including consistent and appropriate education and training relevant to the discipline, so that they are adequately prepared to safely and effectively treat Medicare beneficiaries.

In this proposal, we refer to persons who are licensed, certified, and otherwise regulated by a State. We interpret “otherwise regulated” to mean that, while a State may not regulate a profession by granting a license or certifying educational or training credentials, it may nevertheless regulate the practice of a profession by application of certain other requirements. For example the use of the title physical therapy assistant might be limited to those who have passed a course for PTAs in a State-approved college, even when the State does not grant graduates a license or certificate to practice. By “otherwise regulated,” we do not mean to refer to State regulations that are generally applicable to all health care or other professionals regarding, for example, business practices, employment or hygiene. Rather, we mean to refer to the specific qualifications one must have in order to practice within a particular discipline or use a particular title.

We propose to require that OT's beginning their practice after January 1, 2008, must be licensed, certified, registered or otherwise regulated as an OT, and have graduated from an occupational therapist curriculum accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association (AOTA), and also have successfully completed the certification examination developed and administered by the NBCOT. By “successfully completed” we mean the individual must perform sufficiently well on the exam to receive (or be eligible to receive) certification. For services incident to a physician's or nonphysician practitioner's service where the licensure requirement does not apply, the education requirements continue to apply.

We propose that after January 1, 2008, OTAs must be licensed, certified, registered or otherwise regulated as an OTA and have graduated from an OTA curriculum accredited by the nationally recognized organization for accreditation of occupational therapists, the ACOTE of the AOTA, and successfully completed the certification examination for Certified Occupational Therapy Assistant (COTA) developed and administered by the NBCOT.

We are proposing that OTs who are educated outside the United States or by the U.S. Military— (1) Be graduates of an occupational therapy curriculum accredited by the World Federation of Occupational Therapists (WFOT); (2) have successfully completed the NBCOT International Occupational Therapy Eligibility Determination

(IOTED) review; and (3) have successfully completed the certification examination for Registered Occupational Therapist. We propose to adopt similar standards for OTAs (but with an OTA curriculum) and seek comments on qualifications for internationally educated occupational therapy assistants.

For PTs, we propose the therapist must be licensed as a physical therapist by the State in which practicing and accredited by the Commission on Accreditation in Physical Therapy Education (CAPTE) based on American Physical Therapy Association (APTA) guidelines. When the licensure requirement is not applicable (that is, for services furnished incident to the services of physicians and NPPs), we propose to require that PTs must have been accredited by the CAPTE. We seek comment on qualifications for PTs that include a curriculum and a national examination each approved by the APTA.

We propose that licensure or certification, registration or other regulation by the State in which services are furnished would be required for PTAs under our regulations. We also propose that PTAs be accredited by the CAPTE. We seek comment on appropriate qualifications for PTAs.

#### b. Application of Consistent Therapy Standards

##### (1) Personnel Qualifications

We believe therapy services should be provided according to the same standards and policies in all settings, to the extent possible and consistent with statute. For example, personnel qualifications for therapists and assistants should apply equally to all settings in which Medicare pays for physical therapy, occupational therapy and SLP services. Therefore, we propose to revise our regulations to cross-reference the personnel qualifications for therapists in § 484.4 to the personnel requirements for PTs, OTs, PTAs, OTAs, and SLPs in the following sections:

- § 409.10 and § 409.16 (Inpatient hospital services and inpatient critical access hospital services).
- § 409.23 (Posthospital SNF care).
- § 410.43 (Partial hospitalization services).
- § 410.59 (Outpatient occupational therapy services).
- § 410.60 (Outpatient physical therapy services).
- § 410.62 (Outpatient SLP services).
- § 418.92 (Hospice).
- § 482.56 (Optional hospital services, Rehabilitation services).
- § 485.70 (Specialized providers).

- § 485.705 (Clinics, Rehabilitation agencies, Public health agencies).
- § 491.9 (Rural health clinics and Federally qualified health centers (FQHCs)).

We also welcome comments on whether the personnel qualifications at § 484.4 should be made applicable in other settings.

It is our intention that when Medicare policies describe physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants and speech-language pathologists, the qualifications for those professions would be the same in all settings, without exception.

##### (2) Application of Consistent Therapy Standards

In tandem with cross-referencing Part A and Part B therapy personnel requirements in the regulations, we believe it would be appropriate to clarify our policies to improve consistency in the standards and conditions for Part A and Part B therapy services. Many, but not all, of the policies described for therapy services in Part B settings are also appropriate to Part A settings.

In § 409.17, we propose to clarify that hospital services include physical therapy, occupational therapy and SLP. We propose to add regulations for inpatient hospital services to include a plan of treatment for therapy services consistent with the plan required for outpatient therapy services. We invite comment on PT, OT, and SLP plan of treatment policies that are appropriately applied to all therapy services, whether provided under Medicare Part A or B.

Since inpatient hospital services are always provided under the care of a physician, we believe that the physician's review and certification of the therapy plan of treatment is implied by the physician's review and approval of a facility plan that includes therapy services and, therefore, we are not proposing additional therapy certification requirements for the hospital setting.

##### c. Outpatient Therapy Certification Requirements

The signature of a physician or NPP in the medical record indicating approval of the plan of care for outpatient therapy services certifies the initial need for therapy services furnished under Part B. For other covered medical and health services furnished by providers and suppliers of outpatient services, certification is required only once, either at the beginning or at the end of a series of visits. Recertification is not required for

most health services. In 1988, in an attempt to control the expanding utilization of therapy services, we added a 30-day recertification requirement for outpatient therapy services to our regulation at § 424.24. This requires that a physician certifies a plan of care for 30 days, regardless of the appropriate length of treatment. To continue treatment past 30 days, the physician is required to recertify the plan. After many years of experience with the current recertification requirements, we now believe that requiring recertification at 30-day intervals may not always provide sufficient flexibility to the physician to order the correct amount of therapy for the patient's needs. In some cases, it may impact utilization by encouraging reevaluations at intervals based on certification timing, rather than on necessity. Since the 30-day recertification requirement was initiated in 1988, many other means of ensuring appropriate utilization of therapy services have been developed. Medicare policies have been clarified to define skilled services, reasonable and necessary services, and appropriate documentation. Payments for therapy services are now limited by annual per beneficiary caps, and there are many local medical review policies and system edits to monitor extended treatment. Therapy services are now identified as such on claims, making it easier to analyze and review overutilization of services. Three studies on utilization of therapy services are published and available to medical reviewers and providers or suppliers of services to help identify typical episodes of care. Taken together, these changes may have improved appropriate utilization and limit errors in billing for therapy services, as evidenced in the Improper Medicare Fee-for-Service Payment Report of May 2007.

In 2004 and again in 2006, we engaged a contractor to perform an extensive analysis of the utilization of therapy services. The analyses indicated that the 30-day recertification requirement has not had the anticipated impact on utilization of services and does not serve to limit therapy services payments. About 70 percent of episodes are completed before the first 30-day recertification interval. Although CORFs have a 60-day recertification period, and SNFs and ORFs have 30-day recertification periods, the average number of treatment days is similar in these settings. This suggests that the interval of the recertification requirement does not affect professional decisions regarding the duration of treatment. In fact, contrary to the pattern

expected if certification impacted duration of treatment, the number of physical therapy treatment days is higher in a SNF (30-day recertification interval) than in a CORF (60-day recertification interval).

For these reasons, we do not believe there is a continued need for recertification at the 30-day interval. We propose that review of the plan of care continue to be required at certification and recertification. Since the plan of care may be established by a nurse practitioner, a clinical nurse specialist, or a physician assistant (nonphysician practitioners) as well as a physician, we propose to modify the language in § 410.61 to include those professionals among those who shall review the plan. Since the certification and recertification of the plan requires a signature, we propose to remove the current redundant requirement at § 410.61(e) to date and sign a review at the same time as the plan is certified.

We propose to change the plan of treatment recertification schedule in § 424.24. Currently, the physician must initially certify a plan of treatment at the time the plan is established or as soon thereafter as possible. If the need for treatment continues beyond 30 days, the plan of treatment must be recertified every 30 days until discharge. We propose that the physician (or NPP, as appropriate) would continue to review and certify the initial plan of care as soon as possible, but that the certification would apply for an episode length based on the patient's needs, not to exceed 90 days and would be recertified every 90 days thereafter. Payment would continue to be denied if services were provided without a certified plan of care. Overutilization of services would continue to be monitored, as it is now, by Medicare contractors based on data analysis assisted by system edits.

We believe adjusting the first recertification interval from 30 to 90 days would allow the physician to approve a plan of care that represents the clinically appropriate length of treatment, discourage routine 30-day plans, encourage professional determination of an appropriate length of treatment at the time of the initial certification, protect the patient's access to needed treatment when the certifying physician or NPP is not available at the 30-day interval, reduce the administrative burden on providers, suppliers, physicians, NPPs and Medicare contractors, and provide an appropriate timeline for monitoring the necessity of continuing therapy services. Therefore, we are proposing to amend

§ 424.24 to require recertification every 90 days after beginning treatment.

We propose to revise § 424.24 to remove reference to a certification "statement" and to require that the continuing need for therapy services be documented in the medical record, for example, the plan of treatment. Since each plan must include the duration of treatment, the current requirement for an estimate of how much longer the services will be needed is proposed to be omitted as redundant.

We propose to continue to review the utilization of therapy services to assess any changes in practice that might be related to the proposed changes in our regulations regarding certification of a plan of care for an appropriate length of treatment. After 2 years, if we determine that there are changes in practice that suggest inappropriate utilization of therapy services based on the certification timing, we will consider whether to reinstate the 30-day recertification requirement.

### 3. Proposed Elimination of the Exemption for Computer-Generated Facsimile Transmission from the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information for Part D Eligible Individuals

[If you choose to comment on issues in this section, please include the caption "PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES" at the beginning of your comments.]

#### a. Legislative History

Section 101 of the MMA amended title XVIII of the Act to establish a voluntary prescription drug benefit program. Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA-PD), and other Part D sponsors are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and dispensing pharmacy and pharmacist. This would include information about eligibility, benefits (including drugs included in the applicable formulary, any tiered formulary structure and any requirements for prior authorization), the drug being prescribed or dispensed and other drugs listed in the medication history, as well as the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed. The MMA directed the

Secretary to issue uniform standards for the electronic transmission of such data.

There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, would be required to comply with any applicable final standards that are in effect.

Section 1860D-4(e) of the Act required the Secretary to conduct a pilot project to test initial standards recognized under section 1860D-4(e)(A) of the Act, prior to issuing the final standards in accordance with section 1860D-4(e)(D) of the Act. Initial standards were recognized by the Secretary in 2005 and then tested in a pilot project during CY 2006. The MMA created an exception to the requirement for pilot testing of standards where, after consultation with the National Committee on Vital and Health Statistics (NCVHS), the Secretary determined that there already was adequate industry experience with the standard(s). Such "foundation standards" were recognized and adopted through notice and comment rulemaking as final standards without pilot testing.

Based upon the evaluation of the pilot project, and not later than April 1, 2008, the Secretary is required to issue final uniform standards. These final standards must be effective not later than 1 year after the date of their issuance.

For a complete discussion of the statutory bases for the e-prescribing portions of this proposed rule and the statutory requirements at section 1860D-4 of the Act, please refer to the "Background" section of the E-Prescribing and the Prescription Drug Program proposed rule published in the February 4, 2005 **Federal Register** (70 FR 6256).

#### b. Regulatory History

##### i. Foundation Standards

After consulting with the NCVHS, the Secretary found that there was adequate industry experience with several potential e-prescribing standards. Upon adoption through notice and comment rulemaking, these standards were called "foundation" standards, because they would be the first set of final standards adopted for an electronic prescription drug program. Three standards were adopted in the E-Prescribing and the Prescription Drug Program final rule

published in the November 7, 2005 **Federal Register** (70 FR 67568).

The foundation standards are as follows:

- For the exchange of eligibility information between prescribers and Part D sponsors: ASC X12N-270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, A1, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 transaction).

- For the exchange of eligibility information between dispensers and Part D sponsors: The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard, September 1999, Implementation Guide Version 5, Release 1 (Version 5.1) for NCPDP Data Record in the Detail Data Record (hereafter referred to as the NCPDP Telecommunication Standard).

- For the exchange of new prescriptions, changes, renewals, cancellations and certain other transactions between prescribers and dispensers: NCPDP SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as NCPDP SCRIPT Standard).

#### ii. Exemption to Foundation Standard Requirements for Computer-Generated Facsimiles

The November 7, 2005 final rule included an exemption for entities that transmit prescriptions or prescription-related information by means of computer-generated facsimile (faxes) from the requirement to use the adopted NCPDP SCRIPT standard. “Electronic media” was already defined by the HIPAA, so e-prescribing utilized the same definition. As a result, faxes that were generated by a prescriber’s/dispenser’s computer and sent to a provider’s/dispenser’s fax machine which prints out a hard copy of the original computer-generated fax (that is, “computer-generated” faxes) fell within the definition of “electronic media” for e-prescribing. Absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. Comments received from the health care industry indicated that this would cause computer-generated faxers

to revert to paper prescribing. As the Secretary believed that prescribers/dispensers using computer fax capabilities would eventually migrate to fully functional e-prescribing, possibly at the same time as they implemented electronic health record (EHR) systems, the November 7, 2005 final rule exempted entities transmitting computer-generated faxes from having to comply with the NCPDP SCRIPT standard.

#### c. Proposal of Elimination of Exemption

We propose to revise § 423.160(a)(3)(i) to eliminate the computer-generated facsimiles (faxes) exemption to the NCPDP SCRIPT Standard for the communication of prescription or certain prescription-related information between prescribers and dispensers for the transactions listed at § 423.160(b)(1)(i) through (xii). In the November 7, 2005 final rule (70 FR 67571), we explained that faxes generated by one computer and electronically transmitted to another computer or fax machine would be included under the e-prescribing definition of electronic media. This computer-generated fax technology is used in some e-prescribing software products and under the definition of electronic media, providers and dispensers who utilize these products would be required to comply with adopted e-prescribing standards. Our discussion of computer-generated faxing distinguished between cases where the prescriber’s/dispenser’s software has the ability to generate SCRIPT transactions, but the feature is not activated because the prescriber has not activated the feature on their software, and other cases where software (such as a word processing program) is used that creates and sends a fax that results in a paper prescription or response at the receiving end, but does not have true e-prescribing (electronic data interchange using the SCRIPT standard) capabilities.

We believed that requiring prescribers/dispensers who already use electronic media to e-prescribe to modify or change their software and hardware products to be compliant with the foundation standards would likely result in their simply reverting to paper prescribing and would be counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing. Also, we believed that prescribers and dispensers would begin to migrate to true e-prescribing in time, and therefore, adopted an exemption that permitted prescribers and dispensers to continue to use computer-generated faxes for transmitting certain prescriptions and

prescription-related information. However, at the same time we encouraged all prescribers and dispensers using fax technology to move as quickly as possible to computer-to-computer data interchange via the NCPDP SCRIPT standard.

Since January 2006, we have seen little reduction in the use of computer-generated fax technology. Based on data provided to CMS by SureScripts, which operates the Pharmacy Health Information Exchange, the largest network to link electronic communications between pharmacies and physicians, serving more than 95 percent of all pharmacies and all major physician technology vendors in the United States, it estimates that of the 150,000 prescribers now using software that is capable of generating SCRIPT transactions, only 15 percent are doing so. The remaining 85 percent are still generating paper faxes. The costs to convert to e-prescribing using NCPDP SCRIPT for these prescribers would in most cases be included in the annual maintenance fee they pay their software vendor. However, the cost of conversion for prescribers using e-prescribing software that cannot generate SCRIPT transactions would be higher, as these prescribers would have to purchase and install other software products. Therefore, we are specifically soliciting comments on the impact to providers and pharmacies.

Pharmacy implementation of e-prescribing is considerably more widespread. SureScripts reports that all chain drug stores and 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions. Independent pharmacies are less likely to perceive a return on investment for e-prescribing due to low numbers of practices seeking to move to e-prescribing using the SCRIPT transaction.

Since computer-generated faxing retains some of the disadvantages of paper prescribing (for example, the administrative cost of keying the prescription into the pharmacy system and the related potential for data entry errors that may impact patient safety), we believe it is important to take steps to encourage prescribers and dispensers to move toward use of the SCRIPT standard.

One concrete step we could take to increase the use of the SCRIPT transaction would be to eliminate the exemption for computer-generated faxing. This would move prescribers and dispensers using this technology to upgrade to software products or to new versions of the products they currently use, that would enable electronic

transmission of SCRIPT transactions. Because this requirement would fall on prescribers that already use e-prescribing software, it would increase the number of SCRIPT transactions fairly significantly in a relatively short time period, and this could in turn create a “tipping point” that could create an economic incentive for independent pharmacies to adopt software to begin to exchange SCRIPT transactions with their prescriber partners.

Therefore, we propose to eliminate the computer-generated fax exemption for all provider/dispenser transactions. We anticipate having this change effective 1 year after the effective date of the CY 2008 PFS final rule. This will provide notice to prescribers and dispensers seeking to implement or upgrade e-prescribing software to look for products and upgrades that are capable of generating and receiving NCPDP SCRIPT transactions. It also affords current e-prescribers time to work with their trading partners to eventually eliminate computer to fax machine transactions.

We now believe that, with the additional phase-in period allotted to allow for this transition, with improved and more readily available standards-based e-prescribing products, and the apparent ability of e-prescribing networks to now identify which prescribers and dispensers are capable of making SCRIPT enabled transactions and which use this information to facilitate successful SCRIPT enabled transactions, this elimination of the exemption for computer-generated faxing will encourage e-prescribers and dispensers to move as quickly as possible to use of the SCRIPT standard with what we perceive to be minimal impact.

We are soliciting comments on the impact of the proposed elimination of this exemption, including the total number of affected practices and pharmacies and the time required for them to implement SCRIPT-enabled software. Specifically, we are soliciting information regarding the number of practices that currently use legacy versions of software that are not capable of generating SCRIPT transactions and the amount of lead time they would need to comply. We are also soliciting comments regarding the extent to which eliminating the exemption would cause entities using fax technology to revert to paper prescribing rather than update current software.

*T. Division B of the Tax Relief and Health Care Act of 2006—Medicare Improvements and Extension Act of 2006 (Pub. L. 109-432) (MIEA-TRHCA)*

In addition to the provisions of the MIEA-TRHCA discussed in section II.B. (GPCIs), additional provisions of the MIEA-TRHCA are discussed in this section of the proposed rule.

1. Section 101(b)—Physician Quality Reporting Initiative (PQRI)

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 101(b): PQRI” at the beginning of your comments.]

a. Background

Section 101(b) of the MIEA-TRHCA amended section 1848 of the Act by adding subsection (k). Section 1848(k)(1) of the Act requires the Secretary to implement a system for the reporting by eligible professionals of data on quality measures as described in section 1848(k)(2) of the Act. As specified in section 1848(k)(3)(B) of the Act, for the purpose of the quality reporting system, eligible professionals include physicians, other practitioners as described in section 1842(b)(18)(C) of the Act, physical and occupational therapists, and qualified speech-language pathologists. Section 101(c) of the MIEA-TRHCA authorizes “Transitional Bonus Incentive Payments for Quality Reporting” in 2007, specifically for satisfactory reporting of quality data, as defined by section 101(c)(2) of the MIEA-TRHCA. We have named this quality reporting system for 2007, including the 2007 bonus payment, the “Physician Quality Reporting Initiative (PQRI)” for ease of reference.

For 2007, section 1848(k)(2)(A)(i) of the Act, as added by the MIEA-TRHCA, provides that the quality measures for the PQRI shall be the physician quality measures published as 2007 Physician Voluntary Reporting Program (PVRP) quality measures on the CMS Web site as of the date of enactment of this subsection, except as may be changed based on the results of a consensus-based process in January 2007. The 2007 PVRP quality measures consist of the 66 measures that we had identified and posted on the CMS Web site on December 5, 2006 (see “Transition from 2006 PVRP” below in this section). The statute also allowed for additional quality measures to be added to the original set as the result of a consensus-based process in January 2007. As allowed under the statute, and based on actions approved at the AQA Alliance

(formerly the Ambulatory Care Quality Alliance) meeting on January 22, 2007, 8 quality measures were added to the 66 measures identified and originally posted to the CMS Web site on December 5, 2006. The final result is 74 “2007 PQRI Quality Measures.” A list and description of these 74 measures is available for download from the PQRI Measures/Codes page of the PQRI section of the CMS Web site at [www.cms.hhs.gov/PQRI](http://www.cms.hhs.gov/PQRI).

Although section 1848(k)(2)(A)(ii) of the Act does not allow for any further additions to or deletions from the 2007 PQRI Quality Measures after January 2007, the statute does allow modifications or refinements (such as code additions, corrections, or revisions) to the detailed specifications for the 2007 PQRI quality measures until the beginning date of the reporting period (that is, July 1, 2007). After this date, no further revisions to the specifications for 2007 PQRI measures are allowed by section 1848(k) of the Act. The specifications for the 2007 PQRI quality measures are available as a download from the Measures/Codes page of the PQRI section of the CMS Web site at <http://www.cms.hhs.gov/pqri>. Additional materials containing information on the 2007 PQRI, including but not limited to the calculation of eligibility for and amount of bonus payment for satisfactory reporting, are also available on this section of the CMS Web site.

Section 1848(k)(2)(B) of the Act requires that the Secretary publish in the **Federal Register** not later than August 15, 2007, proposed quality measures that would be appropriate for eligible professionals to use to submit data to the Secretary in 2008. The final 2008 PQRI quality measures must be determined and published by November 15, 2007, as specified in section 1848(k)(2)(B) of the Act as amended by the MIEA-TRHCA.

b. MIEA-TRHCA Requirements for Measures Included in the 2008 PQRI

(i) Overview of MIEA-TRHCA Requirements for 2008 PQRI Quality Measures

Section 1848(k)(2)(B)(i) of the Act requires, “for purposes of reporting data on quality measures for covered professional services furnished during 2008, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and

that the Secretary identifies as having used a consensus-based process for developing such measures. Such measures shall include structural measures, such as the use of EHRs and electronic prescribing technology.”

Section 1848(k)(2)(B)(ii) of the Act requires, that “[n]ot later than August 15, 2007, the Secretary shall publish in the **Federal Register** a proposed set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008. The Secretary shall provide for a period of public comment on such set of measures.”

In examining the statutory requirements of section 1848(k)(2)(B)(i) of the Act, we believe that the requirement that measures be endorsed or adopted by a consensus organization applies to each measure that would be included in the measures set for submitting quality data on covered professional services furnished during 2008. Likewise, the requirement for measures to have been developed using a consensus-based process (as identified by the Secretary) applies to each measure. By contrast, we do not interpret the provision requiring inclusion of measures submitted by a specialty to apply to each measure. Rather, we believe this requirement means that in endorsing or adopting measures, a consensus organization must include in its consideration process at least some measures submitted by one physician or organization representing a particular specialty. Similarly, we interpret the requirement that 2008 measures include structural measures, such as the use of EHRs and electronic prescribing technology, to mean that the 2008 measure set must include at least 2 structural measures.

In examining sections 1848(k)(2)(B)(ii) through (iii) of the Act, we believe that the Secretary is given broad discretion to determine which quality measures meet the statutory requirements and are appropriate for inclusion in the final set of measures for 2008. We do not interpret the Act to require that all measures that meet the basic requirements of section 1848(k)(2)(B)(i) of the Act must be included in the 2008 set of quality measures.

We discuss in the following section the statutory requirements for consensus organizations and the use of a consensus-based process for developing quality measures as they relate to the requirements for the set of measures for 2008 in the context of other applicable Federal law and policy. We also discuss the policies used in proposing the initial

set of quality measures for eligible professionals for use in 2008 and the policies we propose to apply in publishing the final set.

(ii) Consensus Organizations and Consensus-Based Process for Developing Measures

The MIEA–TRHCA requires that measures used for 2008 be identified by the Secretary as having been endorsed or adopted by a consensus organization and having been developed through the use of a consensus-based process. We believe that these requirements should be interpreted in the context of the National Institute of Standards and Technology Act (NISTA) (15 U.S.C. 271 et seq.) as amended by the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) (NTTAA) and implemented by OMB Circular No. A–119 (OMB A–119) dated February 10, 1998.

Per the NTTAA, except when it is inconsistent with applicable law or otherwise impractical, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies and shall also participate with such bodies in the development of technical standards when such participation is in the public interest and compatible with the agency and departmental missions, authorities, priorities, and budget resources.

OMB A–119 provides specific policy guidance to agencies on the appropriate interpretation of agency responsibilities under the NTTAA. Specifically, OMB A–119 establishes as government-wide policy that agencies “must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical.” OMB A–119 explains that in determining whether use of existing voluntary consensus standards in its regulatory and procurement activities is otherwise impractical, “‘Impractical’ includes circumstances in which such use would fail to serve the agency’s program needs; would be infeasible; would be inadequate, ineffectual, inefficient, or inconsistent with agency mission; or would impose more burdens, or be less useful, than the use of another standard.”

OMB A–119 further provides that “voluntary consensus standards” are standards developed or adopted by voluntary consensus standards bodies. OMB A–119 defines “voluntary consensus standards body” as

maintaining the following attributes: (1) Openness; (2) Balance of interest; (3) Due process; (4) An appeals process; (5) Consensus; which is defined as general agreement, but not necessarily unanimity, and also includes a process for attempting to resolve objections by interested parties. The process requires that, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons for the disposition, and the consensus body members are given an opportunity to change their votes after reviewing the comments. Voluntary consensus standards must include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available to all interested parties on a nondiscriminatory, royalty-free, or reasonable royalty basis.

Other types of standards, that are distinct from voluntary consensus standards include the following: (1) Industry standards, company standards, non-consensus standards, or de facto standards which are developed in the private sector but not in the full consensus process of a voluntary consensus standards body; (2) Government-unique standards which are developed by the government for its own uses; (3) Standards mandated by statute such as those contained in the United States Pharmacopeia and the National Formulary, as referenced in 21 U.S.C. 351.

The term “technical standards” under 12(d)(4) of the NTTAA, means “performance-based or design-specific technical specifications and related management systems practices”. When healthcare quality measures are used in a regulatory framework such as contemplated for the 2008 PQRI quality measures under the MIEA–TRHCA, we believe that such measures constitute “technical standards” as used in the NTTAA and that NTTAA applies to such measures.

Two consensus organizations are referenced in MIEA–TRHCA: the National Quality Forum (NQF) and the AQA. The NQF has a formal organizational structure and established processes that are intentionally designed to comply with the NTTAA and OMB A–119. Membership is open and includes physicians and other providers, hospital organizations, purchasers, researchers, payers, and employers. In achieving its determination of whether or not to endorse a standard, the NQF uses a formal process that consists of five principal steps that follow a project’s conceptualization, prioritization, and

planning. The steps are: (1) Consensus Standard Development; (2) Widespread Review; (3) Member Voting and Member Council Approval; (4) Board of Directors Action; and (5) Evaluation that includes an appeals process. The NQF meets the NTTAA requirements for a voluntary consensus standards body within the meaning of the NTTAA and its endorsed healthcare quality measures constitute voluntary consensus standards within the meaning of NTTAA.

The AQA, also referenced in section 1848(k)(2) of the Act as a consensus organization for the purpose of identifying measures that have successfully completed review by a consensus organization, utilizes certain essential practices of a voluntary consensus standards body under NTTAA and the OMB A-119 relating to openness, balance of interest, and consensus. Of particular note is the breadth of formal participation among stakeholders that have an interest in healthcare quality measures dealing with physician care. Participants at AQA may vote without limitation as to which stakeholder category into which they may fall. Voting participation, for example, includes physicians, other providers, purchasers, payers, consumers, accrediting organizations, and employers. However, the AQA does not have a defined organizational structure intended to meet the requirements of the NTTAA and the OMB A-119 and has no formal due process or appeals structure. Therefore, the AQA does not meet the requirements of the NTTAA for a "voluntary consensus standards body".

By citing AQA as an example of an acceptable consensus organization, section 1848(k)(2)(B) of the Act establishes that AQA adoption satisfies the requirement of section 1848(k)(2)(B) of the Act that PQRI quality measures be adopted or endorsed by a consensus organization. We believe it follows that the Congress did not intend to require all 2008 quality measures under section 1848(k)(2)(B) of the Act to meet the requirements to be considered voluntary consensus standards under the NTTAA. However, by giving NQF and AQA as examples of consensus organizations, we believe the Congress intended that consensus organizations should, in the context of section 1848(k)(2)(B) of the Act, have a breadth of stakeholder involvement and voting participation substantially comparable to that of the NQF or AQA.

Inasmuch as we are unaware of any other organizations that engage in endorsement or adoption of healthcare quality measures for physician services that have the level of openness, balance

of interest, and consensus based on voting participation, that is comparable to NQF or AQA, we propose to limit measures for inclusion as 2008 PQRI to measures that are endorsed or adopted by NQF or AQA. However, as elaborated in the policies we set forth below in this section, we invite comment as to other consensus organizations that may have a comparable level of consensus organization characteristics.

Given the overlap of NQF and AQA as consensus organizations under the MIEA-TRHCA, it is important to distinguish their roles. As currently established, the principal purpose of AQA for physician quality measures is to select among NQF endorsed measures for coordinated implementation. Unlike NQF, AQA is not established to serve as a "voluntary consensus standards body" under NTTAA. Therefore, the AQA is not established as an alternative or substitute for NQF endorsement processes as an entity organized to comply with the NTTAA and OMB A-119 requirements for a voluntary consensus standards body. However, during a time of rapid physician quality measures development and implementation, it is impractical to delay implementation of physician quality measures until the formal processes of NQF are completed. Therefore, AQA has been able to facilitate incorporation of new measures into the quality reporting system by providing consensus review acceptable under MIEA-TRHCA for implementation of a measure prior to actual NQF endorsement. In the event of a determination by NQF to decline endorsement of a particular measure after it had been adopted by AQA, we anticipate that AQA would withdraw its adoption of such a measure.

Turning to the requirement of a consensus-based process for developing quality measures, we propose to interpret this requirement in light of the NTTAA and the importance of broad consensus for health care quality measures used for regulatory purposes. In this context we will outline the process of health care quality measurement development and distinguish basic development steps from the completion of a consensus-based development process as required under MIEA-TRHCA.

Many organizations are involved in the development of health care quality measures including physician organizations, health care providers, Federal agencies, accreditation organizations, disease-focused not-for-profit organizations, research organizations, and health plans. The basic development processes of leading

health care quality measure developers generally use standardized methods that include identification of a quality goal or gap, literature and evidence review, expert and technical evaluation, specification development, testing, organizational review, and that may include public comment.

In the framework of the NTTAA, upon completion of the basic development work, healthcare quality measures do not constitute voluntary consensus standards, even though they may have utilized consensus as a mechanism of achieving agreement among the developer's participants or within the developer's organizational structure. Rather, to achieve the status as a voluntary consensus standard under NTTAA, the measure must go through the additional development that occurs through the broader consensus process of consensus endorsement. During this process, based on the need to achieve agreement, quality measures are often modified in order to achieve the necessary broad consensus.

Consistent with this in concept but without proposing that 2008 PQRI measures be limited to those meeting the definition of a voluntary consensus standard under NTTAA, we interpret "consensus-based process for developing measures" as used in MIEA-TRHCA to encompass not only the basic development work of the formal measure developer, but also to include the achievement of consensus among stakeholders in the health care system based on at least a level of openness, balance of interest, and consensus reflected in the structures and processes of the NQF and AQA as of the date of enactment of MIEA-TRHCA and the date of publication of this proposed rule.

Based on the considerations previously discussed, we propose to apply the following policies in identifying measures that meet the MIEA-TRHCA requirements for having used a consensus-based process for development and the requirement for having been endorsed or adopted by a consensus organization such as the NQF or AQA, and that are appropriate for inclusion as 2008 measures:

(1) We interpret "a consensus-based development process" as meaning that in addition to the measure development, the measure has achieved adoption or endorsement by a consensus organization having at least the basic characteristics of the AQA as a consensus organization as of December 2006, when the MIEA-TRHCA incorporating reference to AQA was passed and signed into law. Those basic characteristics include a comparable

level of openness, balance of interest, and consensus based on voting participation. As discussed above and further clarified in points (3) and (5), we do not interpret “consensus-based development process” per section 1848(k)(2)(B) of the Act to require that the consensus organization or process meet all of the criteria of the NTTAA and OMB A–119 definition of a voluntary consensus standards body.

(2) “Voluntary consensus standard” is interpreted to mean a voluntary consensus standard that has been endorsed as such by a consensus organization that meets the requirements of the NTTAA, as implemented by OMB A–119, for a voluntary consensus standards body.

(3) Where there are available quality measures, and some of these measures meet the definition of “voluntary consensus standards” while others do not, those measures that meet the definition of “voluntary consensus standards” are preferred to other measures not meeting the requirements of the NTTAA.

(4) In view of the preference for voluntary consensus standards, if a measure has been specifically considered by NQF for possible endorsement but NQF has declined to endorse it as of November 15, 2007, we propose not to include it in the final set of 2008 PQRI Quality Measures.

(5) Although the AQA does not meet the requirements of the NTTAA for a voluntary consensus standards body, it is a consensus organization per section 1848(k)(2)(B) of the Act. In circumstances where no voluntary consensus standard (NQF-endorsed) measure is available, a quality measure that has been adopted by the AQA (or another consensus organization with comparable consensus-organization characteristics, will meet the requirements of MIEA–TRHCA is we determine that it is appropriate for eligible professionals to use to submit data.

(6) We are unaware of other consensus organizations that are comparable to the NQF in terms of meeting the formal requirements of the

NTTAA or of organizations other than AQA that do not strictly meet the requirements of the NISTA as amended by the NTTAA but that feature the breadth of stakeholder involvement in the consensus process necessary to meet the intent of the MIEA–TRHCA. However, the MIEA–TRHCA does not limit consensus organizations to the NQF or the AQA, nor restrict the field of potential consensus organizations. The MIEA–TRHCA, thereby, maintains flexibility in potential sources of measure consensus review, which is, like having multiple sources of measure development, key to maintaining a robust marketplace for development and review of quality measures.

(7) The basic steps for developing the physician level measures may be carried out by a variety of different organizations. We do not interpret the MIEA–TRHCA to place special restrictions on the type or make up of the organizations carrying out this basic development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of physician quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards.

(8) The policies we propose are based on the preference as articulated in NTTAA and OMB A–119 for “voluntary consensus standards” to government standards, and a preference for quality measures that have achieved broad consensus among stakeholders in the health care system. However, the MIEA–TRHCA does not require that quality measures meet the NTTAA or OMB A–119 definition of “voluntary consensus standards” in order to be used for PQRI. Thus, though we prefer to use quality measures meeting the NTTAA and OMB A–119 criteria for voluntary consensus standards, neither this CMS preference nor the NTTAA or OMB A–119 preclude CMS from selecting measures for PQRI based upon a lesser degree of consensus when necessary to meet CMS’ program needs as determined by the Secretary.

#### c. Proposed 2008 PQRI Quality Measures

The identified measures we propose for 2008 would be made final as of the effective date of the final rule, and no changes (no additions or deletions of measures) will be made after that date. However, as was done for 2007, we may make modifications or refinements, such as code additions, corrections, or revisions, to the detailed specifications for the 2008 measures until the beginning of the reporting period. Such specification modifications may be made through the last day preceding the beginning of the reporting period. The 2008 measures specifications will be available on the PQRI section of the CMS Web site at <http://www.cms.hhs.gov/pqri> when they are sufficiently developed or finalized but in no event later than December 31, 2007. These detailed specifications will include instructions for reporting and identify the circumstances in which each measure is applicable.

For 2008, we propose PQRI Quality measures selected from measures listed in Tables 16 through 22, which fall into 7 broad categories as set forth below in this section. We welcome comments on the implications of including any given measure or measures proposed herein in the final 2008 PQRI quality measures.

#### (i) Measures Selected From the 2007 PQRI Quality Measures

We propose to retain and include in the final 2008 PQRI measures the following 2007 PQRI measures in Table 16 contingent on NQF endorsement of each such included measure by November 15, 2007. All 2007 PQRI measures have been considered or are under consideration for endorsement under NQF projects. Those 2007 PQRI measures that have been declined for endorsement are not included in the list of proposed measures for 2008. The measures in Table 16 include measures submitted by specialties, in compliance with section 1848(k)(2)(B) of the Act, for example, the measures for diabetic retinopathy (ophthalmology).

TABLE 16.—2007 PQRI MEASURES

Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus.

Low Density Lipoprotein Control in Type 1 or 2 Diabetes Mellitus.

High Blood Pressure Control in Type 1 or 2 Diabetes Mellitus.

Screening for Future Fall Risk.

Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).

Oral Antiplatelet Therapy Prescribed for Patients with Coronary Artery Disease.

Beta-blocker Therapy for Coronary Artery Disease Patients with Prior Myocardial Infarction (MI).

Heart Failure: Beta-blocker Therapy for Left Ventricular Systolic Dysfunction.

Antidepressant Medication During Acute Phase for Patients with New Episode of Major Depression.

TABLE 16.—2007 PQRI MEASURES—Continued

Medication Reconciliation.  
 Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.  
 Characterization of Urinary Incontinence in Women Aged 65 Years and Older.  
 Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older.  
 Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.  
 Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.  
 Asthma: Pharmacologic Therapy.  
 Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports.  
 Stroke and Stroke Rehabilitation: Carotid Imaging Reports.  
 Primary Open Angle Glaucoma: Optic Nerve Evaluation.  
 Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy.  
 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care.  
 Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician.  
 Perioperative Care: Selection of Prophylactic Antibiotic—First or Second Generation Cephalosporin.  
 Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures).  
 Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (when indicated in All patients).  
 Osteoporosis: Management Following Fracture.  
 Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture.  
 Aspirin at Arrival for Acute Myocardial Infarction (AMI).  
 Electrocardiogram Performed for Non-Traumatic Chest Pain.  
 Electrocardiogram Performed for Syncope.  
 Vital Signs for Community-Acquired Bacterial Pneumonia.  
 Assessment of Oxygen Saturation for Community-Acquired Bacterial Pneumonia.  
 Assessment of Mental Status for Community-Acquired Bacterial Pneumonia.  
 Empiric Antibiotic for Community-Acquired Bacterial Pneumonia.  
 Asthma Assessment.  
 Perioperative Care: Timing of Prophylactic Antibiotics—Administering Physician.  
 Stroke and Stroke Rehabilitation: Deep Vein Thrombosis Prophylaxis (DVT) for Ischemic Stroke or Intracranial Hemorrhage.  
 Stroke and Stroke Rehabilitation: Discharged on Antiplatelet Therapy.  
 Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge.  
 Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered.  
 Stroke and Stroke Rehabilitation: Screening for Dysphagia.  
 Stroke and Stroke Rehabilitation: Consideration of Rehabilitation Services.  
 Dialysis Dose in End Stage Renal Disease (ESRD) Patients.  
 Hematocrit Level in ESRD Patients.  
 Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older.  
 Osteoporosis: Pharmacologic Therapy.  
 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG) Surgery.  
 Preoperative Beta-blocker in Patients with Isolated Coronary Artery Bypass Graft (CABG) Surgery.  
 Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures).  
 Appropriate Treatment for Children with Upper Respiratory Infection (URI).  
 Appropriate Testing for Children with Pharyngitis.  
 Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow.  
 Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy.  
 Multiple Myeloma: Treatment with Bisphosphonates.  
 Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry.  
 Hormonal Therapy for Stage IC–III ER/PR Positive Breast Cancer.  
 Chemotherapy for Stage III Colon Cancer Patients.  
 Plan for Chemotherapy Documented Before Chemotherapy Administered.  
 Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery.  
 Advance Care Plan.

Please note that measures specifications for 2007 PQRI measures may be updated or modified during the NQF endorsement process or may otherwise be modified prior to 2008. The 2008 PQRI measure specifications for any given measure may, therefore, be different from specifications for the same measure used for 2007. All specifications for 2008 measures must be obtained from the specifications document for 2008 measures, which will be available on the CMS PQRI Web site on or before December 31, 2007.

#### (ii) AMA–PCPI Measures

We propose to include measures in the final 2008 PQRI selected from those listed in Table 17 that are currently under development via the AMA–Physicians Consortium for Performance Improvement (PCPI) provided that they achieve NQF endorsement or AQA adoption by November 15, 2007. We propose to select from among these measures based upon development completion in a sufficiently timely manner that implementation for 2008

would be practical, their importance in relation to quality goals, their meaningfulness as measures of quality, their utility in the PQRI program such as through augmenting the scope of services provided by eligible practitioners to which PQRI measures apply, the degree to which they meet the needs of the Medicare program, and their functionality in terms of their ability to be collected and calculated in the PQRI program.

TABLE 17.—AMA/PCPI MEASURES

Prevention of Ventilator-Associated Pneumonia—Head elevation.

TABLE 17.—AMA/PCPI MEASURES—Continued

Stress Ulcer Disease (SUD) Prophylaxis in Ventilated patients.  
 Prevention of Catheter-Related Bloodstream Infections in Ventilated patients—Catheter Insertion Protocol.  
 Perioperative Temperature Management for Surgical Procedures Under General Anesthesia.  
 Assessment of Thromboembolic Risk Factors in patients with Atrial Fibrillation.  
 Chronic Anticoagulation in patients with Atrial Fibrillation.  
 Monthly INR Measurements in patients with Atrial Fibrillation.  
 GFR Calculation in patients with Chronic Kidney Disease (CKD).  
 Blood Pressure Measurement in patients with CKD.  
 Plan of Care for patients with CKD and Elevated Blood Pressure.  
 ACE Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy in patients with CKD.  
 Calcium, Phosphorus and Intact Parathyroid Hormone Measurement in patients with CKD.  
 Lipid Profile in patients with CKD.  
 Hemoglobin Monitoring in patients with CKD.  
 Erythropoietin Overuse in patients with CKD and normal Hemoglobin.  
 Influenza Vaccination in patients with End Stage Renal Disease (ESRD).  
 Vascular Access for patients Undergoing Hemodialysis.  
 Permanent Catheter Vascular Access for patients Receiving Hemodialysis.  
 Plan of Care for ESRD patients with Anemia.  
 Plan of Care for Inadequate Hemodialysis in ESRD patients.  
 Plan of Care for Inadequate Peritoneal Dialysis.  
 Assessment of GERD Symptoms in Patients Receiving Chronic Medication for GERD.  
 Testing of patients with Chronic Hepatitis C (HCV) for Hepatitis C Viremia.  
 Initial Hepatitis C RNA Testing.  
 HCV Genotype Testing Prior to Therapy.  
 Consideration for Antiviral Therapy in HCV Patients.  
 HCV RNA Testing at Week 12 of Therapy.  
 Hepatitis A and B Vaccination in patients with HCV.  
 Counseling patients with HCV Regarding Use of Alcohol.  
 Counseling of patients Regarding Use of Contraception Prior to Starting Antiviral Therapy.  
 Patients who have Major Depression Disorder who meet DSM IV Criteria.  
 Patients who have Major Depression Disorder who are assessed for suicide risks.  
 Patients with Osteoarthritis who receive Anti-Inflammatory or Analgesia Medication.  
 Patients with Osteoarthritis who have an assessment of their pain and function.  
 Patients with Acute Otitis Externa (AOE) or Otitis Media with Effusion (OME) who receive Topical Therapy.  
 Patients with AOE/OME who have a pain assessment.  
 Patients with AOE/OME who are inappropriately prescribed antimicrobials.  
 Patients with AOE/OME who have an assessment of tympanic membrane mobility.  
 Patients with AOE/OME who undergo hearing testing.  
 Patients with AOE/OME who inappropriately receive antihistamines/decongestants.  
 Patients with AOE/OME who inappropriately receive systemic antimicrobials.  
 Patients with AOE/OME who inappropriately receive systemic steroids.  
 Breast cancer patients who have a pT and pN category and histologic grade for their cancer.  
 Colorectal cancer patients who have a pT and pN category and histologic grade for their cancer.  
 Documentation of hydration status in Pediatric Patients with Acute Gastroenteritis (PAG).  
 Weight measurement in patients with PAG.  
 Recommendation of appropriate oral rehydration solution in PAG patients.  
 Education parents of PAG patients.  
 Perioperative Cardiac risk assessment (history).  
 Perioperative Cardiac risk assessment (current symptoms).  
 Perioperative Cardiac risk assessment (physical examination).  
 Perioperative Cardiac risk assessment (electrocardiogram).  
 Perioperative Cardiac risk assessment (continuation of Beta Blockers).  
 Appropriate initial evaluation of patients with Prostate Cancer.  
 Inappropriate use of Bone Scan for staging Low-Risk Prostate Cancer patients.  
 Review of treatment options in patients with clinically localized Prostate Cancer.  
 Adjuvant Hormonal therapy for High-risk Prostate Cancer patients.  
 Three-dimensional radiotherapy for patients with Prostate Cancer

(iii) Nonphysician Measures Currently Under Development

We propose to include measures in the final 2008 PQRI quality measures selected from those listed in Table 18 that are currently under development by Quality Insights of Pennsylvania (under the Medicare Quality Improvement Organization (QIO) contract for the State of Pennsylvania) and that achieve NQF endorsement or AQA adoption by November 15, 2007. We propose to

select from among these measures based upon: Development completion in a sufficiently timely manner that implementation for 2008 would be practical; their importance in relation to quality goals; their meaningfulness as measures of quality; their utility in the PQRI program such as through augmenting the scope of services provided by eligible professionals to which PQRI measures apply; the degree to which they meet the needs of the

Medicare program and their functionality in terms of ability to be collected and calculated in the PQRI program.

TABLE 18.—QUALITY INSIGHTS OF PENNSYLVANIA NONPHYSICIAN MEASURES

Universal Weight Screening (BMI).  
 Universal Weight Screening Follow-up (BMI).  
 Universal Hypertension Screening.  
 Universal Hypertension Screening Follow-up.

**TABLE 18.—QUALITY INSIGHTS OF PENNSYLVANIA NONPHYSICIAN MEASURES—Continued**

Universal Influenza Vaccine Screening and Counseling.  
 Universal Documentation and Verification of Current Medications in the Medical Record.  
 Screening for Clinical Depression.  
 Screening for Cognitive Impairment.  
 Patient Co-development of Treatment Plan.  
 Patient Co-development of Plan of Care.  
 Pain Assessment Prior to Initiation of Patient Treatment.

(iv) Structural Measures Currently Under Development

We propose to include measures in the final 2008 PQRI measures selected from the structural measures listed in Table 19 that are currently under development by Quality Insights of Pennsylvania (under the Medicare QIO contract for the State of Pennsylvania) and that achieve NQF endorsement or AQA adoption by November 15, 2007. These measures meet the requirement of section 1848 (k)(2)(B)(i) of the Act that the quality reporting system for 2008 include structural measures.

**TABLE 19.—QUALITY INSIGHTS OF PENNSYLVANIA STRUCTURAL MEASURES**

HIT—Adoption/Use of E-Prescribing  
 HIT—Adoption/Use of Health Information Technology (Electronic Health Records)

(v) Additional AQA Starter-Set Measures

We propose to include measures in the final 2008 PQRI measures selected from the AQA starter set that were not included in the 2007 PQRI quality measures but that are relevant to Medicare beneficiaries. Specifications necessary for PQRI reporting of these measures will be completed for such measures by November 15, 2007, and posted on the CMS Web site. Each of the AQA starter-set measures that is identified in Table 20 we propose to include in the 2008 PQRI quality measures provided it retains NQF endorsement and AQA adoption as of November 15, 2007.

**TABLE 20.—ADDITIONAL AQA STARTER-SET MEASURES**

Dilated eye exam in diabetic patient.  
 Beta-Blocker Therapy (persistent for 6 months or more)—Post MI.  
 Screening Mammography.  
 Colorectal Cancer Screening.  
 Inquiry regarding Tobacco Use.  
 Advising Smokers to Quit.

(vi) Other NQF-Endorsed Measures

We propose to include in the final 2008 PQRI measures other measures endorsed by the NQF that were not included in the 2007 PQRI quality measures but that are relevant to Medicare beneficiaries, address overuse/misuse of pharmacologic therapy, and that expand the specialty applicability and patient population. Specifications necessary for PQRI reporting of these measures will be completed for such measures by November 15, 2007, and posted on the CMS Web site. We propose to include in the 2008 PQRI quality measures each of the NQF-endorsed measures identified in Table 21 provided it retains NQF endorsement as of November 15, 2007.

**TABLE 21.—OTHER NQF-ENDORSED MEASURES**

Inappropriate antibiotic treatment for adults with acute bronchitis.  
 Disease Modifying Anti-rheumatic Drug Therapy in Rheumatoid Arthritis.  
 Angiotensin Converting Enzyme Inhibitor (ACE) or Angiotensin Receptor Blocker (ARB) Therapy for patients with coronary artery disease and diabetes and/or left ventricular systolic dysfunction (LSDV).  
 Urine screening for microalbumin or medical attention for nephropathy in diabetic patients.  
 Annual Therapeutic monitoring for patients on the following persistent medications:  
 • Angiotensin Converting Enzyme Inhibitor (ACE)/Angiotensin Receptor Blocker (ARB);  
 • Digoxin;  
 • Diuretics;  
 • Anticonvulsants; and  
 • Statins.  
 Influenza vaccination for patients ≥ 50 years old.  
 Pneumonia vaccination for patients 65 years and older.

(vii) Podiatric Measures

We propose to include measures in the final 2008 PQRI quality measures selected from those listed in Table 22 that are currently under development by the American Podiatric Medical Association and that achieve NQF endorsement or AQA adoption by November 15, 2007. We propose to select from among these measures based upon development completion of the measures in a sufficiently timely manner that implementation for 2008 would be practical.

**TABLE 22.—PODIATRIC MEASURES**

Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation.

**TABLE 22.—PODIATRIC MEASURES—Continued**

Diabetic Foot and Ankle Care, Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement.  
 Diabetic Foot and Ankle Care, Ulcer Prevention: Evaluation of Footwear.

d. Addressing a Mechanism for Submission of Data on Quality Measures Via a Medical Registry or Electronic Health Record

Section 1848(k)(4) of the Act, as amended by the MIEA—TRHCA, requires that “as part of the publication of proposed and final quality measures for 2008 under clauses (i) and (iii) of paragraph (2)(B), the Secretary shall address a mechanism whereby an eligible professional may provide data

on quality measures through an appropriate medical registry”.

A medical registry, which is also often referred to as a “clinical registry” or “clinical data registry”, henceforth “registry”, may be broadly defined as a file of documents containing uniform information about a defined population of individual persons or events, collected using an observational study design in a systematic way, in order to serve a predetermined scientific, clinical, or policy purpose. It is generally agreed that clinical data registries are one potential means to measure and report physician and other eligible professionals’ performance for purposes of quality improvement, public reporting, quality based payment, continuous certification, and credentialing. Other possible uses of

data collected by a registry include satisfying requirements for maintenance of professional or specialty board certification status, and ongoing improvement of professional performance.

The MIEA–TRHCA lists the Society of Thoracic Surgeons (STS) National Database registry as an example of a registry. The STS registry collects outcomes and quality data on cardiac surgeries. The data output provides an analysis of the participant's adult cardiac surgery outcomes, resulting in a benchmarking of each participant's data against regional and national outcomes. The STS registry currently collects data on two PQRI quality measures that have been adapted from existing STS measures. These two measures are: Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG) Surgery; and Pre-operative Beta-blocker in Patient with Isolated Coronary Artery Bypass Graft (CABG) Surgery.

To be eligible for the incentive payment under MIEA–TRHCA, cardiac and thoracic surgeons who report data to the STS registry will in 2007 and 2008 still find it necessary under PQRI to report quality data with reference to those same measures through the claims process. To avoid duplication of data submission and to support the use of registries, generally, we believe that it would be desirable to establish a mechanism whereby the quality data relevant to PQRI measures could be reported from the registries, on behalf of eligible professionals.

At this point, it is unclear which registries currently collect or plan to collect data for PQRI quality measures and which approach or approaches should be utilized to allow registries to report quality data to PQRI. For this reason, in 2008, we anticipate evaluating and testing the mechanisms to use registries for the reporting of PQRI quality data. We plan to use the results of this evaluation and testing to determine whether and how to implement the use of registries for the reporting of quality data in the future.

In concept, we anticipate that upon implementation of registry-based quality data reporting, eligible professionals would be able to provide data on PQRI quality measures through an appropriate medical registry by authorizing or instructing the registry to submit data on their behalf. Thus, the registry would act as a data submission vendor for the eligible professional. A "data submission vendor" is defined as an entity that has permission from the eligible professional to provide medical registry data to the Quality Reporting System developed per the statute. The

registry, acting as such a data submission vendor, would submit data to the CMS clinical data warehouse component of the Quality Reporting System, using a CMS-specified record layout based on the quality measures' specifications as published by CMS. For purposes of this proposed rule, the term, "CMS clinical data warehouse," is defined as a clinical data warehouse designated by CMS.

For 2008, we expect to explore at least the five different data submission options described below, and to test in CY 2008 one or more of these options. There are several data formats and analytical options that we see as potentially available to fulfill the objectives of registry inclusion in PQRI. These options vary with regard to whether individual beneficiary-level data is submitted by the registry, as well as to the number and type of data elements needed from the registry.

*Option 1:* Registries provide the quality-data codes required for a particular PQRI measure plus beneficiary/service identifier information needed to link the registry data to Medicare Part B claims. The beneficiary/service identifiers would be used to pull in the denominator data by CMS. All non-registry analytics payment information and diagnosis would come from claims. Reporting/performing rates would be calculated from the registry-submitted data.

Examples of data elements needed from a registry are:

- Beneficiary HIC Number
- Beneficiary Date of Birth
- Date of Service
- NPI and Tax ID
- CPT category II and G codes and modifiers

• Clinical data elements required to compute the appropriate CPT category II codes, G codes and modifiers

*Option 2:* Registries provide the quality codes and diagnosis codes. We would use claims to capture the payment information at the NPI/Tax ID level. The beneficiary-specific information is de-identified. All PQRI reporting and performance calculations would be performed using registry data. Payment information would be extracted from Medicare claims. The registries would be required to add data elements to the database to allow collection of appropriate codes.

Examples of data elements needed from a registry:

- Beneficiary/procedure level data (ICD–9 and CPT codes)
- HCPCS codes (G-codes and CPT category II codes and modifiers)
- NPI and Tax ID

*Option 3:* Registries calculate the reporting and performance rates for Medicare beneficiaries only, and submit these rates to CMS (that is, aggregate information by NPI within a Tax ID). We assume no beneficiary-level information will be shared. Registries would be required to add data elements to the database to allow collection of appropriate quality-data codes or clinical data needed to compute the quality-data codes. Registries would be required to perform the necessary calculations to be able to submit completed numerator/denominators for both reporting and performance rates.

*Option 4:* Registries provide all of the claims data elements as submitted using the Part B claims process. We perform all rate calculations.

Examples of data elements needed from a registry include the following:

- Line Item TIN
- Line Item Individual NPI
- Line Item Group NPI
- Claim Beneficiary Claim Account Number (CAN)
- Claim Beneficiary Identification Code (BIC)
- Claim Date of Birth
- Line Item First Expense Date
- Line Item Last Expense Date
- Line Item Diagnosis Code
- Line Item HCPCS (HCPCS Level 1, CPT Category I, CPT Category II, HCPCS Level 2 G Codes)
- Line Item Initial Modifier Code
- Line Item Secondary Modifier Code
- Claim CMS Claims Processing Date
- Claim Overall Allowable Charges
- Line Item Allowable Charges
- Claim Gender
- Claim Carrier Number
- Claim Control Number
- Claim Final Action Status
- Claim Carrier Claim Receipt Date
- Claim Payment Denial Code
- Line Item Procedure Indicator Code
- Line Item Carrier Locality Code
- Line Item Provider State Code
- Line Item Place of Service
- Line Processing Indicator Code

*Option 5:* Registry data dump for Medicare beneficiaries *only*; for all information in the registry for the service period of interest. There is an assumption that the registry is able to submit either: (1) the ICD–9, HCPCS, and CPT category II codes and exclusions as stated in the measures specifications; or (2) supply the clinical information needed for CMS to make those judgments (eligibility and quality of care). We would be required to use a series of linkage algorithms to attempt to connect the registry data with the matching claims.

Examples for linkage of registry data to the corresponding Medicare Part B claims include some combination of:

- Beneficiary-level identifiers: HIC (or SSN), DOB, gender
- Procedure-level identifiers: date of service (or procedure date)
- Provider identifiers: NPI, Tax ID, or even UPIN

For CMS to maintain compliance with applicable statutes, including but not limited to HIPAA, the registry must maintain compliance with HIPAA requirements for processing, storing, and transmitting data. To be considered an appropriate registry from which we can accept and process data for the purposes of calculating PQRI measures, a registry must also comply with the Consolidated Health Informatics Initiative (CHI) standards adopted by the Federal government, and therefore, applicable to the HHS. A description of the CHI, including its purpose, Federal member agencies, and the specific standards adopted by the Federal government, is available on the HHS Office of the National Coordinator for Health Information Technology (ONC) Web site at <http://www.hhs.gov/healthit/chiinitiative.html>.

Upon determination of the preferred option and conclusion of the testing phase for registry-based reporting to PQRI, we anticipate that all necessary information and instructions will be made available on the PQRI section of the CMS Web site at <http://www.cms.hhs.gov/pqri>. This information will include at a minimum:

- (a) The exact data elements needed and the CMS-specified record layout for transmitting the data to the CMS clinical data warehouse; and
- (b) a detailed description of the proposed CMS infrastructure for accepting registry-based submission of PQRI quality data, including, but not limited to, electronic data exchange specifications, and applicable processes for authenticating registry users for access to the warehouse submission interface.

We anticipate requesting that registries interested in participating in the testing of the registry-based quality data submission mechanism will be invited to self-nominate via a simple process that will be published on the PQRI section of the CMS Web site, and via one or more additional CMS communication venues, in the fourth quarter of 2007. We propose and expect to begin testing with the registries in the first quarter of 2008.

We plan to select for testing, from the self nominees, a group of registries that are HIPAA and CHI compliant and technically capable of interfacing with the CMS clinical warehouse electronic data exchange interface (EDI). The number of registries selected for testing may be all that are technically capable

or may need to be limited to some or all of those that already contain key minimum data elements on at least a test basis, depending on the number of registries falling into these categories and on the actual level of complexity and effort required for the testing from the CMS data infrastructure.

(Experience with other initiatives has suggested that some data submission vendors and their software are more easily interfaced and tested with the CMS data warehouse EDI than others.)

We invite comments on these plans for evaluation and testing mechanisms for registry-based quality-data reporting to PQRI with reference to the 5 data submission options described. We also invite comments on appropriate validation methodologies for reporting and performance rates.

In addition to the testing of registry-based submission of quality data, CMS is considering for 2008 the feasibility and utility of accepting clinical quality data submitted from EHRs. For 2008, we plan to consider accepting EHR-extracted clinical data for a limited number of ambulatory-care PQRI measures for which data may also be submitted under the current Doctors Office Quality-Information Technology (DOQ-IT) Project. The listing of and specifications for DOQ-IT ambulatory-care measures are available at <http://www.qualitynet.org>, under the subsidiary headings Physician Offices, Doctors Office Quality Information Technology (DOQ-IT), Ambulatory-Care Measures. If implemented in 2008, the EHR-based submission of PQRI/DOQ-IT overlapping ambulatory-care measures would serve as an alternative method to claims-based reporting of submitting quality data for those measures, not a required method.

## 2. Section 110—Reporting of Anemia Quality Indicators (§ 414.707(b))

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 110: ANEMIA QUALITY INDICATORS” at the beginning of your comments.]

Medicare Part B provides payment for certain drugs used to treat anemia.

Anemia is common in cancer patients and may be caused by the cancer itself or by various anti-cancer treatments, including chemotherapy, radiation therapy and surgical therapy. Anemia occurs when the number of red blood cells is reduced by an anti-cancer treatment. This happens due to the effect of chemotherapy or radiation therapy on the bone marrow, wherein red blood cells are produced by dividing precursor cells. This chemotherapy effect is commonly referred to as “bone

marrow suppression.” Anemia may also result from blood loss in association with surgical therapy for the cancer.

Anemia adversely impacts the quality of life for beneficiaries being treated for cancer. Fatigue and reduced performance capacity are the side effects of anemia that cancer patients report as the most disabling and contributing to poor quality of life. The treatment of anemia in cancer patients commonly includes the use of drugs, specifically erythropoiesis stimulating agents (ESAs) such as recombinant erythropoietin and darbepoietin. Although other pharmacologic interventions are available, ESAs have received the greatest attention. Notably, recent research has raised concerns that these drugs may be associated with significant adverse effects including a higher risk of mortality in some populations, possibly related to the amount of drug administered.

In 2006, we implemented a revised ESA claims monitoring policy based on the last hemoglobin or hematocrit value from the preceding month on Medicare claims for payment of ESAs administered to beneficiaries with anemia due to ESRD receiving dialysis treatments in facilities. For many years prior, we have required the reporting of these red blood cell indicators by ESRD facilities to ensure that the beneficiaries' anemia was addressed.

Section 110 of the MIEA-TRHCA amends section 1842 of the Act by adding a new subsection (u) that reads as follows: “Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.” Section 110 of the MIEA-TRHCA requires such reporting for drugs furnished on or after January 1, 2008. In addition, subsection (b) directs the Secretary to use the rulemaking process under section 1848 of the Act to address the implementation of this requirement.

By requiring the reporting of the anemia quality indicators in cancer patients undergoing treatment for anemia, we will facilitate assessment of the quality of care for this condition. We will use the information reported to help determine the prevalence and severity of anemia associated with cancer therapy, the clinical and hematologic responses to the institution of anti-anemia therapy, and the outcomes associated with various doses of anti-anemia therapy.

While not specifically addressing other indications, the recent research on the adverse effects of ESAs in patients with cancer does raise concerns as to whether patients receiving ESAs for other conditions, such as in the treatment of HIV–AIDS and for some surgical patients, are also at higher risk. While not required by this statute, we are requesting public comment on the potential of expanding this regulation to include all uses of ESAs.

### 3. Section 104—Extension of Treatment of Certain Physician Pathology Services Under Medicare

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 104: PHYSICIAN PATHOLOGY SERVICES” at the beginning of your comments.]

The TC of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist will interpret. (In contrast, the pathologist’s interpretation of the slide is the PC service. If this service is furnished by the hospital pathologist for a hospital patient, it is separately billable. If the independent laboratory’s pathologist furnishes the PC service, it is usually billed with the TC service as a combined service.)

In the CY 2000 PFS final rule, we stated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to hospital patients. Before that provision, any independent laboratory could bill the carrier under the PFS for the TC of physician pathology services for hospital patients. As stated in the CY 2000 PFS final rule, this policy has contributed to the Medicare program paying twice for the TC service, first through the inpatient prospective payment rate to the hospital where the patient is an inpatient and again to the independent laboratory that bills the carrier, instead of the hospital, for the TC service.

Therefore, in the CY 2000 PFS final rule, in § 415.130 we specified that for services furnished on or after January 1, 2001, the carriers would no longer pay claims to the independent laboratory under the PFS for the TC of physician pathology services for hospital patients.

Ordinarily, the provisions in the PFS final rule are implemented in the following year. However, in this case, the change to § 415.130 was delayed one year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements. Moreover, our full implementation of § 415.130 was further delayed through CY 2006.

In the CY 2007 PFS final rule with comment period (71 FR 69700), we announced that beginning January 1, 2007, we would no longer allow the carriers to pay the independent laboratory for the TC of physician pathology services to hospital patients. In effect, we would be implementing the provisions of the CY 2000 PFS final rule whose implementation had been delayed by section 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA) and section 732 of the MMA.

Subsequent to publication of the CY 2007 PFS final rule with comment period, the MIEA–TRHCA was enacted. Section 104 of the MIEA–TRHCA provided for an additional 1 year extension to allow carriers to continue to pay independent laboratories under the PFS for the TC portion of physician pathology services furnished to patients of a covered hospital.

Consistent with this legislative change we are amending § 415.130(d) to reflect that for services furnished after December 31, 2007, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

### 4. Section 201—Extension of Therapy Cap Exception Process

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 201: THERAPY CAPS” at the beginning of your comments.]

Section 1833(g)(1) of the Act applies an annual per beneficiary combined cap beginning January 1, 1999, on outpatient physical therapy and speech-language pathology services, and a similar separate cap on outpatient occupational therapy services. These caps apply to expenses incurred for the respective therapy services under Medicare Part B, with the exception of outpatient hospital services. The caps were implemented from January 1, 1999 through December 31, 1999, from September 1, 2003 through December 7, 2003, and beginning January 1, 2006 (with an exception process). In CY 2000 through CY 2002, and from December 8, 2003 through December 31, 2005, the Congress placed moratoria on implementation of the caps. Section 1833(g)(2) of the Act provides that, for CY 1999 through CY 2001, the caps were \$1500, and for the calendar years after 2001, the caps are equal to the preceding year’s cap increased by the percentage increase in the Medicare Economic Index (MEI) (except that if an increase for a year is not a multiple of

\$10, it is rounded to the nearest multiple of \$10).

Section 5107(a) of the DRA required the Secretary to develop an exceptions process for the therapy caps effective for expenses incurred during CY 2006. Details of the CY 2006 exceptions process were published in a manual change on February 13, 2006 (CR4364 consists of Transmittal 855, Transmittal 47, and Transmittal 140). Section 201 of the MIEA–TRHCA extended the exceptions process to apply for expenses incurred through December 31, 2007. Therapy cap exception policies for 2007 were specified in Change Request 5478 which consists of three transmittals with current numbers of—

- Transmittal 1145CP, Pub. 100–04;
- Transmittal 63BP, Pub. 100–02; and
- Transmittal 181PI, Pub. 100–08.

The transmittals are incorporated into the Internet Only Manuals available at <http://www.cms.hhs.gov/Manuals> and are also available on our Web site at <http://www.cms.hhs.gov/Transmittals/>.

In accordance with the statute as amended by the MIEA–TRHCA, we will continue to implement therapy caps, but the exceptions process will no longer be applicable, for expenses incurred beginning on January 1, 2008. The dollar amount of the therapy caps in CY 2008 will be the CY 2007 rate (\$1,780) increased by the percentage increase in the MEI.

As noted previously in this section, under current law therapy caps will continue to apply to expenses incurred for therapy services after December 31, 2007, with one exception. That is, the therapy caps will remain inapplicable to expenses incurred for therapy services furnished in the outpatient hospital setting as provided in section 1833(g) of the Act.

### 5. Section 101(d)—Physician Assistance and Quality Initiative (PAQI) Fund

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 101(d): PAQI” at the beginning of your comments.]

Section 1848(1) of the Act, as added by section 101(d) of the MIEA–TRHCA requires the Secretary to establish a Physician Assistance and Quality Initiative Fund (PAQI) which shall be available for physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the PFS CF. The provision makes available \$1.35 billion to the Fund for services furnished during 2008. Specifically, the provision directs the Secretary to provide for expenditures from the Fund

in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire \$1.35 billion for payment for physicians' services furnished during CY 2008. The provision also requires that if expenditures from the Fund are applied to, or otherwise affect, a conversion factor for a year, the conversion factor for a subsequent year shall be computed as if the adjustment to the conversion factor had never occurred.

As the legislation indicates, this Fund can be used to either buy down the negative update to the fee schedule or for quality improvement initiatives. We believe it is essential that Medicare continue to encourage improvement in the efficiency and quality of health care delivered to Medicare beneficiaries. Therefore, we are proposing that the \$1.35 billion be used to fund bonus payments to be made during 2009 for physician reporting of measures during 2008. Specifically, we propose that the physician quality initiative for 2008 be structured and implemented in the same manner as the 2007 PQRI with regard to the professionals eligible to participate in the program, reporting quality measures via claims submission, and the standards for satisfactory reporting. If, as discussed in section II.T.1 of this proposed rule, we determine that a quality measure reporting mechanism based on EHRs can be effectively implemented in 2008, we would plan to also offer eligible professionals the option of reporting quality measures via such EHR-based mechanism based in lieu of claims-based reporting. If the EHR-based reporting mechanism is implemented for 2008, we would expect to apply to professionals opting to report via that mechanism the same standards for satisfactory reporting as are applicable to professionals reporting quality measures via claims.

The differences between 2007 and 2008 that we currently anticipate are noted below in this section. As we monitor the implementation of the 2007 PQRI and possibly make refinements to the 2007 program, we anticipate that such refinements would also apply under the 2008 program. Such refinements, should they be needed, will be noted with guidance linked from the CMS quality reporting Web site at [http://www.cms.hhs.gov/PQRI/01\\_Overview.asp#TopOfPage](http://www.cms.hhs.gov/PQRI/01_Overview.asp#TopOfPage).

As with the 2007 PQRI, we are proposing that eligible professionals who successfully report a designated set of quality measures in 2008 may earn a bonus payment of a percentage of total allowed charges for covered Medicare services, subject to a cap based on the volume of quality reporting. In contrast

to 2007, we propose that physicians could report applicable measures for services furnished from January 1, 2008 through December 31, 2008, and allowed charges during such period would be the basis for calculating the bonus payments. We propose that the 2008 measures that we finalize in the PFS final rule would apply for 2008. We also propose to estimate all of the bonus payments that would be payable to physicians using the same method as the one used for reporting during 2007 and to calculate the amount of the bonus payment, after the close of 2008 reporting period. Given that we are proposing to use the PAQI Fund for the 2008 PQRI program, we also propose that the bonus payments to individual physicians be subject to an aggregate cap of \$1.35 billion. Because we are proposing to scale aggregate payments to physicians in a manner such that Medicare would pay \$1.35 billion during 2009 for measures reported for services furnished during 2008, we are unable to provide an exact percentage for the bonus payment at this time. However, we anticipate that the bonus payments will be approximately 1.5 percent of allowed charges for participating professionals (and we do not expect that the ultimate percentage amount will exceed 2 percent).

Medicare payment systems need to encourage reliable, high quality and efficient care, rather than making payment simply based on the quantity of services provided and resources consumed. This approach allows CMS to fully expend the \$1.35 billion fund and further the goal of improving quality and efficiency by utilizing the infrastructure that both physicians and Medicare have invested in for the 2007 PQRI. We believe implementing this Fund through an extension of the PQRI program is the best way to ensure physicians get the greatest benefit from the Fund's resources while ensuring that the Fund is being used to increase quality and efficiency of care for Medicare beneficiaries.

We recognize that there is an alternative approach to using this fund. That is, the \$1.35 billion could be used in some manner to reduce the update to the PFS of -9.9 percent that is projected for 2008. However, there are fundamental legal and operational problems with this approach that make it not feasible. The \$1.35 billion is a fixed dollar amount. Once the amount is reached, there is no authority to pay any more than that amount. Medicare is an entitlement program that covers medically necessary services for eligible beneficiaries, but such coverage is not limited to a fixed dollar amount for a

year. While we estimate that the \$1.35 billion would reduce the negative update by approximately two percentage points, actual spending could be above or below the estimate. To insure that we do not exceed the Fund amount, we would have to estimate an amount to reduce the update by that is low enough to ensure the \$1.35 billion funding cap is not exceeded. While this approach might reduce the 2008 negative update, it could still leave money in the Fund, and we would be faced with the same problem of how to spend such remaining funds in the future. Therefore, as previously stated, we believe the best use of the Fund is to apply it to extend PQRI into 2008.

#### 6. Section 108—Payment Process Under the Competitive Acquisition Program (CAP)

[If you choose to comment on issues in this section, please include the caption "TRHCA—SECTION 108: CAP" at the beginning of your comments.]

Section 108 of the MIEA-TRHCA made changes to the CAP Payment methodology. Section 108(a)(1) of the MIEA-TRHCA amended section 1847B(a)(3)(A)(iii) of the Act by adding new language which requires that payment for drugs and biologicals shall be made upon receipt of a claim for a drug or biological supplied for administration to a beneficiary.

Section 108(a)(2) of the MIEA-TRHCA required the Secretary to establish (by program instruction or otherwise) a post-payment review process (which may include the use of statistical sampling) to assure that payment is made for a drug or biological only if the drug or biological has been administered to a beneficiary. The Secretary shall recoup, offset, or collect any overpayments determined by the Secretary under this process.

Section 108(b) of the MIEA-TRHCA, Construction, states that nothing in this section shall be construed as requiring the conduct of any additional competition under section 1847B(b)(1) of the Act; or requiring an additional physician election process.

Section 108(c) of the MIEA-TRHCA states that the amendments of this section apply to payments for drugs and biologicals supplied (1) on or after April 1, 2007, and (2) on or after July 1, 2006 and before April 1, 2007, for claims that are unpaid as of April 1, 2007.

### III. Fee Schedule for Payment of Ambulance Services Update for CY 2007; Ambulance Inflation Factor Update for CY 2008; and Proposed Revisions to the Publication of the Ambulance Fee Schedule (§ 414.620)

[If you choose to comment on issues in this section, please include the caption "AMBULANCE SERVICES" at the beginning of your comments.]

Under the ambulance fee schedule, the Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the following levels of service:

For Ground—

- Basic Life Support (BLS)
- Advanced Life Support, Level 1 (ALS1)

- Advanced Life Support, Level 2 (ALS2)

- Specialty Care Transport (SCT)
- Paramedic ALS Intercept (PI)

For Air—

- Fixed Wing Air Ambulance (FW)
- Rotary Wing Air Ambulance (RW)

#### A. History of Medicare Ambulance Services

##### 1. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

##### 2. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations as specified in § 410.40. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

##### 3. Transition to National Fee Schedule

The national fee schedule for ambulance services was phased in over a 5-year transitional period beginning April 1, 2002, as specified in § 414.615. As of January 1, 2006, the total payment amount for air ambulance providers and suppliers is based on 100 percent of the national ambulance fee schedule. In accordance with section 414 of the MMA, we added § 414.617 which specifies that for ambulance services furnished during the period July 1, 2004, through December 31, 2009, the ground ambulance base rate is subject to a floor amount, which is determined by establishing nine fee schedules based on each of the nine census divisions and using the same methodology as was used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is lower than or equal to the national ground base rate, then it is not used, and the national fee schedule amount applies for all providers and suppliers in the census division. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the fee schedule portion of the base rate for that census division is equal to a blend of the national rate and the regional rate through CY 2009. Thus, as of January 1, 2007, the total payment amount for ground ambulance providers and suppliers is based on either 100 percent of the national ambulance fee schedule amount, or a combination of 80 percent of the national ambulance fee schedule and 20 percent of the regional ambulance fee schedule.

#### B. Ambulance Inflation Factor (AIF) During the Transition Period

As we noted in the previous section, the national fee schedule for ambulance services was phased in over a 5-year transition period beginning April 1, 2002, as specified in § 414.615. During

the transition period, the ambulance inflation factor (AIF) was applied separately to both the fee schedule portion of the blended payment amount (regardless of whether a national or regional fee schedule applied) and to the supplier's reasonable charge or provider's reasonable cost portion of the blended payment amount, respectively, for each ambulance provider or supplier. Then, the two amounts were added together to determine the total payment amount for each provider or supplier.

#### C. Ambulance Inflation Factor (AIF) for CY 2008

Section 1834(l)(3)(B) of the Act provides the basis for updating payment amounts for ambulance services. Section 414.610(f) specifies that certain components of the ambulance fee schedule are updated by the AIF annually, based on the consumer price index for all urban consumers (CPI-U) (U.S. city average) for the 12-month period ending with June of the previous year. At this time, the CPI-U for the 12-month period ending with June 2007 is not available. We will announce the AIF for CY 2008 in the final rule which will be published in the **Federal Register** later this year. In addition, as set forth in Section III.D., we propose to announce the AIF for CY 2009 and subsequent years via CMS instruction and on the CMS Web site.

#### D. Proposed Revisions to the Publication of the Ambulance Fee Schedule (§ 414.620)

Currently, section 414.620 specifies that changes in payment rates resulting from incorporation of the AIF will be announced by notice in the **Federal Register** without opportunity for prior comment. We believe it is unnecessary to undertake notice and comment rulemaking to update the AIF because the statute and regulations specify the methods of computation of annual inflation updates, and we have no discretion in that matter. Thus, the annual AIF notice does not change or establish policy, but merely applies the update methods specified in the statute and regulations.

By mid-July of each year, we have the CPI-U for the 12-month period ending with June of such year. Therefore, we know what the AIF for the upcoming calendar year will be by mid-July of each year. However, the AIF is not published by CMS until November because § 414.620 currently states that the AIF will be announced in the **Federal Register**. Each document published in the **Federal Register** requires scheduling and a thorough

review by CMS, HHS, and OMB prior to publication. Therefore, even though we know the AIF by mid-July of each year, the final rule announcing the AIF is not published until November. This publication timeframe does not allow Medicare contractors the optimal amount of time to update their systems so that they can effectuate the proper payment on Medicare ambulance claims timely. In addition, it does not provide an optimal amount of time for either the Medicare contractors or the ambulance industry to take advantage of testing practices to make sure that the update is working properly as implemented. We believe that announcing the AIF via CMS instructions and on the CMS Web site would enable the AIF to be released earlier in the calendar year, allowing the Medicare contractors to test their data systems, and to timely effectuate and provide accurate payments on Medicare ambulance claims.

Therefore, we are proposing to revise § 414.620 to state that we will announce the AIF via CMS instruction and on the CMS Web site and to remove the language that states that we will announce the AIF by notice in the **Federal Register**.

#### **IV. Collection of Information Requirements**

Under the Paperwork Reduction Act of 1995, we are required to provide 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. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

##### *Section 410.33 Independent diagnostic testing facility*

Section 410.33(g)(2) states that an independent diagnostic testing facility (IDTF) should provide complete and accurate information on its Medicare

enrollment application. In addition, an IDTF is required to notify its designated fee-for-service contractor within 30 days of any changes in ownership, location, general supervision, and any adverse legal actions. The notification must be made on the Medicare enrollment application. All of the changes to the enrollment application must be reported within 90 days.

The aforementioned requirements are not new. The burden associated with completing the Medicare enrollment application is currently approved under OMB control number 0938-0685. The collection has an expiration date of April 30, 2009.

Section 410.33(g)(6) states the comprehensive liability insurance requirements for IDTFs. Specifically, § 410.33(g)(6)(1) states that must have a comprehensive insurance policy or notify the CMS designated contractor, in writing, of any policy changes or cancellations. The burden associated with this requirement is the time and effort necessary to draft and submit the written notification to the CMS designated contractor. While this requirement is subject to the PRA, we believe it is exempt from the PRA as stipulated under 5 CFR 1320.3(h)(6). This information will be collected on a case-by-case basis.

Section 410.33(g)(8) requires an IDTF to answer, document, maintain documentation of beneficiaries questions, and responses to beneficiary complaints at the physical site of the IDTF. Sections 410.33(g)(8)(i) through (iii) list the minimum amount of documentation needed to comply with this requirement. The burden associated with these requirements is the time and effort associated with responding to beneficiary questions and complaints, documenting the actions taken in response to the questions and complaints, and maintaining the documentation. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). The burden associated with documenting and maintaining the documentation of the corrective actions is a usual and customary business practice. The time, effort, and financial resources necessary to comply this information collection requirement would be incurred by persons in the normal course of their activities (for example, in compiling and maintaining business records) is not subject to the PRA.

##### *Section 414.707 Basis of payment*

Section 414.707(c) states that effective January 1, 2008, each request for payment for anti-anemia drugs

furnished to treat anemia resulting from the treatment of cancer must report the beneficiary's most recent hemoglobin or hematocrit level. The burden associated with this requirement is the time and effort associated with obtaining the most recent hemoglobin or hematocrit levels and documenting it on the request for payment. The requirement and its associated burden are not subject to the PRA under 5 CFR 1320.3(h)(5). The interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens is not subject to the PRA.

##### *Section 414.914 Term of contract*

Section 414.914(h) states that the approved CAP vendor must verify drug administration prior to the collection of any applicable cost sharing amount. As part of the verification process, § 414.914(h)(1) through (2) lists the documentation that is required as part of the verification process. Section 414.914(h)(3) states that the approved CAP vendor must provide this information to CMS or the beneficiary upon request.

The burden associated with the requirements in § 414.914(1) through (3) is the time and effort needed to verify the drug administration. When obtaining written verification, the CAP vendor must document the elements listed in § 414.914(h)(1)(i) through (vi). When obtaining verbal verification, the CAP vendor must document the elements listed in § 414.914(h)(2)(i) through (ii). We believe the requirements and their associated burden are not subject to the PRA; they are part of the CAP vendor's usual and customary business practices as stipulated under 5 CFR 1320.3(h)(5).

In addition, § 414.914(h)(3) imposes both recordkeeping and reporting requirements. We believe that the burden associated with the recordkeeping requirement imposed by § 414.914(h)(3) is not subject to the PRA under 5 CFR 1320.3(c)(4) because it would affect less than 10 persons.

The reporting requirement places burden on the CAP vendor to provide the information listed in § 414.914(h)(1) through (2) to a beneficiary upon request. We estimate that the CAP vendor will receive 72 requests per year from beneficiaries. We believe it will take 15 minutes per request for the vendor to provide this information to the beneficiary. The total annual burden associated with this requirement is 1080 minutes or 18 burden hours. However, we believe this information collection requirement and the associated burden is not subject to the PRA as defined in

5 CFR 1320.3(c)(4) because it would affect less than 10 persons.

*Section 414.930 Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen*

Section 414.930(b) states the process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment. We will annually solicit requests for changes to the list of compendia. As stated in § 414.930(c)(1), we will review a complete written request that is submitted in writing, electronically, or via hard copy. A complete written request must contain the following information as stated in § 414.930(c)(1)(i) through (vi):

- Full name and contact information for the requestor;
- Full identification of the compendium in question;
- A complete written copy of the compendium in question;
- The specific action requested of CMS;
- Supporting documentation for the requested action;
- Address a single compendium per request.

Section 414.930(d) states that for each compendium that is determined by CMS to be included on the list, the publisher or its designee must notify CMS, within 45 days of any update or revision, that a new edition or version is available.

The burden associated with the requirements contained in § 414.930(b) through (d) is the time and effort required to draft and submit to CMS a complete written request for changes to the list of compendia. In addition, there is additional time and effort for each compendium that is determined by CMS to be included on the list; the publisher or its designee must furnish to CMS, within 45 days of listing and within 45 days of any update or revision, a written copy of the current edition or version of the compendia, including updates. While these requirements are subject to the PRA, we believe the burden is exempt under 5 CFR 1320.3(c)(4) because it would affect less than 10 persons or entities. There are currently only 6 compendia that could reasonably be expected to be the subject of a request, so 6 requests is a likely maximum.

*Section 424.36 Signature Requirements*

Section 424.36(a) requires the beneficiary's signature on a claim for payment of services unless the beneficiary has died or the provisions of

§ 424.36(b), (c), or (d) apply. Section 424.36(b) states that if the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed by one of the persons specified in § 424.36(b)(1) through (5). Proposed § 424.36(b)(6) states that, for emergency ambulance transport services, if certain conditions and documentation requirements are met, an ambulance provider or supplier would be permitted to sign the claim on behalf of the beneficiary. Specifically, § 424.36(b)(6)(ii)(A) through (C) lists the documentation that would be required, all of which would have to be maintained by the ambulance provider or supplier in its files for a period of at least 4 years from the date of service. An ambulance provider or supplier would be required to obtain a signed, contemporaneous statement from an ambulance employee present during transport of the patient that, at the time the service was provided, the beneficiary was physically or mentally incapable of signing the claim and that none of the other qualified persons listed in § 424.36(b)(1) through (5) were available or willing to sign the claim on behalf of the beneficiary.

The ambulance provider or supplier would also be required to maintain documentation of the date and time that the beneficiary was transported and the name and location of the facility that received the beneficiary. In addition, the ambulance provider or supplier would be required to obtain and maintain a signed contemporaneous statement from a representative of the facility that received the beneficiary. The statement would have to contain the name of the beneficiary and the date and time the beneficiary was received at the facility.

The burden associated with the recordkeeping requirements contained in § 424.36(b)(6) is the time and effort associated with drafting, obtaining, and maintaining written statements from both employees of the ambulance provider or supplier transporting the beneficiary and employees of the facility receiving the beneficiary. We estimate that approximately 9,000 ambulance providers or suppliers will comply with these requirements. We estimate that it will take no more than 5 minutes for each provider or supplier to comply with the recordkeeping requirements. Based on the best available data at this time, we estimate the total annual burden associated with the requirements in § 424.36(b)(6) to be 541,667 hours nationwide. The annual total number of burden hours was arrived at by multiplying 5 minutes by the total estimated number of emergency ambulance transports of

6,500,000. We note that the total number of burden hours may be overstated, because not every beneficiary who receives emergency ambulance transport services is unable to sign the claim. However, we also note that the 6.5 million figure for emergency transports is the estimated number of ALS1-emergency and BLS-emergency ambulance claims processed by Part B carriers, incurred in 2006 and processed through April 2007, and thus, does not include the number of emergency ambulance transport services billed to fiscal intermediaries by ambulance providers (this number is not available to us). In any event, we believe our proposal will benefit ambulance providers and suppliers by allowing them an alternative procedure for submitting claims to Medicare. In the absence of the proposed procedure for signing claims on behalf of beneficiaries for emergency ambulance transport services, ambulance suppliers and providers would be required to track down beneficiaries after the emergency transport services have been rendered, in an attempt to have the beneficiary sign the claim. Moreover, such attempts may prove fruitless, thereby preventing the ambulance suppliers and providers from submitting the claim to Medicare.

*Additional Information Collection Requirements*

This proposed rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this proposed rule also makes reference to several associated information collections that are not discussed in the regulation text. The following is a discussion of these collections, which have already received OMB approval.

*Part B Drug Payment*

Section II.F.1 of the preamble of this proposed rule discusses payment for Medicare Part B drugs and biologicals under the ASP methodology. Drug manufacturers are required to submit ASP data to us on a quarterly basis. As stated in section II.F.1.a. of the preamble, the ASP reporting requirements are set forth in section 1927(b) of the Act.

The collection of ASP data imposes a reporting requirement on the public. The burden associated with this requirement is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to calculate, record, and submit the required data to CMS. While the burden associated with this requirement is subject to the PRA, it is currently approved under OMB

control number 0938–0921, with an expiration date of May 31, 2009.

#### *Competitive Acquisition Program (CAP)*

In section II.F.2.c. of the preamble, we propose to revise the CAP physician election agreement. In conjunction with post-payment review process, we are revising the CAP physician election agreement to reflect the physician's obligation to provide medical records to assist with claims review. The CAP physician election agreement is currently approved under 0938–0955 with an expiration date of August 31, 2009. Under a separate notice, we will make the revised instrument available for public comment prior to submitting the revised information collection request to OMB for approval.

Section II.F.2.e. of the preamble discusses details of the CAP. Each year, physicians are given the option to elect to obtain Medicare Part B drugs and biologicals through the CAP. In addition, physicians are also given an opportunity to select an approved CAP vendor. The burden associated with these election requirements is the time and effort necessary for a physician to make an election and notify CMS. The burden associated with election requirements for participating in the CAP and selecting an approved CAP vendor is subject to the PRA. However, it is currently approved under OMB control numbers 0938–0955 and 0938–0987 with expiration dates of August 31, 2009 and April 30, 2009, respectively.

Section II.F.2.e. of the preamble also discusses the exigent circumstances exception for leaving the CAP outside of the annual election process. A physician may request a release from the CAP within the first 30 days of its participation if it can prove that staying in the program would impose a significant burden. Specifically, the physician must submit a release request to the CAP designated carrier.

While this burden is subject to the PRA, we believe it is exempt under 5 CFR 1320.3(h)(6). Facts or opinions collected from a single person or entity are not subject to the PRA. The aforementioned information collection request will be reviewed individually on a case-by-case basis.

Once the CAP-designated carrier receives a removal request, they are required to refer the physician to their approved CAP vendor. As part of the grievance process, the CAP vendor will try to work with the physician to address their concerns for participation in the program. Then, the CAP vendor

has 2 business days to address the physician's concerns. If the CAP vendor and the physician cannot resolve the outstanding issues within 2 business days, the CAP vendor may submit a request to CMS for an extension to allow for an additional 2 business days to resolve the physician's issues.

The burden associated with this requirement is the time and effort necessary to submit an extension request to CMS. While this burden is subject to the PRA, we currently have no way to quantify how many requests of this type we will receive. Requests from physicians will be reviewed by CAP vendors on an individual case-by-case basis. Similarly, requests for extensions from the CAP vendors will be reviewed individually, on a case-by-case basis. We will continue to monitor the process. If we believe that we will receive 10 or more requests, we will submit an information collection request to OMB.

#### *Physician Quality Reporting Initiative (PQRI)*

Section II.T.1.a. of the preamble discusses the background of the reporting initiative and provides information about the measures available to eligible professionals who choose to participate in PQRI. Section 1848(k)(1) of the Act requires the Secretary to implement a system for eligible professionals to submit data pertaining to certain quality measures. As stated in section II.T.1.a., eligible professionals, for the purpose of the quality reporting system, include physicians, other practitioners as described in section 1842(b)(18)(c) of the Act, physical and occupational therapists, and qualified speech-language pathologists. As also stated in section II.T.1.a, this is a voluntary initiative. Eligible professionals may choose whether to participate and, to the extent they satisfactorily submit data on quality measures applicable to covered professional services they furnish to Medicare beneficiaries, they can qualify to receive a bonus incentive payment.

Specifically, to qualify to receive a bonus incentive payment for satisfactory reporting of quality data on covered professional services furnished in 2007, an eligible professional must submit data on at least 1, 2, or 3 measures selected from the 74 PQRI 2007 quality measures. The minimum number of measures each professional must report to qualify for the bonus payment is determined by how many available

measures are applicable to the services that professional furnishes to Medicare beneficiaries. For a majority of the eligible professionals, three or more available measures will be applicable to their practice, and thus, the MIEA–TRHCA requires that they report on at least three measures at a rate of at least 80 percent for each of those three measures to meet statutory criteria for satisfactory reporting and qualify for the bonus payment. An eligible professional could meet the satisfactory reporting requirement, and thus be eligible for the bonus incentive payment, by reporting fewer than three measures only if his or her practice has fewer than three applicable measures available. The quality measures are posted and available for download on the CMS Web site at <http://www.cms.hhs.gov/pqri>.

The burden associated with this requirement is the time and effort associated with eligible professionals identifying applicable PQRI quality measures for which they can report the necessary information. In addition, they must gather the required information, select the appropriate quality-data codes, and include the appropriate quality-data codes on the claims they submit for payment.

In 2007, the PQRI will collect quality-data codes exclusively as additional (optional) line items on the existing HIPAA transaction 837–P and CMS Form 1500. There will be no new forms and no modifications to the existing transaction or form in support of 2007 PQRI. We also do not anticipate changes to the 837–P or CMS Form 1500 for 2008.

Because this is a voluntary program, it is impossible to estimate with any degree of accuracy how many eligible professionals will opt to participate in the PQRI in 2007. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. We estimate that the additional time required to put quality data codes on each claim is not a material increment to the time required to code the claim for payment. The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported.

TABLE 23.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control number	Respondents	Responses	Total annual burden (hours)
Preamble section II.F.1 .....	0938–0921	120	480	17,760
Preamble section II.F.2.f .....	0938–0955	12	12	480
	0938–0987	10,000	10,000	20,000
§ 410.33 .....	0938–0685	400,000	400,000	1,000,000
§ 424.36 .....	0938–New	9,000	6,500,000	541,667
Total .....	.....	.....	.....	1,579,907

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: William N. Parham, III, CMS–1385–P, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, [CMS–1385–P], [carolyn\\_lovett@omb.eop.gov](mailto:carolyn_lovett@omb.eop.gov). Fax (202) 395–6974.

#### V. Response to Comments

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

#### VI. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption “IMPACT” at the beginning of your comments.]

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) 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 must be prepared for proposed rules with economically significant effects (that is, a proposed rule that would have an annual effect on the economy of \$100 million or more in any one year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities). As indicated in more detail below in this regulatory impact analysis, we estimate that the PFS provisions included in this proposed rule will redistribute more than \$100 million in 1 year. We are considering this proposed rule to be economically significant because its provisions are estimated to result in an increase, decrease or aggregate redistribution of Medicare spending that will exceed \$100 million. Therefore, this proposed rule is a major rule and we have prepared a regulatory impact analysis.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year. (For further information, see the Small Business Administration’s regulation at 70 FR 72577, December 6, 2003.) Individuals and States are not included in the definition of a small entity. The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less

significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, NPPs, and suppliers, including IDTFs, are considered small businesses if they generate revenues of \$6.5 million or less. Approximately 95 percent of physicians are considered to be small entities. There are about 980,000 physicians, other practitioners and medical suppliers that receive Medicare payment under the PFS.

The CAP provides alternatives to physicians who do not wish to purchase drugs directly or collect coinsurance. The impact of the CAP provisions on an individual physician is dependent on whether the drugs they provide to Medicare beneficiaries are included in the list of CAP drugs, whether the physician chooses to obtain drugs administered to Medicare beneficiaries through the CAP. The proposed CAP provisions in this proposed rule will also have a potential impact on entities that are involved in the dispensing or distribution of drugs, plan to become approved CAP vendors, or are approved CAP vendors.

For purposes of the RFA, approximately 80 percent of clinical diagnostic laboratories are considered small businesses according to the Small Business Administration’s size standards. Ambulance providers and suppliers for purposes of the RFA are also considered to be small entities.

In addition, most ESRD facilities are considered small entities, either based on nonprofit status or by having revenues of \$31.5 million or less in any year. We consider a substantial number of entities to be affected if the proposed rule is estimated to impact more than 5 percent of the total number of small entities. Based on our analysis of the 930 nonprofit ESRD facilities considered small entities in accordance with the above definitions, we estimate that the combined impact of the proposed changes to payment for renal dialysis services included in this proposed rule would have a 0.8 percent increase in overall payments relative to current overall payments. The analysis

and discussion provided in this section, as well as elsewhere in this proposed rule, complies with the RFA requirements.

For the e-prescribing provisions, physician practices and independent pharmacies are considered small entities.

Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our initial regulatory flexibility analysis for the remaining provisions. Therefore, we are soliciting comments on our estimates and analysis of the impact of this proposed rule on those small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this proposed rule would have minimal impact on small hospitals located in rural areas. Of the 202 hospital-based ESRD facilities located in rural areas, only 40 are affiliated with hospitals with fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$120 million. This proposed rule will not mandate any requirements for State, local, or tribal governments. Medicare beneficiaries are considered to be part of the private sector for this purpose. A discussion concerning the impact of this rule on beneficiaries is found later in this section.

We have examined this proposed rule in accordance with Executive Order 13132 and have determined that this regulation would not have any significant impact on the rights, roles, or responsibilities of State, local, or tribal governments.

We have prepared the following analysis, which, together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures

we propose to use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we propose a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

#### A. RVU Impacts

##### 1. Resource-Based Work and PE RVUs

Section 1848(c)(2)(B)(ii) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve BN. In the CY 2007 PFS final rule with comment period, the \$4 billion impact of changes in work RVUs resulting from the 5-Year Review required that a BN adjustment be made.

As discussed in section IV.D.3 of the CY 2007 PFS final rule with comment period (71 FR 69735), we carefully reviewed the comments received concerning the BN adjustment needed to offset the \$4 billion impact of changes in work RVUs resulting from the 5-Year Review. To meet the requirements set forth in section 1848(c)(2)(B)(ii)(II) of the Act, we implemented a BN adjuster of 0.8994 or 10.1 percent to be applied to the work RVUs.

Subsequent to the publication of the CY 2007 PFS final rule with comment period and the announcement of the 0.8994 BN adjustment to the work RVUs, the AMA RUC supplied work RVU recommendations on additional CPT codes from the 5-Year Review and recommendations for an increase in the work of anesthesia services. See Table 10 in Section II.E. for a listing of the RUC recommendations and CMS decisions on these additional codes reviewed for the 5-Year Review. As stated in the CY 2007 PFS final rule with comment period, these additional codes are still considered part of the 5-Year Review. The impact of these additional recommendations and increases in the work of anesthesia services on the BN adjustment must be accounted for by revising the current work adjuster of 0.8994. The proposed

revised work adjuster for 2008, based upon the proposed work RVUs for these additional CPT codes and proposed increases in the work of anesthesia services, is approximately 0.8816. Table 24 shows the specialty-level impact of the work and PE RVU changes.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2007 with proposed payment rates for CY 2008 using CY 2006 Medicare utilization for all years. We are using CY 2006 Medicare claims processed and paid through March 30, 2007, that we estimate are 98 percent complete. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown in Table 24. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 80 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Table 24 shows only the payment impact on PFS services. The following is an explanation of the information represented in Table 24. Note that Table 24 does not include the impact of the estimated CY 2008 update.

- Specialty: The physician specialty or type of practitioner/supplier.
- Allowed Charges: Allowed charges are the Medicare Fee Schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary.) These amounts have been summed across all services provided by physicians, practitioners, or suppliers with a specialty to arrive at the total allowed charges for the specialty.
- Impact of Work RVU Changes for additional proposed changes in work RVUs from the 5-Year Review.
- Impact of PE RVU changes. The impact is shown for both 2008 which is the second year of the 4-year transition using the new methodology and the fully implemented 2010 PE RVUs.
- Combined impact of the proposed work RVUs and PE RVUs for both 2008

and the fully implemented 2010 PE RVUs.

TABLE 24.—PROPOSED COMBINED TOTAL ALLOWED CHARGE IMPACT FOR WORK AND PRACTICE EXPENSE RVU CHANGES

Specialty	Impact of work RVU changes 2008 (percent)	Impact of PE RVU changes (percent)		Combined impact of PE and work changes* (percent)	
		2008 (PE trans. year 2)	2010 (PE full implement.)	2008 (PE trans. year 2)	2010 (PE full implement.)
TOTAL .....	0	0	0	0	0
ALLERGY/IMMUNOLOGY .....	0	1	2	1	3
ANESTHESIOLOGY .....	15	-1	-3	14	13
CARDIAC SURGERY .....	-1	-1	-2	-2	-3
CARDIOLOGY .....	-1	0	0	-1	-1
COLON AND RECTAL SURGERY .....	-1	1	2	0	1
CRITICAL CARE .....	-1	0	-1	-1	-2
DERMATOLOGY .....	-1	2	7	2	6
EMERGENCY MEDICINE .....	-1	0	-1	-2	-2
ENDOCRINOLOGY .....	-1	0	0	-1	-2
FAMILY PRACTICE .....	0	0	0	0	0
GASTROENTEROLOGY .....	-1	1	4	0	3
GENERAL PRACTICE .....	0	0	-1	0	-1
GENERAL SURGERY .....	-1	0	0	-1	-1
GERIATRICS .....	2	0	0	2	3
HAND SURGERY .....	-1	-1	-3	-2	-4
HEMATOLOGY/ONCOLOGY .....	-1	0	-1	-1	-2
INFECTIOUS DISEASE .....	-1	0	1	-1	0
INTERNAL MEDICINE .....	0	0	0	0	-1
INTERVENTIONAL RADIOLOGY .....	-1	-1	-4	-2	-4
NEPHROLOGY .....	-1	-1	-4	-2	-5
NEUROLOGY .....	-1	0	-1	-1	-2
NEUROSURGERY .....	-1	-1	-2	-2	-3
NUCLEAR MEDICINE .....	-1	4	13	4	12
OBSTETRICS/GYNECOLOGY .....	-1	0	-1	-1	-2
OPHTHALMOLOGY .....	2	-1	-3	1	-1
ORTHOPEDIC SURGERY .....	-1	-1	-2	-1	-2
OTOLARNGOLOGY .....	2	-1	-4	1	-2
PATHOLOGY .....	-1	-1	-3	-2	-4
PEDIATRICS .....	0	0	0	0	-1
PHYSICAL MEDICINE .....	0	-1	-2	-1	-2
PLASTIC SURGERY .....	-1	0	1	-1	0
PSYCHIATRY .....	-1	0	1	0	1
PULMONARY DISEASE .....	-1	0	1	-1	0
RADIATION ONCOLOGY .....	-1	0	1	0	1
RADIOLOGY .....	-1	1	2	0	1
RHEUMATOLOGY .....	-1	-1	-2	-2	-3
THORACIC SURGERY .....	-1	-1	-2	-2	-3
UROLOGY .....	-1	0	0	-1	-1
VASCULAR SURGERY .....	-1	0	-1	-1	-1
AUDIOLOGIST .....	26	-14	-43	12	-17
CHIROPRACTOR .....	-1	-1	-2	-2	-3
CLINICAL PSYCHOLOGIST .....	-1	-2	-6	-3	-7
CLINICAL SOCIAL WORKER .....	-1	-2	-5	-3	-6
NURSE ANESTHETIST .....	22	0	0	22	22
NURSE PRACTITIONER .....	1	0	1	2	2
OPTOMETRY .....	4	0	-1	4	3
ORAL/MAXILLOFACIAL SURGERY .....	-1	1	3	0	3
PHYSICAL/OCCUPATIONAL THERAPY .....	-1	1	4	1	4
PHYSICIAN ASSISTANT .....	-1	0	0	0	0
PODIATRY .....	-1	1	4	1	3
DIAGNOSTIC TESTING FACILITY .....	0	0	0	0	0
INDEPENDENT LABORATORY .....	0	3	9	3	9
PORTABLE X-RAY SUPPLIER .....	0	2	6	2	6

\*Components may not sum to total due to rounding.

2. Adjustments for Payments for Imaging Services

Section 5102 of the Deficit Reduction Act of 2005 (Pub. L. 109-171) (DRA) exempts the estimated savings from the application of the OPSS-based payment limitation on PFS imaging services from the PFS BN requirement. We estimate that the combined impact of the current BN exemptions instituted by section 5102 of the DRA, the proposed addition of 6 codes to the list of services subject to the DRA OPSS cap (discussed in section II.E.1.), and the proposed payment revisions to OPSS cap amounts would result in no measurable changes in the specialty specific impacts of the DRA provisions with the exception of vascular surgery in CY 2008.

3. Combined Impact

Table 25 shows the specialty-level impact of the proposed work and PE RVU changes, section 5102 of the DRA (including the additional 6 services that were added to the list of services subject to the DRA OPSS cap and the proposed revision to OPSS payment amounts), and our most recent estimate (-9.9 percent) of the CY 2008 Medicare PFS update. Additionally, the impacts in this proposed rule reflect the use of updated physician time data from the AMA-RUC.

As indicated in Table 25, our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2007 with proposed payment rates for CY 2008 using CY 2006 Medicare utilization crosswalked to 2007 services. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown in Table 25. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides.

Table 25 shows only the payment impact on PFS services. The following is an explanation of the information represented in Table 25.

- Specialty: The physician specialty or type of practitioner/supplier.
- Allowed Charges: Allowed charges are the Medicare Fee Schedule amounts for covered services and include copayments and deductibles (which are the financial responsibility of the beneficiary.) These amounts have been summed across all services provided by physicians, practitioners, or suppliers

with a specialty to arrive at the total allowed charges for the specialty.

- Impact of the 2008 Work and PE RVU proposed changes using the methodology finalized in the CY 2007 PFS final rule with comment period and the revised data sources discussed in this proposed rule.

- Impact of section 5102 of the DRA: The CY 2008 percentage decrease in allowed charges attributed to section 5102 of the DRA with the proposed addition of six codes to the OPSS cap list.

- Combined impact of the proposed work and PE RVUs, section 5102 of the DRA and the proposed addition of six codes to the OPSS cap list, and the proposed revisions to OPSS payment amounts.

- CY 2008 Update: The percentage decrease in allowed charges attributed to the estimated CY 2008 PFS conversion factor update (-9.9 percent).

- Combined impact with CY 2008 update: The CY 2008 percentage decrease in allowed charges attributed to the impact of the work and PE RVU changes, section 5102 of the DRA (plus six proposed additions to OPSS cap list), and the proposed revisions to OPSS payment amounts, and the CY 2008 update.

TABLE 25.—COMBINED CY 2008 TOTAL ALLOWED CHARGE IMPACT FOR THE REMAINING 5-YEAR REVIEW OF WORK RVUS AND PRACTICE EXPENSE CHANGES, OPSS IMAGING CAP, AND THE CY 2008 UPDATE

Specialty	Allowed charges (mil)	Impact of work and PE RVU changes* (percent)	Impact of DRA 5102 (percent)	Combined impact RVU and DRA 5102** (percent)	CY 2008 update (percent)	Combined impact with CY 2008 update** (percent)
TOTAL .....	\$75,819	0	0	0	-10	-10
ALLERGY/IMMUNOLOGY .....	172	1	0	1	-10	-9
ANESTHESIOLOGY .....	1,600	14	0	14	-10	4
CARDIAC SURGERY .....	393	-2	0	-2	-10	-12
CARDIOLOGY .....	7,447	-1	0	-1	-10	-11
COLON AND RECTAL SURGERY .....	121	0	0	0	-10	-10
CRITICAL CARE .....	197	-1	0	-1	-10	-11
DERMATOLOGY .....	2,237	2	0	2	-10	-8
EMERGENCY MEDICINE .....	2,170	-2	0	-2	-10	-12
ENDOCRINOLOGY .....	347	-1	0	-1	-10	-11
FAMILY PRACTICE .....	5,011	0	0	0	-10	-10
GASTROENTEROLOGY .....	1,737	0	0	0	-10	-10
GENERAL PRACTICE .....	964	0	0	0	-10	-10
GENERAL SURGERY .....	2,282	-1	0	-1	-10	-11
GERIATRICS .....	145	2	0	2	-10	-8
HAND SURGERY .....	79	-2	0	-2	-10	-12
HEMATOLOGY/ONCOLOGY .....	1,905	-1	0	-1	-10	-11
INFECTIOUS DISEASE .....	499	-1	0	-1	-10	-11
INTERNAL MEDICINE .....	9,867	0	0	-1	-10	-11
INTERVENTIONAL RADIOLOGY .....	241	-2	0	-2	-10	-12
NEPHROLOGY .....	1,649	-2	0	-2	-10	-12
NEUROLOGY .....	1,385	-1	0	-1	-10	-11
NEUROSURGERY .....	568	-2	0	-2	-10	-12
NUCLEAR MEDICINE .....	77	4	0	4	-10	-6
OBSTETRICS/GYNECOLOGY .....	621	-1	0	-1	-10	-11
OPHTHALMOLOGY .....	4,642	1	0	1	-10	-9
ORTHOPEDIC SURGERY .....	3,221	-1	0	-1	-10	-11
OTOLARNGOLOGY .....	906	1	0	0	-10	-10

TABLE 25.—COMBINED CY 2008 TOTAL ALLOWED CHARGE IMPACT FOR THE REMAINING 5-YEAR REVIEW OF WORK RVUS AND PRACTICE EXPENSE CHANGES, OPPTS IMAGING CAP, AND THE CY 2008 UPDATE—Continued

Specialty	Allowed charges (mil)	Impact of work and PE RVU changes* (percent)	Impact of DRA 5102 (percent)	Combined impact RVU and DRA 5102** (percent)	CY 2008 update (percent)	Combined impact with CY 2008 update** (percent)
PATHOLOGY .....	939	-2	0	-2	-10	-12
PEDIATRICS .....	72	0	0	-1	-10	-11
PHYSICAL MEDICINE .....	775	-1	0	-1	-10	-11
PLASTIC SURGERY .....	268	-1	0	-1	-10	-11
PSYCHIATRY .....	1,076	0	0	0	-10	-10
PULMONARY DISEASE .....	1,679	-1	0	-1	-10	-11
RADIATION ONCOLOGY .....	1,599	0	0	0	-10	-10
RADIOLOGY .....	5,197	0	0	0	-10	-10
RHEUMATOLOGY .....	491	-2	0	-2	-10	-12
THORACIC SURGERY .....	432	-2	0	-2	-10	-12
UROLOGY .....	2,021	-1	0	0	-10	-10
VASCULAR SURGERY .....	634	-1	-1	-2	-10	-12
AUDIOLOGIST .....	31	12	0	12	-10	2
CHIROPRACTOR .....	717	-2	0	-2	-10	-12
CLINICAL PSYCHOLOGIST .....	521	-3	0	-3	-10	-13
CLINICAL SOCIAL WORKER .....	347	-3	0	-3	-10	-13
NURSE ANESTHETIST .....	605	22	0	22	-10	12
NURSE PRACTITIONER .....	783	2	0	2	-10	-8
OPTOMETRY .....	782	4	0	4	-10	-6
ORAL/MAXILLOFACIAL SURGERY .....	36	0	0	0	-10	-10
PHYSICAL/OCCUPATIONAL THERAPY .....	1,371	1	0	1	-10	-9
PHYSICIAN ASSISTANT .....	591	0	0	0	-10	-10
PODIATRY .....	1,554	1	0	1	-10	-9
DIAGNOSTIC TESTING FACILITY .....	1,162	0	0	0	-10	-10
INDEPENDENT LABORATORY .....	1,081	3	0	3	-10	-7
PORTABLE X-RAY SUPPLIER .....	80	2	0	2	-10	-8

\* PE changes are CY 2008 second year transition changes. For fully implemented CY 2010 PE changes see Table 1.

\*\* Components may not sum to total due to rounding.

Table 26 shows the estimated impact on total payments for selected high-volume procedures of all of the changes discussed previously. We selected these

procedures because they are the most commonly provided by a broad spectrum of physician specialties. There are separate columns that show the

change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility PE refer to Addendum A of this proposed rule.

TABLE 26.—IMPACT OF PROPOSED RULE AND ESTIMATED PHYSICIAN UPDATE ON PROPOSED 2008 PAYMENT FOR SELECTED PROCEDURES

CPT/ HCPCS	MOD	Description	Facility			Nonfacility		
			2007	Proposed 2008	Percent change	2007	Proposed 2008	Percent change
11721 .....		Debride nail, 6 or more .....	\$28.80	\$24.92	-13	\$39.03	\$35.50	-9
17000 .....		Destruct premalg lesion .....	44.72	41.64	-7	63.29	60.42	-5
27130 .....		Total hip arthroplasty .....	1,360.52	1,199.16	-12	NA	NA	NA
27244 .....		Treat thigh fracture .....	1,100.92	967.04	-12	NA	NA	NA
27447 .....		Total knee arthroplasty .....	1,464.74	1,288.25	-12	NA	NA	NA
33533 .....		CABG, arterial, single .....	1,908.52	1,664.76	-13	NA	NA	NA
35301 .....		Rechanneling of artery .....	1,071.74	938.37	-12	NA	NA	NA
43239 .....		Upper GI endoscopy, biopsy .....	155.00	140.98	-9	325.16	293.90	-10
66821 .....		After cataract laser surgery .....	253.53	224.61	-11	270.97	239.63	-12
66984 .....		Cataract surg w/iol, 1 stage .....	641.98	563.91	-12	NA	NA	NA
67210 .....		Treatment of retinal lesion .....	556.34	491.54	-12	580.59	511.68	-12
71010 .....		Chest x-ray .....	NA	NA	NA	26.15	22.87	-13
71010 .....	26	Chest x-ray .....	8.72	7.85	-10	8.72	7.85	-10
77056 .....		Mammogram, both breasts .....	NA	NA	NA	97.40	90.46	-7
77056 .....	26	Mammogram, both breasts .....	41.31	37.55	-9	41.31	37.55	-9
77057 .....		Mammogram, screening .....	NA	NA	NA	81.86	74.07	-10
77057 .....	26	Mammogram, screening .....	33.35	30.38	-9	33.35	30.38	-9
77427 .....		Radiation tx management, x5 .....	176.22	159.07	-10	176.22	159.07	-10
78465 .....	26	Heart image (3d), multiple .....	73.14	66.56	-9	73.14	66.56	-9
88305 .....	26	Tissue exam by pathologist .....	37.90	32.77	-14	37.90	32.77	-14
90801 .....		Psy dx interview .....	129.99	112.65	-13	145.15	131.76	-9
90862 .....		Medication management .....	44.72	39.60	-11	50.40	46.76	-7
90935 .....		Hemodialysis, one evaluation .....	67.46	59.05	-12	NA	NA	NA

TABLE 26.—IMPACT OF PROPOSED RULE AND ESTIMATED PHYSICIAN UPDATE ON PROPOSED 2008 PAYMENT FOR SELECTED PROCEDURES—Continued

CPT/ HCPCS	MOD	Description	Facility			Nonfacility		
			2007	Proposed 2008	Percent change	2007	Proposed 2008	Percent change
92012		Eye exam established pat	34.11	38.23	12	61.77	62.47	1
92014		Eye exam & treatment	55.71	59.39	7	91.33	91.14	0
92980		Insert intracoronary stent	795.85	721.61	-9	NA	NA	NA
93000		Electrocardiogram, complete	24.63	20.48	-17	24.63	20.48	-17
93010		Electrocardiogram report	8.34	7.51	-10	8.34	7.51	-10
93015		Cardiovascular stress test	104.22	92.51	-11	104.22	92.51	-11
93307	26	Echo exam of heart	46.99	42.33	-10	46.99	42.33	-10
93510	26	Left heart catheterization	242.92	215.73	-11	242.92	215.73	-11
98941		Chiropractic manipulation	28.80	25.60	-11	33.35	29.36	-12
99203		Office/outpatient visit, new	67.08	59.05	-12	91.71	81.58	-11
99213		Office/outpatient visit, est	42.07	37.55	-11	59.50	53.59	-10
99214		Office/outpatient visit, est	66.32	59.05	-11	90.20	80.56	-11
99222		Initial hospital care	119.00	105.48	-11	NA	NA	NA
99223		Initial hospital care	173.57	154.29	-11	NA	NA	NA
99231		Subsequent hospital care	35.62	31.75	-11	NA	NA	NA
99232		Subsequent hospital care	63.67	57.01	-10	NA	NA	NA
99233		Subsequent hospital care	90.95	81.24	-11	NA	NA	NA
99236		Observ/hosp same date	205.40	180.57	-12	NA	NA	NA
99239		Hospital discharge day	94.74	83.63	-12	NA	NA	NA
99243		Office consultation	93.23	83.29	-11	122.41	109.57	-10
99244		Office consultation	145.91	130.74	-10	179.26	160.43	-10
99253		Inpatient consultation	108.77	97.63	-10	NA	NA	NA
99254		Inpatient consultation	156.52	140.64	-10	NA	NA	NA
99283		Emergency dept visit	60.64	52.91	-13	NA	NA	NA
99284		Emergency dept visit	110.28	97.97	-11	NA	NA	NA
99291		Critical care, first hour	208.82	183.65	-12	256.19	224.95	-12
99292		Critical care, add'l 30 min	104.60	92.16	-12	114.45	100.70	-12
99348		Home visit, est patient	NA	NA	NA	66.32	58.03	-13
99350		Home visit, est patient	NA	NA	NA	150.83	131.42	-13
G0008		Admin influenza virus vac	NA	NA	NA	18.95	18.43	-3
G0317		ESRD related svcs 4+mo 20+yrs	283.09	246.45	-13	283.09	246.45	-13

*B. Geographic Practice Cost Index Changes*

Section 1848(e)(1)(A) of the Act requires that payments under the Medicare PFS vary among payment areas only to the extent that area costs vary as reflected by the area GPCIs. The GPCIs measure area cost differences in the three components of the PFS: Physician work; PEs (employee wages, rent, medical supplies, and equipment); and malpractice insurance. Section 1848(e)(1)(C) of the Act requires that GPCIs be reviewed and, if necessary, revised at least every 3 years. The first GPCI revision was implemented in 1993. The second revision was implemented in 1998, the next in 2001, and the last in 2005. In section II.C. of this proposed rule, we are proposing the next GPCI update. The proposed GPCI values are shown in Addendum E. These values reflect the expiration of the 1,000 floor on physician work as provided under section 102 of the MIEA-TRHCA. Section 1848(e)(1)(c) of the Act also requires that the GPCI revisions be phased-in equally over a 2-year period if more than 1 year has elapsed since the last adjustment.

An estimate of the overall effects of proposed GPCI changes on fee schedule area payments can be demonstrated by a comparison of area geographic adjustment factors (GAFs). The GAFs are a weighted composite of each area's work, PE, and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall area costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE, and malpractice expense RVUs for the service differ from those of the GAF. Addendum D shows the estimated effects of the revised GPCIs on area GAFs in descending order. The GAFs reflect the expiration of the 1,000 floor on physician work as provided under section 102 of the MIEA-TRHCA.

The effects of the 2008 transition year will be only one-half of the total amount of the revisions associated with the updated GPCI values. As required by law, the GPCIs would be phased in over a 2 year period. The total impact of the

GPCI revisions is shown in the 2009 GPCI values of Addendum E.

The most significant changes occur in 11 payment localities where the GAF moves up by 1 or more percent or down by more than 2 percent.

*C. Telehealth*

In section II.D of this rule, we are proposing to add neurobehavioral status exam as represented by HCPCS code 96116 to the list of telehealth services. To date, Medicare expenditures for telehealth services have been extremely low. For instance, in CY 2006, the total Medicare payment amount for telehealth services (including the originating site facility fee) was approximately \$2 million. Moreover, previous additions to the list of Medicare telehealth services have not resulted in a significant increase in Medicare program expenditures. For example, the psychiatric diagnostic interview examination (as described by CPT code 90801) was added to the list of Medicare telehealth services in CY 2003. The addition of CPT code 90801 resulted in an increase in Medicare payment amounts of approximately \$100,000 in CY 2006.

The neurobehavioral status exam (CPT code 96116) includes an initial assessment and evaluation of the mental status for a psychiatric patient. In this regard, the neurobehavioral status exam is similar to the psychiatric diagnostic interview examination (CPT code 90801). However, the utilization rate of psychiatric diagnostic interview examination is much greater than the neurobehavioral status exam. For instance, in CY 2006, the total allowed services for CPT code 90801 was approximately 1.3 million while total allowed services for neurobehavioral status exam in CY 2006 was approximately 105,000. Because utilization of neurobehavioral status exam is substantially less than the psychiatric diagnostic interview examination, we believe the budgetary impact of adding neurobehavioral status exam to the list of Medicare telehealth services will be even less than the previously added psychiatric diagnostic interview examination.

While we believe that addition of this service to the telehealth service list will enable more beneficiaries to access to these services, we do not anticipate that this proposed change will have a significant budgetary impact on the Medicare program.

#### *D. Payment for Covered Outpatient Drugs and Biologicals*

##### 1. ASP Issues

The proposed changes discussed in section II.F.1. with respect to payment for covered outpatient drugs and biologicals, are estimated to have no impact on Medicare expenditures. However, we believe the changes will assist in clarifying existing policy with respect to ASP payment.

##### 2. CAP Issues

This proposed rule describes a significant change in how CAP drug claims are paid due to the implementation of section 108(a)(2) of the MIEA-TRHCA. This rule also contains proposals and seeks comment on certain approaches to refining the CAP seek to improve service by improving compliance, increasing flexibility, and increasing choices available to participating CAP physicians. The proposed CAP provisions will also have a potential impact on entities that are involved in the dispensing or distribution of drugs, plan to become approved CAP vendors, or are approved CAP vendors. Changes associated with section 108(a)(2) of the MIEA-TRHCA, especially the provision for payment to vendors upon receipt of a claim, will almost certainly be

perceived as a positive step. Other changes which are proposed or are being contemplated seek to improve service by improving compliance, and increasing the services that an approved CAP vendor may offer to participating CAP physicians. At this time we anticipate these changes will result in no significant additional cost savings or increases associated with the CAP, relative to the ASP payment system.

#### *E. Clinical Laboratory Fee Schedule issues*

As discussed in section II.G. of this preamble, we have proposed two additions to § 410.508 for determining payment for a new clinical diagnostic laboratory paid under the Medicare Part B clinical laboratory fee schedule. These proposals will not increase or decrease payment amounts for existing clinical diagnostic laboratory tests because the payment amounts are not subject to these regulatory changes. For new tests, the proposals would primarily permit additional comment opportunity for establishing a payment amount for a new test but not result in an increase or decrease in payment amounts. Because any new laboratory tests to undergo a reconsideration request of a payment amount are unknown to us at the current time, we do not have any data to estimate the impact of our proposal to establish a reconsideration process. By improving the comment opportunities and timeframes for establishing payment amount for new tests, we expect less than five tests per year to undergo a subsequent reconsideration process with the resulting adjustments in payment amounts to be very modest if any.

#### *F. Provisions Related to Payment for Renal Dialysis Services Furnished by End State Renal Disease (ESRD) Facilities*

The ESRD-related provisions in this proposed rule are discussed in section II.H. To understand the impact of the proposed changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments under the current year (CY 2007 payments) to estimated payments under the revisions to the composite rate payment system (CY 2008 payments) as discussed in II.H. of this proposed rule. To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and proposed payments contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both

current 2006 payments and proposed 2007 payments.

ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from the Healthcare Cost Report Information System (HCRIS). We also used the December 2006 update of CY 2006 National Claims History file as a basis for Medicare dialysis treatments and separately billable drugs and biologicals. While the December 2006 update of the 2006 claims is not complete, we wanted to use the most recent data available, and plan to use an updated version of the 2006 claims file for the final rule. Due to data limitations, we are unable to estimate current and proposed payments for 168 of the 4,712 ESRD facilities that bill for ESRD dialysis treatments.

Table 27 shows the impact of this year's proposed changes to CY 2008 payments to hospital-based and independent ESRD facilities. The first column of Table 27 identifies the type of ESRD provider, the second column indicates the number of ESRD facilities for each type, and the third column indicates the number of dialysis treatments.

The fourth column shows the effect of the proposed change to the wage index floor as it affects the composite rate payments to ESRD facilities for CY 2008. The fourth column compares aggregate ESRD wage adjusted composite rate payments in the third year of the transition (CY 2008) using the CY 2008 wage index with a 0.80 floor compared to aggregate ESRD wage adjusted composite rate payments in the third year of the transition (CY 2008) using the CY 2008 wage index with a 0.75 floor. Note that the fourth column only includes the effect of the proposed change to the wage index floor and does not include the effects of other wage index changes, such as, moving from the second to third year of the transition and updated wage index values from CY 2007 to CY 2008.

The fifth column shows the effect of all proposed changes to the ESRD wage index for CY 2008 as it affects the composite rate payments to ESRD facilities. It is inclusive of the changes in the fourth column. The fifth column compares aggregate ESRD wage adjusted composite rate payments in the third year of the transition (CY 2008) to aggregate ESRD wage adjusted composite rate payments in the second year of the transition (CY 2007). In the third year of the transition (CY 2008), ESRD facilities receive 75 percent of the CBSA wage adjusted composite rate and

25 percent of the MSA wage adjusted composite rate. In the second year of the transition, ESRD facilities receive 50 percent of the CBSA wage adjusted composite rate and 50 percent of the MSA wage adjusted composite rate. The overall effect to all ESRD providers in aggregate is zero because the proposed CY 2008 ESRD wage index has been multiplied by a BN adjustment factor to comply with the statutory requirement that any wage index revisions be done in a manner that results in the same aggregate amount of expenditures as would have been made without any changes in the wage index. The decreases shown among census regions is primarily due to reducing the wage

index floor, as there were areas in these areas with wage index values below the proposed floor.

The sixth column shows the overall effect of the proposed changes in composite rate payments to ESRD providers. The overall effect is measured as the difference between the proposed CY 2008 payment with all changes as proposed in this rule and current CY 2007 payment. This payment amount is computed by multiplying the wage adjusted composite rate with the drug add-on for each provider times the number of dialysis treatments from the CY 2006 claims. The CY 2008 proposed payment is the transition year 3 wage-adjusted composite rate for each

provider (with the 15.5 percent drug add-on) times dialysis treatments from CY 2006 claims. The CY 2007 current payment is the transition year 2 wage-adjusted composite rate for each provider (with the current 14.9 percent drug add-on) times dialysis treatments from CY 2006 claims.

The overall impact to ESRD providers in aggregate is 0.5 percent. This increase corresponds to the proposed 0.5 percent increase to the drug add-on. The variation shown in column 6 is due to variation in changes in the wage index (column 5). All provider types receive the same 0.5 percent increase to the drug add-on.

TABLE 27.—IMPACT OF CY 2008 PROPOSED CHANGES IN PAYMENTS TO HOSPITAL-BASED AND INDEPENDENT ESRD FACILITIES

[Percent change in composite rate payments to ESRD facilities (both program and beneficiaries)]

ESRD provider	Number of facilities	Number of dialysis treatments (in millions)	Effect of changes in floor only <sup>1</sup>	Effect of changes in Wage Index <sup>2</sup>	Overall effect <sup>3</sup>
All Providers: .....	4,541	31.4	0.0	0.0	0.5
Independent .....	3,958	28.1	0.0	-0.1	0.5
Hospital-Based .....	583	3.3	0.0	0.5	1.0
By Facility Size:					
Less than 5000 treatments .....	1,821	5.4	-0.1	-0.2	0.3
5000 to 9999 treatments .....	1,805	13.0	0.0	0.0	0.6
Greater than 9999 treatments .....	915	13.0	0.0	0.1	0.6
Type of Ownership:					
Profit .....	3,611	25.6	0.0	-0.1	0.4
Nonprofit .....	930	5.9	0.0	0.3	0.8
By Geographic Location:					
Rural .....	1,227	6.5	-0.3	-0.5	0.0
Urban .....	3,314	25.0	0.1	0.1	0.6
By Region:					
New England .....	154	1.1	0.1	1.6	2.2
Middle Atlantic .....	549	4.0	0.1	0.4	1.0
East North Central .....	717	5.1	0.1	-0.7	-0.2
West North Central .....	343	1.7	0.0	-0.3	0.3
South Atlantic .....	1,023	7.3	0.0	0.1	0.6
East South Central .....	357	2.3	-0.3	-1.1	-0.6
West South Central .....	622	4.4	-0.1	-0.6	-0.1
Mountain .....	248	1.4	0.1	0.5	1.0
Pacific .....	498	3.9	0.1	1.3	1.8
Puerto Rico .....	30	0.4	-2.1	-3.1	-2.6

<sup>1</sup> This column only shows the effect of the proposed wage index floor changes on ESRD providers for CY 2008. Composite rate payments computed using the CY 2008 wage index with a 0.80 floor are compared to composite rate payments using the CY 2008 wage index with a 0.75 floor.

<sup>2</sup> This column shows the overall effect of wage index changes on ESRD providers. Composite rate payments computed using the current wage index are compared to composite rate payments using the CY 2008 wage index changes.

<sup>2</sup> This column shows the overall effect of wage index changes on ESRD providers. Composite rate payments computed using the current wage index are compared to composite rate payments using the CY 2008 wage index changes.

<sup>3</sup> This column shows the percent change between CY 2008 and CY 2007 composite rate payments to ESRD facilities. The CY 2008 payments include the CY 2008 wage adjusted composite rate, and the 15.5 percent drug add-on times treatments. The CY 2007 payments to ESRD facilities includes the CY 2007 wage adjusted composite rate and the 14.9 percent drug add-on times treatments.

**G. IDTF Changes**

We believe that our proposals regarding IDTFs as discussed in section II.I. of this proposed rule would have no budgetary impact. However, we believe that these changes are necessary to ensure that only legitimate IDTFs are enrolled into the program. In addition, we believe that the proposed IDTF provisions contained in this rule will

help ensure that beneficiaries receive quality care. Therefore, we expect to have an impact on an unknown number of persons and entities who will be denied enrollment into the Medicare program.

**H. CORF Issues**

The revisions to the CORF regulations discussed in section II.K. update the regulations for consistency with the PFS

payment rules. These revisions will help to clarify payment for CORF services and are expected to have minimal impact on Medicare expenditures.

*I. Compendia for Determination of Medically-Accepted Indications for Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen*

We anticipate that the proposals related to the compendia discussed in section II.L. of this proposed rule will have a negligible cost to the Medicare program. The proposed changes will enable CMS to respond quickly should changes in the number and quality of the compendia indicate a need to amend the list.

*J. Physician Self-referral Provisions*

We anticipate that our proposals in section II.M. of this proposed rule for the reassignment and anti-markup provisions, and the physician self-referral provisions would result in savings to the program by reducing overutilization and anti-competitive business arrangements. We cannot gauge with any certainty the extent of these savings to the Medicare program.

*K. Beneficiary Signature for Ambulance Transport Services*

We believe that our proposal in section II.N. of this proposed rule for allowing the ambulance provider or supplier to sign the claim on behalf of the beneficiary with respect to emergency transport services, provided that certain conditions are satisfied, will have no budget impact.

*L. Update to Fee Schedules for Class III DME for CYs 2007 and 2008*

In section II.O. of this proposed rule, we discuss the proposed update to the fee schedules for class III DME for CYs 2007 and 2008. Total allowed charges for class III devices in 2005 were \$71 million. Accordingly, with a zero percent increase for DME, other than class III devices, for 2005 and 2006 and with the proposed establishment of an update for 2007 of zero percent for class III devices, rather than 4.3 percent based on the CPI-U, this would result in a savings to the Medicare program of approximately \$2 million in FY 2007, \$4 million in FY 2008, \$4 million in FY 2009, \$5 million in FY 2010, \$5 million in FY 2011, and \$5 million in FY 2012.

*M. Therapy Services*

In section II.S.2., we proposed to change the certification the plan of care, for outpatient physical therapy, occupational therapy and speech-language pathology services from every 30 days to an appropriate length, based on the patient's needs, limited to 90 days. Analysis of Medicare claims data shows negative or no impact for this change. In most cases, the appropriate length of treatment will be less than 30

days. Certification of the appropriate length of treatment will discourage the practice of billing for re-evaluations prior to recertification regardless of need.

The 30-day recertification allows treatment under a plan of care for 30 days after initial certification, regardless of the appropriate length of treatment. The initial certification cannot assure that a physician reviews the plan or follows the patient's progress.

In 2004 and again in 2006, we received an extensive analysis of the utilization of therapy services. The analysis indicates that the recertification has no impact on utilization of services and does not limit payment. About 70 percent of episodes are completed before the first 30-day recertification interval. Although CORFs have a 60-day certification period, and SNFs and outpatient rehabilitation facilities (ORFs) have 30-day certification periods, the average number of treatment days is similar in these settings. Contrary to the pattern expected if certification impacted length of care, the number of physical therapy treatment days is higher in SNF than in CORF.

We propose to review the utilization of therapy services after a 2-year trial to assess any changes that might be related to certification of a plan of care for an appropriate length of treatment. At that time, if we determine that this change has caused an increase in inappropriate utilization, we will reconsider the 30-day certification requirement.

*N. TRHCA 101(b) Physician Quality Reporting Initiative*

As discussed in section II.T.1. of this proposed rule, the proposed 2008 PQRI measures satisfy the requirement of section 1848(k)(2)(B)(ii) of the Act that the Secretary publish in the **Federal Register** by August 15, 2007 a proposed set of measures that the Secretary determines would be appropriate for eligible professionals to use to submit data to the Secretary in 2008. We also expect to address registry-based data submission on a test basis in 2008. As discussed in section II.T.1. of this proposed rule, we will also explore and may offer an option in 2008 for reporting some of the 2008 PQRI measures via submission of clinical data extracted from EHRs. Although there may be some cost incurred for maintaining the measures and their associated code sets, and for expanding an existing clinical data warehouse to accommodate registry-based data submission, we do not anticipate a significant cost impact on the Medicare program.

*O. TRHCA 101(d) Physician Assistance and Quality Initiative Fund*

As discussed in section II.T.5. of this proposed rule, section 101(d) of the MIEA-TRHCA created the Physician Assistance and Quality Initiative Fund (PAQI) which provides \$1.35 billion for physician payment and quality improvement initiatives. The legislation directs the Secretary to provide for expenditures from the Fund in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire \$1.35 billion for payment for physician's services furnished during 2008.

*P. TRHCA 110 Reporting of Anemia Quality Indicators*

As discussed in section II.T.2. of this proposed rule, there are no program cost savings or increased expenditure associated with this proposed change; however, we expect that the regulation will have a positive impact on patient care.

*Q. Proposed Elimination of Exemption From NCPDP SCRIPT Standard for Computer-Generated Facsimile Transmissions Under Medicare Part D*

The proposed elimination of the exemption for computer-generated fax transactions under Medicare Part D is discussed in section II.S.3. of this proposed rule. E-prescribing is voluntary for providers and pharmacies. This proposal would affect only providers and pharmacies that already conduct e-prescribing using products that generate faxes rather than SCRIPT transactions.

We believe that providers and pharmacies that are now e-prescribing using products that generate faxes generally already possess the hardware necessary to e-prescribe. Many would need to obtain software upgrades to send and receive the SCRIPT transaction. This software will generally be available to providers through automatic version upgrades built into annual software vendor maintenance fees. However, providers currently using software that cannot be upgraded to generate SCRIPT transactions would need to purchase and install new e-prescribing software or revert to sending paper fax transactions to pharmacies.

Dispensers that currently e-prescribe but have not established the connectivity necessary to receive and send SCRIPT transactions would need to connect to a network, and may need to install software upgrades, which will generally be covered under annual fees. Because pharmacies customarily bear

the cost of transaction fees for the SCRIPT transactions they receive and send, these costs would increase as the rate of e-prescribing increases.

The proposed elimination of this exemption will have indirect benefits in that it will help to encourage e-prescribing using electronic data interchange, which will ultimately result in improved patient safety.

Because of the voluntary nature of e-prescribing for physicians and pharmacies, the relatively small number of entities currently e-prescribing, and the minimal nature of the anticipated costs, we believe this provision does not constitute a major rule for purposes of this analysis. However, we specifically solicit comments on the impact to providers and pharmacies.

*R. Revisions to Payment Policies Under the Ambulance Fee Schedule and the Ambulance Inflation Factor Update for CY 2008*

Ambulance providers and suppliers for purposes of the RFA are considered to be small entities. The proposal to remove the requirement that the AIF be published annually via **Federal Register** notice, as discussed in Section III. of this proposed rule has no monetary impact on small entities, or small businesses. It merely allows for the earlier dissemination of necessary information to the ambulance industry, the Medicare contractors, and the general public.

*S. Alternatives Considered*

This proposed rule contains a range of policies, including some provisions

related to specific MMA provisions. The preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our decisions and, where relevant, alternatives that were considered.

*T. Impact on Beneficiaries*

There are a number of changes made in this proposed rule that would have an effect on beneficiaries. In general, we believe these changes, particularly the implementation of the PQRI with its continuing focus on measuring, submitting, and analyzing quality data, will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

We do not believe that beneficiaries will experience drug access issues as a result of the proposed changes with respect to Part B drugs and CAP.

As explained in more detail subsequently in this section, the regulatory provisions may affect beneficiary liability in some cases. Most changes in aggregate beneficiary liability from a particular provision would be a function of the coinsurance (20 percent if applicable for the particular provision after the beneficiary has met the deductible) and the effect of the aggregate cost (savings) of the provision on the calculation of the Medicare Part B premium rate (generally 25 percent of the provision's cost or savings). In 2008, total cost sharing (coinsurance and deductible) per Part B enrollee associated with physician fee schedule services is estimated to be \$590. In

addition, the portion of the 2008 standard monthly Part B premium attributable to PFS services is estimated to be \$38.60.

To illustrate this point, as shown in Table 26, the 2007 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new), is 91.71 which means that currently a beneficiary is responsible for 20 percent of this amount, or 18.34. Based on this proposed rule, the 2008 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 26, is \$81.58 which means that, in 2008, the beneficiary coinsurance for this service would be \$16.32.

Proposed policies discussed in this rule that do affect overall spending, such as the proposed additions to the list of codes that are subject to section 5102 of the DRA imaging provisions, would similarly impact beneficiaries' coinsurance.

*U. Accounting Statement*

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 28, we have prepared an accounting statement showing the classification of the expenditures associated with this proposed rule. This estimate includes the incurred benefit impact associated with the estimated CY 2008 PFS update, shown in this proposed rule, based on the 2007 Trustees Report baseline. All estimated impacts are classified as transfers.

TABLE 28.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM CY 2007 TO CY 2008

Category	Transfers
Annualized Monetized Transfers .....	Estimated decrease in expenditures of \$ 5.9 billion.
From Whom To Whom? .....	Physicians, other practitioners and suppliers who receive payment under the Medicare Physician Fee Schedule; ESRD Medicare Providers; ambulance suppliers, DME suppliers, and Medicare suppliers billing for Part B drugs to Federal Government.

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

**List of Subjects**

*42 CFR Part 409*

Health facilities, Medicare.

*42 CFR Part 410*

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

*42 CFR Part 411*

Kidney diseases, Medicare, Physician Referral, Reporting and recordkeeping requirements.

*42 CFR Part 413*

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

*42 CFR Part 414*

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping.

*42 CFR Part 415*

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

*42 CFR Part 418*

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

*42 CFR Part 423*

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health Professionals, Medicare, Penalties,