of an individual's current depression status. Another commenter asked us to clarify our intent with respect to the use of a screening instrument for persons with a current diagnosis of depression.

Response: We agree with the commenters that the regulation language on depression screening needs to be clarified. We are revising service element 2 to read ''review of the individual's potential (risk factors) for depression, including current or past experience with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.''

Comment: Three commenters expressed the view that the proposed screening tests for falls risk and home safety in service element 3 were not supported by direct scientific evidence, and should be dropped from the IPPE benefit in the final rule.

Response: Falls are among the most common and serious problems facing elderly persons. They are associated with considerable morbidity such as hip fractures and overall reduced level of functioning. The USPSTF also notes that falls are the second leading cause of unintentional injury deaths in the United States. The death rate due to falls increases as a person ages. According to the National Center for Injury Prevention and Control, approximately one-half to two-thirds of all falls occur in and around a person's home. Therefore, discussing with patients home safety tips may reduce some home hazards. In addition, the USPSTF recommends counseling patients on specific measures to reduce the risk of falling, although direct evidence of effectiveness has not yet been established. Therefore, we believe that questioning and counseling patients to determine their risk of falling and home safety is warranted as part of the IPPE benefit.

Comment: Several commenters from the audiology community have asked us to clarify the meaning of the proposed requirement in service element 3, which includes (among other things) a review of any hearing impairment. In addition, several commenters have requested that we clarify whether a hearing assessment is required as part of service element 3, or whether questions (or a questionnaire) advanced to an individual about any possible hearing problems would suffice for purposes of this part of the new benefit. The commenters ask for provider flexibility in meeting this requirement.

Response: The regulatory intent of service element 3 is that we expect that the physician or qualified NPP will engage in a dialogue with patients concerning these issues by asking the individual appropriate questions or using a written questionnaire to address hearing impairment, activities of daily living, falls risk, and home safety. We do not intend for actual screening instruments such as audiometric screening tests to be used. After questioning the individual, if abnormalities are identified, additional follow-up services may be warranted and may include education, counseling, and referral (if appropriate.)

Therefore, we are revising the language of service element 3 to read ''review of the individual's functional ability and level of safety, based on the use of appropriate screening questions or a screening questionnaire which the physician or qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national medical professional organizations.''

Medically necessary diagnostic hearing tests, including hearing and balance assessment services, performed by a qualified audiologist are covered as other diagnostic tests under section 1861(s)(3) of the Act and would be separate from the new IPPE benefit. These services may be appropriate when a physician or other qualified NPP orders a diagnostic hearing test for the purpose of obtaining information necessary for the physician's diagnostic evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem. However, coverage of this testing is excluded by virtue of section 1862 (a)(7) of the Act when the diagnostic information required to determine the appropriate medical or surgical arrangement is already known to the physician, or the diagnostic services are performed only to determine the need for the appropriate type of hearing aid. For further information about the application of the hearing test exclusion to diagnostic hearing tests and payment for these services, we suggest review of section 80.3 to 80.3.1 of the Medicare Benefit Policy Manual.

Comment: Several commenters suggested that we expand the services to be included as part of service element 4 that was proposed for coverage under the IPPE benefit to include: (1) Palpitation/auscultation of carotid arteries; (2) palpitation/auscultation of abdominal aorta; and (3) the ankle-brachial index (ABI) test for peripheral arterial disease (PAD).

Response: Currently, routine screening of asymptomatic persons for carotid artery stenosis via palpation/auscultation of the carotid arteries or carotid ultrasound is not recommended by organizations such as the USPSTF, which provides guidelines on this issue. Therefore, we are not adding routine screening of asymptomatic individuals for carotid artery stenosis to service element 4 in the absence of evidence of the effectiveness of the screening. In addition, the USPSTF has determined that there is insufficient evidence to recommend for or against routine screening of asymptomatic adults for abdominal aortic aneurysm (AAA) by palpation/auscultation or ultrasound of the abdominal aorta so we are not adding that type of screening to service element 4.

Finally, the USPSTF does not recommend routine screening for PAD in asymptomatic persons. However, they also state that clinicians, should be aware of symptoms and risk factors for PAD and evaluate patients accordingly. Therefore, routine screening for PAD with the use of the ABI will not be required as part of the initial preventive physical examination.

Comment: One commenter asked for clarification on whether the proposed regulatory language ''and other factors deemed appropriate by the physician or qualified nonphysician practitioner,'' as specified in service element 4, would permit inclusion of coverage of a screening for chronic obstructive pulmonary disease (COPD) through spirometric testing under the IPPE benefit.

Response: The intent of this language for the actual physical examination portion of the IPPE benefit is to leave to the discretion of the physician or other qualified NPP whether to perform commonly utilized physical examination measures such as auscultation of the heart or lungs on a particular patient, if needed. Spirometry as a screening test for COPD, however, would not be considered to fall within the scope of the physical examination element of the IPPE benefit.

Comment: A number of commenters suggested that we add an assessment of abdominal obesity or alternatively the calculation of the body mass index (BMI) to the vital signs part of service element 4 to help in determining if an individual is at risk for a heart attack, diabetes, or other medical problems.

Response: By requiring measurement of height and weight as part of the IPPE in element 4 (an examination to include

measurement of an individual's height, weight, blood pressure), we believe that the physician or other qualified NPP performing the IPPE will use that information to determine an individual's BMI if necessary.

Comment: Three commenters expressed concern about the wide latitude given to physicians and other qualified NPPs providing the IPPE benefit to select whichever screening test they prefer to use in connection with the assessment of visual acuity. The commenters believe that setting vague boundaries around what constitutes an appropriate screening instrument could open the door for inappropriate use of preventive services. To avoid this, the commenters recommend narrowly defining the appropriate screening instrument for visual acuity in service element 4 by specifying the use of the Snellen test for that purpose.

Response: We agree that the Snellen test is a widely available test used to assess a person's visual acuity. Other similarly available tests for visual acuity also exist, however, and may convey similar results for individual physicians and other clinicians. While we expect that many physicians will utilize the Snellen test in assessing a beneficiary's visual acuity for the purpose of this new benefit, we are not mandating the use of the Snellen test or any other specific visual acuity test in order to meet the requirements of element 4 in the final rule.

Comment: One commenter noted that the proposed rule allows for coverage of the assessment in service element 4 of ''other factors as deemed appropriate based on the individual's comprehensive medical and social history.'' The commenter expressed the view that the quoted language might result in the possibility that virtually any patient's abnormality identified during the preventive physical examination might lead to further evaluation of the patient and a cascade of diagnostic workup of questionable health benefit to the patient and potentially of great cost to the Medicare program. In view of these concerns, the commenter recommended using more restrictive language that would allow for additional assessment of other factors only when they are supported by evidence-based clinical practice guidelines.

Response: Our purpose in proposing the specific quoted language referenced in service element 4 was to allow for the physician or other qualified NPP to perform a limited physical examination of those key elements such as height, weight, blood pressure, and a visual acuity screen that may be important in detecting disease. However, we have specified that additional physical examination measures may be performed if deemed appropriate based on the issues identified by the physician or other clinician in the review of service elements 1 to 3. While we will not specify in the final rule that these additional measures must be supported by evidence-based practice guidelines, we will state that the practitioner performing the preventive examination follow current clinical standards and those guidelines, of course, may include the evidence-based guidelines referenced by the commenter.

Comment: One commenter recommends that we include in our guidelines for the IPPE benefit information that informs the physician or other qualified NPP of: (1) The need to refer patients to occupational therapists when a more extensive evaluation of activities of daily living, falls risk, and home safety is warranted; and, (2) when, such referrals would be medically appropriate.

Response: As part of the final rule, service element 6 of the IPPE benefit will require, education, counseling, and referral, as appropriate, based on the individual's results of the previous 5 elements of the IPPE benefit. However, appropriate referral of a patient to an occupational therapist is left to the discretion of the physician or other qualified NPP who is treating the patient for the medical problem that is identified, subject to contractors' medical necessity review. We do not believe there is a need for us to issue guidelines to our contractors on this point.

Comment: Several commenters indicated that they were concerned about use of the term ''counseling'' in service elements 6 and 7 of the definition of the IPPE because it lacked sufficient clarity. The commenters indicated that counseling may include varying amounts of time depending upon the intensity of the type of service provided, the ability of the individual receiving the counseling to understand the information that is being communicated, etc. The commenters suggested that either we not use the term counseling or clarify its meaning in the final rule.

Response: Use of the term counseling in connection with service element 7 is mandated by section 611 of the MMA, and thus, it is appropriate to use the term in the final rule. However, we would like to clarify this issue in connection with both service elements 6 and 7 of the new benefit. In most cases, we do not expect that the physician or other qualified NPP performing the service should need to spend more than a few minutes of brief education and counseling with a new beneficiary on appropriate topics as required by element 7. Nonetheless, it is possible that it may be necessary to spend more than a few minutes on the education and counseling required by element 6. As the commenters have indicated, the education and counseling required may involve varying amounts of time depending upon the medical problem or problems that are being considered, based on the results of elements 1 to 5, and the intensity of the service that is believed to be medically necessary at that time.

Comment: Three commenters indicated that they support proposed service element 6 on ''education, referral, and counseling deemed appropriate based on the results of the review and evaluation of services,'' in service elements 1 to 5 because it offers an unprecedented opportunity to counsel beneficiaries about health behaviors (for example, stopping smoking, losing weight). Nonetheless, they were concerned about possible over-utilization of services that might result from that provision, and suggest that we clarify that these education, counseling and referral efforts be concordant with evidence-based practice guidelines.

Response: We will not specify in the final rule that education, counseling, and referral efforts must be consistent with evidence-based practice guidelines. We expect that physicians and other qualified NPPs will provide appropriate education, counseling, and referral that utilizes evidence-based practice guidelines and current clinical standards. In addition, follow-up care obtained outside of the IPPE Benefit must be reasonable and necessary based on Section 1862(a)(1)(A) of the Act.

Comment: A number of commenters requested that we clarify the written plan provision of service element 7 that was included in the proposed rule. Several commenters indicated that two problems they see with this requirement are: (1) It is not clearly defined and thus could impose a significant burden on physicians and other clinicians, if it is not more carefully written; and, (2) it does not acknowledge that alternative mechanisms may already be in place that could better facilitate coordination of care for these beneficiaries than the proposed written plan requirement. For example, one commenter suggests that some physicians and other clinicians may currently be using electronic technology to track the delivery of preventive services and should not be

required to file written plans. Instead, the commenter recommends that we craft language to require physicians to demonstrate a system for ensuring that beneficiaries receive recommended screening and preventive services and allow physicians flexibility to determine the design and medium that such a system would employ.

Response: We agree that the term written plan may not offer a sufficiently clear description of our intentions in requiring the physician or other qualified NPP who also performs the IPPE to carry out the statutory mandate that eligible beneficiaries be provided with education, counseling, and referral for screening and other preventive services described in section 1861(ww)(2) of the Act. Our intent in the proposed rule was that each physician or other qualified NPP provide their eligible beneficiaries at the time of the examination with appropriate education, counseling, and referral(s), including a brief written plan such as a checklist, which is provided to the beneficiary for obtaining the appropriate screening and/or other preventive services that are covered as separate Medicare Part B benefits to which he or she is entitled. We acknowledge that physicians or qualified NPPs may have an alternative mechanism in place to ensure that beneficiaries receive recommended screening and other preventive services that does not provide for a written plan to be provided to the beneficiary. However, the intent of the written plan requirement is to promote and encourage beneficiary participation in the health care process by making them aware, briefly in writing of the screening and prevention services for which they are entitled under the Medicare Part B program.

In conclusion, we will revise service element 7 to read ''education, counseling, and referral, including a brief written plan such as a checklist, be provided to the individual for obtaining appropriate screening and other preventive services, which are separately covered under Medicare Part B benefits.''

The ''Physician'' Definition (§ 410.16(a))

Comment: One commenter expressed concerns regarding the definition of a physician. The commenter expressed concern that the proposed rule limits the type of practitioner who is considered qualified to perform the new preventive physical examination. The commenter states that this restriction was not specified by the Congress in section 611 of the MMA or its accompanying conference committee report, and suggests that it should be revised to allow all practitioners, including doctors of podiatric medicine, who are defined as a physician under section 1861(r) of the Act, to be considered qualified to perform the preventive physical examination.

Response: Section 611 of the MMA amended the statute to provide that payment for the IPPE must be made under the Medicare physician fee schedule, as provided in section 1848(j)(3) of the Act, but it did not specifically define what type of physician is eligible for performing this examination. In developing the proposed rule on which physicians are considered qualified to perform the IPPE, we considered the various types of physicians that are identified in section 1861(r)(2), (r)(3), (r)(4), and (r)(5) of the Act. These include doctors of dental surgery, doctors of podiatric medicine, doctors of optometry, and chiropractors, whose scope of medical practice is generally limited by State law to a particular part (or parts) of the human anatomy.

These state licensing restrictions would likely make it difficult for those practitioners to perform all of the services required. Based on this information, we are leaving the definition of a physician unchanged in the final rule.

The ''Qualified Nonphysician Practitioner'' Definition (§ 410.16(a))

Comment: One commenter indicated concern that in the proposed rule certified nurse-midwives (CNMs) are not eligible to furnish the new preventive physical examinations, but physicians and certain other NPPs are eligible to provide those services to Medicare beneficiaries. The commenter indicates that CNMs are fully qualified to provide physical examination and checkups covered by the statute and that they do so on a daily basis as a basic component of the care they provide their clients. The commenter states that we may be constrained by the statute as enacted by Congress on this subject, but suggests that we should review the issue and if possible revise the proposed rule to include CNMs among those who are considered to be eligible to provide the new service in the final rule.

Response: Section 611 of the MMA amended the statute to provide that in addition to physicians certain NPPs, that is, PAs, NPs, and CNS (as authorized under section 1861(s)(2)(K)(i) and (ii) of the Act, and defined in section 1861(aa)(5) of the Act, or in regulations at § 410.74, § 410.75, and § 410.76) will be able to furnish the new preventive physical examination to eligible beneficiaries effective January 1, 2005. Thus, Congress did not specifically authorize CNMs to perform the IPPE. Unless CNMs are able to qualify as one of these other types of NPPs designated by the statute for purposes of the new IPPE benefit, they will not be eligible to provide this service to beneficiaries for Medicare Part B coverage purposes.

Other Issues

Comment: One commenter requested that we clarify application of the proposed IPPE definition to managed care plans where preventive physical examinations are available to Medicare enrollees on an annual basis and they are not limited to a one-time benefit. Generally in the case of managed care plans, it is indicated that the extent of their typical annual preventive examination is determined by the enrollee's physician or other treating physician, depending upon the patient's history and clinical indications. The commenter asks that we allow managed care plans greater flexibility in providing their Medicare enrollees with the various service elements described in the proposed rule. Alternatively, the commenter requests that we clarify in the final rule that managed care plans will need to provide their Medicare enrollees with all elements of the new benefit only if requested to do so by a particular Medicare enrollee.

Response: Section 611 of the MMA requires that IPPEs be made available to all Medicare beneficiaries who first enroll in Medicare Part B on or after January 1, 2005, and who receive that benefit within 6 months of the effective date of their initial Part B coverage period. The new statute does not allow for any exceptions to be made to the coverage of IPPEs for beneficiaries who are members of managed care plans. In fact, section 1852(a) of the Act provides that generally each managed care plan must, at a minimum, provide to its Medicare members all of those items and services (other than hospice care) for which benefits are available under Parts A and B for individuals residing in the area served by the plan. Nonetheless, if a particular Part B member of the plan chooses not to take advantage of the IPPE benefit, for example, because it would duplicate an annual preventive physical exam that has already been provided to that member, the plan would not be obligated to provide the IPPE to that member.

Comment: One commenter noted that while the screening benefits listed in paragraph (A)(1) on **Federal Register**

page 47514 (vol. 69, No. 150) includes ''(5) colorectal cancer screening test,'' the list of screening benefits described in the same section, paragraph (7) on page 47515 does not include that type of cancer screening test. The commenter requests that we include colorectal cancer screening in the list of screening services described on page 47515 of the Physician Fee Schedule Proposed Rule and any other sections of any proposed rule in which covered screening benefits are listed to ensure there is no confusion regarding what services should discussed with patients during the IPPE.

Response: We agree with the commenter that there was an error of omission relative to colorectal cancer screening in the language in the preamble to the proposed rule in the list of screening benefits described on page 47515 of the Physicians Fee Schedule, and we have corrected that oversight in this final rule.

Comment: One commenter requests that we clarify the part of the definition of the IPPE (service element 7) that refers to the provision of education, counseling, and referral of the individual for coverage of bone mass measurements by adding the term ''Dual Energy X–Ray Absorptiometry'' (DEXA) to that provision. The commenter states that DEXA testing is the most accurate method available for diagnosis of osteoporosis and that early detection of this condition paramount for preventing further bone loss and eventual fractures. The commenter is concerned that unless this is clarified in the final rule, local Medicare contractors may exclude coverage for the DEXA test as part of the IPPE benefit.

Response: Our existing regulations governing bone mass measurements are published in § 410.31. While we agree that the DEXA scan is a very commonly used method for the initial diagnosis of osteoporosis, we do not believe that it would be appropriate to add any specific reference to the DEXA test in the IPPE definition because it may be perceived as endorsing one test over another. We do not believe this would be appropriate. Physicians and other qualified NPPs who perform IPPE services may provide appropriate education, counseling, and referral of their Medicare patients for the bone density tests. The counseling and referral may include choosing the appropriateness of the diagnostic modalities for the particular patient.

Comment: A number of commenters have asked us to provide information to Medicare physicians and qualified NPPs performing the IPPE for appropriate referral of their patients when treatment or a more extensive evaluation of patients is needed as part of service element 6.

Response: As part of the final rule, under service element 6, providers are required to furnish their patients with education, counseling, and referral, as appropriate, based on the individual's results of service elements 1–5 of the IPPE service. However, appropriate referral of a patient, of course, is left to the discretion of the physician or other qualified NPP who is treating the patient for the medical problem that is identified.

Comment: One commenter asked us how we plan to monitor the effectiveness of the IPPE benefit over the next several years.

Response: As indicated in the final rule, we have established unique billing codes for the IPPE service which physicians and other qualified NPPs must use in billing Medicare Part B for the new service. Establishing those codes will allow us to monitor over time the extent to which the eligible Medicare Part B population is utilizing the new service, which will be of interest to our program administrators, members of the Congress, and the general public.

Comment: One commenter asked how providers of IPPE services will know if a particular beneficiary is eligible to receive the new benefit due to the statutory time and coverage frequency (one-time benefit) limitations.

Response: The statute provides for coverage of a one-time IPPE benefit that must be performed for new beneficiaries by qualified physicians or certain specified NPPs within the first 6 months period following the effective date of the beneficiary's first Part B coverage. Since physicians or other qualified NPPs may not have the complete medical history for a particular new beneficiary, including information on possible use of the one-time benefit, these clinicians are largely relying on their own medical records and the information the beneficiary provides to them in establishing whether or not the IPPE benefit is still available to a particular individual and was not performed by another qualified practitioner. Since a second IPPE will always fall outside the definition of the new Medicare benefit, an advance beneficiary notice (ABN) need not be issued in those instances where there is doubt regarding whether the beneficiary has previously received an IPPE. The beneficiary will always be liable for a second IPPE no matter when it is conducted. However, for those instances where there is sufficient doubt as to whether the statutory 6-month period has lapsed, the physician or other qualified NPP should issue an ABN indicating that Medicare may not cover and pay for the service. If the physician or other qualified NPP does not issue an ABN and Medicare denies payment because the statutory time limitation for conducting the initial IPPE has expired, then the physician or other qualified NPP may be held financially liable.

Comment: Several commenters asked that we provide explicit instructions and guidelines, respectively, to providers and beneficiaries regarding the details of what will be included in the new benefit, the eligibility requirements, and how providers must bill Medicare for the new service.

Response: Medicare will release appropriate manual and transmittal instructions and information from our educational components for the medical community, including a MedLearn Matters article and fact sheets like the ''2005 Payment Changes for Physicians and Other Providers: Key News From Medicare for 2005''. The medical community can join this effort in educating physicians, qualified NPPs, and beneficiaries by distributing their own communications, bulletins or other publications.

In addition, we have specifically included information on the new IPPE benefit in the 2005 version of the *Medicare and You Handbook* and the revised booklet, *Medicare's Preventive Services.* A new 2-page fact sheet on all of the new preventive services, including the IPPE benefit, is currently under development, and a bilingual brochure for Hispanic beneficiaries will also be available in the new future. This information will be disseminated by our regional offices, State Health Insurance Assistance Programs (SHIPs), and various partners at the national, State, and local levels. Information on the new benefit will also be made available to the public through medicare.gov, the cms.gov partner Web site, 1–800–MEDICARE, numerous forums hosted by CMS, and conference exhibits and presentations.

Comment: Many of the major physician specialty societies believe the payment, as proposed, is undervalued for what is believed to be a labor-intensive IPPE. They request that we use the existing CPT preventive medicine services code series rather than creating a new G-code. These codes have higher RVUs than the office or other outpatient visit code 99203. For example, preventive medicine services visit code 99387 has total nonfacility RVUs of 4.00 while the corresponding value for 99203 is 2.58.

Response: The existing CPT preventive medicine services codes

(99381–99397) are not covered by Medicare. In accordance with section 1862(a)(1)(A) of the Act that requires us to pay only for services that are reasonable and necessary for the treatment of an illness or injury or to improve the function of a malformed body member, we have not covered E/M visits for screening purposes.

The IPPE is intended to target selected modifiable risk factors and secondary prevention opportunities shown by evidence to improve the health and welfare of the beneficiary, and is less focused on a comprehensive physical examination compared to the typical service provided in accordance with CPT code 99397. We equated the resources anticipated with this service to the existing new office or other outpatient visit. For CPT code 99203 the RUC survey data shows 53 physician minutes (including pre-service time, intra-service time and post-service time) with 51 minutes of staff time. We believe the IPPE will reflect these time approximations. We will be looking at the data and consulting with the medical community after initial experience with this new benefit to determine if this payment has been valued appropriately.

Comment: Two commenters suggested that we allow the IPPE either on a yearly basis or every decade after the initial evaluation.

Response: The IPPE was specifically legislated as a one time only benefit for the beneficiary newly enrolled in the Medicare program. This visit familiarizes the beneficiary with a physician or qualified NPP who will highlight the assessments available to help prevent and detect disease and also make available the educational, counseling and referral opportunities to the new Medicare recipient. Our policy anticipates physicians will make appropriate and individualized referrals for the beneficiary. Expanding the number of routine physicals would require additional legislation (See section 1862(a)(7) of the Act).

Comment: Many commenters asked if the IPPE may be provided without performing the EKG at the same visit. They asked to have the EKG component unbundled from the evaluation and management component that had been specified in the proposed rule for the IPPE service since a physician may not have the equipment and capability of providing EKG services to their patients in the office suite or clinic. Additionally, others asked if a physician would be denied payment for the IPPE if the screening EKG was not performed because a diagnostic EKG was performed in a recent visit or if a diagnostic EKG was warranted at the IPPE visit.

Response: Section 611 of the MMA does require a screening EKG to be performed as part of the IPPE visit. We recognize that there are a number of primary care physicians or other clinicians furnishing the service who may want to refer their beneficiaries to outside practitioners or entities for performance and interpretation of the EKG service rather than performing it themselves. Therefore, if an individual physician or other qualified NPP does not have the capacity to perform the EKG in the office suite, then alternative arrangements will need to be made with an outside physician or other entity in order to make certain that the EKG is performed. In circumstances where the primary care physician or qualified NPP refers the beneficiary to an outside physician or entity for the EKG service, we expect that the primary care physician or qualified NPP will incorporate the results of the EKG into the beneficiary's medical record to complete the IPPE. Both components of the IPPE, the examination portion and the EKG, must be performed for either of the components to be paid. Billing instructions for physicians, qualified NPPs and providers will be issued. In order to address these potentially occurring scenarios to complete the IPPE and EKG we have created the following HCPCS codes:

- G0344: *Initial preventive physical examination; face-to-face visit services limited to new beneficiary during the first six months of Medicare enrollment*
- G0366: *Electrocardiogram, routine ECG with at least 12 leads with interpretation and report, performed as a component of the initial preventive physical examination*

A physician or qualified NPP performing the complete service would report both G0344 and G0366.

- G0367: *tracing only, without interpretation and report, performed as a component of the initial preventive physical examination*
- G0368: *interpretation and report only, performed as a component of the IPPE*

RVUs for payment for these new HCPCS codes will be crosswalked from the following CPT codes:

- G0344 will crosswalk from CPT code 99203 *(Office or other outpatient visit)*
- G0366 will crosswalk from CPT code 93000 *(Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report)*
- G0367 will crosswalk from CPT code 93005 *(Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report)*
- G0368 will crosswalk from CPT code 93010 *(Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only)*

Note that HCPCS codes G0366 and G0367 are not payable under the physician fee schedule in the facility setting.

To comply with MMA the IPPE must include the EKG regardless of whether a diagnostic EKG was recently performed. An EKG performed by the physician or qualified NPP during the IPPE visit must be reported with HCPCS code G0366. Medicare does not cover a screening EKG alone.

Comment: One commenter asked if physicians and qualified NPP who see patients in Federally Qualified Healthcare Centers (FQHCs) will be able to provide and bill under the FQHC all-inclusive rate.

Response: Physicians and other qualified NPPs in RHCs and FQHCs may provide this new benefit and follow normal procedures for billing for RHCs and FQHC services. Payment for the professional services will be made under the all-inclusive rate.

Comment: Many physician specialty societies did not agree with our proposal to limit the level of a medically necessary E/M visit when performed and billed with the IPPE. They contend that most Medicare patients, even if known to their physician, come to the IPPE visit with multiple chronic problems often necessitating immediate evaluation and treatment at a level of care equal to a level 4/5 E/M visit code. They also state that current Medicare policy does permit a medically necessary E/M visit at whatever level is appropriate when the noncovered preventive medicine services (CPT codes 99381–99397) are performed. They ask that we eliminate the restriction for the level of service for a medically necessary E/M visit performed at the same visit as the IPPE visit.

Response: The physician will need to schedule time with the beneficiary identifying the available preventive and educational opportunities. A level 2 new or established patient office or other outpatient visit code was proposed because we believe there is a substantial overlap of practice expense, malpractice expense and physician work in both history taking and examination of the patient with the IPPE and another E/M service. We do not want to prohibit the use of an appropriate level of service when it is necessary to evaluate and treat the beneficiary for acute and chronic

conditions. At the same time, we believe the physician is better able to discuss health promotion, disease prevention and the educational opportunities available with the beneficiary when the health status is stabilized and the beneficiary is physically receptive.

We will remove the restriction limiting the medically necessary E/M service to a level 2 visit code. CPT codes 99201 through 99215 may be used depending on the circumstances and appended with CPT modifier ''25 identifying the E/M visit as a separately identifiable service from the IPPE code G0344 reported.

We do not believe this scenario will be the typical occurrence and, therefore, we will monitor utilization patterns for the level 4/5 new or established office or other outpatient visit codes being reported with the IPPE. If there are consistent data that demonstrate high usage of level 4/5 E/M codes we may need to revise the policy.

Comment: Two commenters asked if we would permit separate payment for a digital rectal exam (DRE) when performed on the same day as the initial preventive physical examination.

Response: Currently Medicare does not make separate payment for DRE (code G0102) when performed on the same day as an E/M service. We will maintain the current policy and not pay separately for a DRE performed during the IPPE visit. A DRE is usually furnished as part of an E/M service and is bundled into the payment for an E/M service when a covered E/M service is furnished on the same day as a DRE. It is a relatively quick and simple procedure and if it is the only service furnished or is provided as part of an otherwise noncovered service it would be payable if coverage requirements are met.

Comment: Several commenters requested guidance on documentation.

Response: It is expected that the physician will use the appropriate screening tools. As for all E/M services, the 1995 and 1997 E/M documentation guidelines must be followed for recording information in the patient's medical record. The screening tools used, EKG documentation, referrals and a written plan for the patient also must be included in the patient's medical record. These forms and methods of documentation mirror those that would be used in typical physician practice with patient visits and do not add an additional burden to the physician.

Comment: Several commenters expressed concern that the non-waived deductible and coinsurance will be a disincentive to the beneficiary having the IPPE. They are concerned that some beneficiaries will not avail themselves of the opportunity of the IPPE visit because of the beneficiary's cost share.

Response: The MMA did not waive the deductible and coinsurance, therefore, we must implement the provision as written.

Result of Evaluation of Comments

In view of the comments, we have decided to make several revisions in § 410.16(a) relative to service elements 1, 2, and 3. We are revising § 410.16(a)(1)(i) language in service element 1 to read as follows: ''Review of the individual's medical and social history with particular attention to modifiable risk factors for disease.''

We are clarifying the regulation language on depression screening (service element 2) by revising § 410.16(a)(1)(ii) to specify that review of the individual's potential (risk factors) for depression, including current or past experience with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations. To allow for a certain amount of provider flexibility in meeting the requirements of the regulatory intent of service component 3 we are revising § 410.16(a)(1)(iii) to specify that review of the individual's functional ability and level of safety, based on the use of appropriate screening questions or a screening questionnaire, which the physician or qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national medical professional organizations.

To clarify the requirements of the regulatory intent of service component 7 we are revising § 410.16(a)(1)(vii) to specify that education, counseling, and referral, including a brief written plan such as a checklist be provided to the individual for obtaining the screening and other preventive services for the individual that are covered as separate Medicare Part B benefits.

The ''social history'' definition in the final rule will be revised to include 3 elements:

- History of alcohol, tobacco, and illicit drug use.
- Diet.
- Physical activities.

With regard to payment of the IPPE, we will use the new HCPCS codes and payment will be based on the RVUs of the CPT codes crosswalked as stated above. We will not finalize our proposal to allow a medically necessary E/M service no greater than a level 2 to be reported at the same visit as the IPPE.

B. Section 613—Diabetes Screening

Section 613 of the MMA adds section 1861(yy) to the Act and mandates coverage of diabetes screening tests.

The term ''diabetes screening tests'' is defined in section 613 of the MMA as testing furnished to an individual at risk for diabetes and includes a fasting blood glucose test and other tests. The Secretary may modify these tests, when appropriate, as the result of consultations with the appropriate organizations. In compliance with this directive, we consulted with the American Diabetes Association, the American Association of Clinical Endocrinologists, and the National Institute for Diabetes and Digestive and Kidney Diseases.

1. Coverage

We proposed in § 410.18 that Medicare cover—

- A fasting blood glucose test; and
- Post-glucose challenge tests; either an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, or a 2-hour post-glucose challenge test alone.

We would not include a random serum or plasma glucose for persons with symptoms of uncontrolled diabetes such as excessive thirst or frequent urination in this benefit because it is already covered as a diagnostic service. This language is not intended to exclude other post-glucose challenge tests that may be developed in the future, including panels that may be created to include new diabetes and lipid screening tests. We also would include language that would allow Medicare to cover other diabetes screening tests, subject to a NCD process.

The statutory provision describes an ''individual at risk for diabetes'' as having any of the following risk factors:

- Hypertension.
- Dyslipidemia.
- Obesity, defined as a body mass index greater than or equal to 30 kg/m2.
- Previous identification of an elevated impaired fasting glucose.
- Previous identification of impaired glucose tolerance.
- A risk factor consisting of at least two of the following characteristics:

+ Overweight, defined as a body mass index greater than 25 kg/m2, but less than 30.

+ A family history of diabetes.

+ A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

+ 65 years of age or older.

For individuals previously diagnosed as diabetic, there is no coverage under this statute.

The statutory language directs the Secretary to establish standards regarding the frequency of diabetes screening tests that will be covered and limits the frequency to no more than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

We proposed that Medicare beneficiaries diagnosed with pre-diabetes be eligible for the maximum frequency allowed by the statute, that is, 2 screening tests per 12 month period. We defined ''pre-diabetes'' as a previous fasting glucose level of 100–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL. This definition of pre-diabetes was developed with the assistance of the American Association of Clinical Endocrinologists, concurs with the Centers for Disease Control and Prevention (CDC) definition, and complements the definition of diabetes that we published November 7, 2003 (68 FR 63195).

2. Payment

We proposed to pay for diabetes screening tests at the same amounts paid for these tests when performed to diagnose an individual with signs and symptoms of diabetes. We would pay for these tests under the clinical laboratory fee schedule. We proposed to pay for these tests under CPT code 82947 Glucose; quantitative, blood (except reagent strip), CPT code 82950, post glucose dose (includes glucose), and CPT code 82951 Glucose; tolerance test (GTT), three specimens (includes glucose). To indicate that the purpose of the test is for diabetes screening, we would require that the laboratory include a screening diagnosis code in the diagnosis section of the claim. We proposed V77.1 special screening for diabetes mellitus as the applicable ICD–9–CM code for this purpose. Because laboratories are required and accustomed to submitting diagnosis codes when requesting payment for testing, we believe including a screening diagnosis code is appropriate for this benefit.

Comment: One commenter questioned whether there is statutory authority to expand eligibility for individuals. Adding that, section 613 of the MMA gives authority for additional test and frequency, not additional individuals.

Response: There is no statutory authority to expand eligibility for individuals. Section 613 of the MMA establishes coverage for beneficiaries who are at risk for developing diabetes. Beneficiaries who are pre-diabetic fall within 1861(yy)(2)(D) or (E) and are at an increased risk for developing diabetes. This increased risk separates them from the general at-risk population and requires the course of their care to be managed closer and more frequently.

For individuals not meeting the ''pre-diabetes'' criteria, we proposed that one diabetes screening test be covered per individual per year.

Comment: Several comments were received that recommended we provide physicians with clear guidance about Medicare's covered services to help patients control their diabetes. The commenters also asked that we inform providers about other covered services, such as Hgb1AC tests, that will help patients avoid painful diabetes-related complications.

Response: We will be releasing two publications. The *Dear Doctor Package* publication, which includes the ''2005 FACT SHEET'', will be sent to the contractors on a CD on or about October 15, 2005 and distributed to the providers by November 15, 2005. The *Medicare Coverage of Diabetes Services and Supplies* publication was originally written in 2002. It was revised in 2003 to update the Part B premium amount and is being revised again this year to update the premium amount and to include any information relevant to the MMA. This document will be available on the CMS Web site and at 1–800–MEDICARE.

Comment: We received several comments suggesting that screening should not require a physician's prescription or referral in order to be covered under Medicare Part B. This approach would follow the successful precedent established by us with other screening tests such as mammograms.

Response: The legislative history on mammography did result in us allowing self-referral for mammograms. However, Medicare rules have required that laboratory tests for screening or other diagnoses must be ordered by licensed health care practitioners, specifically physicians, PAs, NPs, or CNSs.

Comment: Comments were received recommending that the final rule include coverage of one annual diabetes screening for all Medicare beneficiaries.

Response: The benefit of screening all Medicare beneficiaries is not supported by current evidence. We plan risk-based frequency limitations of coverage for diabetes screening based upon the statute requirements. Furthermore, we believe beneficiaries with pre-diabetes may warrant a more frequent follow-up and this is permitted at the professional judgment of the health care practitioner.

Comment: We received a few comments suggesting the addition of the C-peptide test, as it is sometimes useful in Type 1 or Type 2 diabetes.

Response: We believe that C-peptide testing is appropriate for diagnostic evaluation, but not for screening. It is currently covered under the general lab benefit as a diagnostic test when it is medically necessary.

Comment: The American Society for Clinical Pathology (ASCP) has urged us to add CPT 82950 glucose; post glucose dose (includes glucose). This test is more frequently used to screen for diabetes. GTT is a more definitive test usually requested when questionable results from random, fasting or postprandial glucose levels are obtained. As written, the proposed rule appears to exclude 82950 as a screening test.

Response: We appreciate attention being drawn to the apparent exclusion of CPT code 82950, which was not our intention and we have corrected that omission.

Comment: A commenter suggested that due to increased incidence of obesity in recent years that family history of diabetes be defined as persons with Type 2 Diabetes in one or more first or second-degree relatives.

Response: The comments received did not provide a clear consensus on the definition of family history of diabetes. Thus the definition of family history of diabetes will be left to the professional judgment of the treating physician or qualified non-physician practitioner based on the beneficiary's medical history and best practice standards.

Comment: The American Clinical Laboratory Association (ACLA) believes that the other codes on the NCD routine screening list that currently result in a diabetes denial on the basis of routine screening should be covered under the new diabetes screening benefit.

Response: We believe the majority of individuals who will seek care under this benefit will conform to the V77.1 code. We are willing to review a sample of claims and determine if other specific codes are appropriate code for this benefit. Codes that need to be considered for this new benefit can be brought to our attention through the national coverage determination process for laboratories.

Comment: A comment was received recommending that the proposed rule be clarified to refer to a ''fasting blood glucose test'' rather than a ''fasting plasma glucose test'' since the CPT code

does not differentiate between blood and plasma.

Response: We agree with the recommendation to change the term ''fasting plasma glucose test'' to ''fasting blood glucose test''.

Comment: A comment was received recommending additional diabetes screening tests be added through a less formal process of consultation with manufacturers, health care providers, patients, and other stakeholders, as contemplated by Congress. The commenter further stated that the NCD process is complex and time consuming, delaying the coverage of new tests.

Response: We believe the evidence-based NCD process is an effective process to review and analyze items and services as potential benefits for Medicare beneficiaries. Because the NCD process allows for public comment before we make any changes, we believe this is the appropriate process for any future changes. Further, we may not be able to accept every stakeholder's recommendation because of instructional, coding, or claims issues which must be resolved before any benefit can be implemented.

Result of Evaluation of Comments

Our review of the comments has led to the elimination of the word ''plasma'' from the term ''fasting plasma glucose test.'' The word ''plasma'' will be replaced with the term ''blood''. We have corrected the unintentional omission of CPT code 82950, post glucose dose (includes glucose) as a diabetes screening test. The providers and beneficiaries are reassured that there will be clear guidance on covered services by way of two publications: The *Dear Doctor Package*, which includes the ''2005 Fact Sheet'' and *Medicare Coverage of Diabetes Services and Supplies*. We continue to promote healthcare practitioner autonomy with our policy of risk-based frequency limitations on items and services provided to our beneficiaries. We recognize the differing opinions with regard to the usage of the NCD process to review potential new items and services such as new diabetes screening tests for our beneficiaries. To provide transparency, timeliness and fairness, a formal process is necessary. Historically, the NCD process has been open to all interested parties and has proven to be an effective process.

Based on reasoning from the responses to the comments we received, at this time we will not be accepting the following suggestions.

- Reversing policy requiring a physician's or a qualified non-physician's prescription or referral for diabetes screening tests.
- Providing coverage of one annual diabetes screening test for all Medicare beneficiaries.
- Adding coverage of C-peptide test as a screening test.
- Bypassing the current NCD process for a less formal process to add additional diabetes screening tests.

C. Section 612—Cardiovascular Screening

Section 612 of the MMA adds section 1861(xx) to the Act and provides for Medicare coverage of cardiovascular (CV) screening blood tests for the early detection of CV disease or abnormalities associated with an elevated risk for that disease effective on or after January 1, 2005.

Upon reviewing the USPSTF reports, the scientific literature and comments of professional societies, trade associations, the industry, and the public, we proposed in the August 5, 2004 **Federal Register**, that the benefit for CV screening would include the use of three clinical laboratory tests to detect early risk for CV disease. Since the three tests, a total cholesterol, a HDL-cholesterol, and a triglycerides test, could be ordered as a lipid panel or individually, the frequency was limited to one of each individual test or combination as a panel every 5 years.

When we researched the benefit, some scientific experts proposed that the use of only the total cholesterol test as a single test every 2 years was adequate. After reviewing the literature and comments, we concluded that each test in the lipid panel is important since each test predicts the risk for CV disease independently. It would be prudent, therefore, to promote the benefit as three separate tests every 5 years. The decision to limit the frequency to 5 years, rather than more frequent testing every 2 years was due to information found in the Clinical Considerations of the USPSTF which indicate that the cholesterol values of elderly persons, who are the majority of the Medicare population, change slowly as they age. We also proposed that any changes to the list of tests could be made after a review of recommendations by the USPSTF and the use of the NCD process.

We proposed that for the claims processing and payment system, the coding of the tests would be made using the CPT codes available for the lipid panel or the three tests individually coded with the use of V codes to identify the tests were ordered for screening purposes. We also stated that we would pay for these CV screening tests at the same amounts paid for these tests to diagnose an individual with signs of CV disease and that these would be paid under the clinical laboratory fee schedule. The proposed coverage requirements were set forth in new § 410.17.

In response to the proposed rule, we received letters and e-mails from 28 commenters representing professional societies, trade groups, the industry, and individuals, who wrote on 26 different issues. One commenter represented 14 medical societies. Each commenter had many concerns and the comments were grouped into 26 areas of concern.

Comment: Three commenters expressed concern that many laboratories perform direct measurement LDL reflexively when triglycerides exceed certain parameters. The commenters are concerned that if screening direct measurement LDL is statutorily excluded then the Medicare beneficiaries would be liable for these tests without prior notice.

Response: Section 410.32 requires that tests be ordered by a treating physician and used in the management of the patient. We have interpreted this provision to restrict the furnishing of reflex testing to situations where it is clear that the physician is ordering reflex testing at specific parameters and where the physician has an option to order the test without the reflex portion. Thus, laboratories must offer physicians the ability to order a lipid panel without the option to perform the direct measurement LDL. We strongly encourage physicians to order lipid panels without the direct measurement LDL reflex option to protect Medicare beneficiaries from incurring a charge for this service without advanced notice.

If the screening lipid panel results indicate a triglyceride level that indicates the need for a direct measurement LDL, the physician may order this test once the results of screening lipid panel are reported. The NCD for lipid testing includes coverage of direct measurement LDL for patients with hyperglyceridemia. *[http://www.cms.hhs.gov/ mcd/viewncd.asp ?ncd_id=190.23&ncd_ version=1&show=all]*

We do not require the patient to physically return to the treating physician for an office visit and ordering of subsequent testing. Physicians may order such tests based on the results of the CV screening. The Medicare law and regulations do not prohibit the use of the same sample of blood to be used for direct measurement LDL following a lipid panel with very high triglycerides. Laboratories may archive the initial specimen and use it

for subsequently ordered medically necessary direct measurement LDL.

Comment: One commenter suggested that if the direct LDL cholesterol is included in the CV risk screening benefit, we must provide guidance to laboratories regarding whether or not the direct LDL must be billed with the −59 modifier for the charge to be reimbursed.

Response: Since the direct LDL cholesterol is not being added to the CV screening benefit, there is no change to the billing.

Comment: One commenter requested that the V codes (V81.0, V81.1, and V81.2) be added to the Lipid NCD and that the NCD Edit Software be modified to accept these V codes (V81.0, 81.1, and 81.2) on a frequency basis.

Response: The Laboratory NCD Edit Module will be modified to accept the V codes for matching the CPT codes with the ICD–9–CM code for those tests within the lipid NCD that are part of this statutory benefit. The entire lipid NCD is not open for modification. The frequency is determined by the NCD process and implemented through changes to the claims processing system to edit the patient history and coding.

Comment: One commenter asked that Medicare contractors provide explicit instructions to physicians to provide the necessary V codes (or their corresponding narratives) since screening is normally non-covered.

Response: We will release the appropriate manual, transmittal instructions and information from our educational components for the medical community including a MedLearn Matters article and fact sheets such as the ''2005 Payment Changes for Physicians and Other Providers: Key News From Medicare for 2005.'' Laboratories can join this effort to educate physicians and beneficiaries by distributing their own communication, bulletins or other publications. Some of this information will also be part of the ''Welcome to Medicare Preventive Services Package.''

Comment: Three commenters recommended that high sensitivity C-reactive protein (hsCRP) be considered as a test for this benefit since the AHA and CDC issued a Class IIa recommendation stating that hsCRP measurements for risk stratification add important information to the ''classic'' cholesterol and HDL measurement. They cited that given Congressional intent, we should include this measure in its list of ''approved'' screening tests and, if not, that we immediately request that USPSTF conduct a formal review of hsCRP as a screening test. Four commenters recommended the addition of the ABI test. Another requested the inclusion of the 12-lead ECG, the echocardiogram, and tests for carotid artery disease. Another requested the coverage of blood pressure screening. Finally, another commenter suggested that we allow the broadest access and maximize the potential for tests.

Response: We appreciate the commenters' suggestions to include hsCRP and the other tests. In our efforts to develop the proposed rule, many tests were considered for inclusion in the list of screening tests for this benefit. There was insufficient evidence to include any additional tests beyond the lipid panel tests. The information we received in the development of the proposed rule did not support the inclusion of these additional tests but we invite the public to submit scientific literature for our consideration. Other new types of CV screening blood tests may be added under this new screening benefit if we determine them appropriate through a subsequent NCD. 68 FR 55634 (Sept 26, 2003) or *http://www.cms.hhs.gov/coverage/8a.asp].*

Comment: Two commenters recommended that we add HCPCS codes for the Lipid Panel and components as waived tests since they are performed in physician offices and other sites with Clinical Laboratory Improvement Amendments (CLIA) Certificates of Waiver.

Responses: Under CLIA, a facility with a CLIA certificate of waiver can only perform those tests that are approved by the FDA as waived tests. We update the list of waived tests and their appropriate CPT codes on a quarterly basis through our program transmittal process. When we program the claims system to look for the AMA CPT codes for Lipid Panel or any of the three tests which make up the panel, the system will recognize those waived tests performed using the same code plus the QW modifier that are medically necessary.

Comment: Two commenters requested clarification of the frequency limits for the three tests considered for this benefit. They asked if we would cover: (1) A lipid panel; (2) one or more component tests making up the lipid panel once every 5 years; or (3) each of the 4 HCPCS codes listed every 5 years.

Response: The intent of the benefit is to screen for CV disease. Since we believe most physicians would order the Lipid Panel as a single test, our intention was to cover the panel. We recognize that physicians may have different approaches to reaching their decision to treat, and therefore, we have to make available the possibility that physicians could order the individual tests which make up the panel. No matter how the physician(s) order the tests, our intention is to cover each of the 3 component tests (that is, a total cholesterol, a triglycerides test, and an HDL cholesterol) once every 5 years.

Comment: Two commenters asked that we clarify the reasons for having V codes for screening tests added from the MMA rather than the past practice of developing G codes (unique HCPCS codes; temporary codes). This commenter believed that the change to V codes would cause confusion to the databases like the Physician/Supplier Procedure Summary Master File. This confusion would result in improperly filed provider claims and this would lead to a different and confusing method of processing claims.

Response: The decision to use ICD–9–CM codes rather than continue to add G codes was made because we try to utilize existing coding structures where possible and create G codes if there is a specific programmatic need. The laboratory community has lobbied against the use of G codes for a few years. Also the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Standardization Requirements are working toward phasing out G codes, which are CMS only codes. The claims processing and editing systems are expected to be adjusted to manage this change.

Comment: Five commenters questioned the reasons for establishing limits on the frequency of this benefit since this places great legal, administrative, and financial burden for providers to manage this type of information. One commenter suggested the use of a chit that beneficiaries would receive and redeem for testing so laboratories would not need to keep records.

Response: The statute requires a frequency limit. Since laboratories may not have the complete medical history for individuals, including their history of CV screening tests, they are largely relying on the physician's order in establishing whether the test is medically necessary and covered by Medicare. However, relying on the physician's order does not provide the laboratory with proof that the CV screening test is medically necessary since the beneficiary may be treated by multiple physicians who may have ordered these tests independently within the 5 year coverage window. If the laboratory has sufficient doubt, the laboratory may issue an Advanced Beneficiary Notice (ABN) to the beneficiary indicating that Medicare may not cover the CV screening test. If the laboratory does not issue an ABN to

the beneficiary who has received more that one CV screening test during the previous five years, the laboratory may be financially liable for the cost of the test. Laboratories are not required to issue an ABN if the physician has already issued one.

In addition, section 40.3.6.4(C) titled ''Frequency Limited Items and Services'' of Chapter 30 of Pub 100–4 of the ''Internet Only Manual'' provides additional guidance for those instances where Medicare has imposed frequency limitations on items or services. This section instructs providers that the provider may routinely give ABNs to beneficiaries and that whenever such a routine ABN is provided to a beneficiary, the ABN must include the frequency limitation as the reason for which Medicare will deny coverage.

Comment: Several commenters, including the ACR and the SIR, offered their assistance to us when we determine whether noninvasive testing for CV disease is necessary.

Response: Since the organizations that suggested noninvasive tests for inclusion in this benefit provided the materials for our review, it is not necessary for us to seek outside assistance. We appreciate the commenters' offer of assistance.

Comment: Four commenters suggested that the CV screening benefit stipulate an age for the population to be tested. We reviewed the USPSTF recommendation that promoted testing for men 35 years and older and women 45 years and older. The commenters believe this age range should be lowered to include those aged 20 years and older and asked us to consider including younger people in this benefit.

Response: The statutory change for this benefit did not include an age for the person to be tested. While some of the USPSTF recommendations included an age or an age range, none was selected for the proposed rule. Since the majority of the individuals in Medicare are generally 65 and older, the belief was that we are looking at an older population rather than concentrating our resources on the younger beneficiaries who may also be disabled and Medicaid eligible or could be eligible for other services due to other complications of CV disease. While there may be individuals younger than 65 years of age that could benefit from this testing, this benefit is intended for those entitled to Medicare. Therefore, any patient entitled to Medicare would be covered for this benefit as specified in this rule.

Comment: One commenter noted that if the patient did not fast for the screening test (fasting may be difficult for some patients), the calculation of LDL cholesterol may be inaccurate. This commenter recommended that for screening purposes, an alternative to repeating the full lipoprotein profile in the fasting state would be a follow-up direct measurement of LDL cholesterol.

Response: If a patient cannot fast and the physician believes the patient's medical history and circumstances suggest the beneficiary is at risk of CV disease, then any additional testing beyond an initial screening would need to be done under the diagnostic clinical laboratory benefit. Under the screening benefit, a repeated full lipoprotein profile (fasting) or a second LDL cholesterol (fasting) would not be covered for anyone who failed to fast when they had their first set of tests.

Comment: Several commenters suggested that the tests that the USPSTF approves for CV screening blood tests be automatically adopted and covered by Medicare for the purposes of this benefit. We would not need to use the NCD process to add tests to this benefit. Immediate adoption of USPSTF recommendations will remove us from our own lengthy review.

Response: While the USPSTF process is well established, we believe it is prudent to review any recommendations from the USPSTF before implementing them. In the proposed rule, we asked the public how we should make changes for this benefit. Because the national coverage determination process allows for public comment before we make any changes, we believe this is the most appropriate basis for any future changes. Further, we may not be able to accept every USPSTF recommendation because of instructional, coding or claims issues that must be resolved before any benefit can be implemented.

Comment: Several commenters questioned whether the screening benefit for CV disease included noninvasive tests or whether it was limited only to blood tests. Further, they recommended that the adoption of noninvasive tests be tied to recommendations of the USPSTF or to an NCD.

Response: We interpreted this portion of the screening benefit to permit noninvasive tests for which there was a blood test recommended by the USPSTF (for example, there is a blood test for cholesterol and if a noninvasive test was developed that detected characteristics of cholesterol, could provide a meaningful (comparison) result and accurate reading) then the noninvasive test could be considered for inclusion in the screening benefit. Noninvasive tests would not be immediately included but would be subject to a review before adoption. When it is time to consider the addition of tests or changes to the list of tests, we will consider any changes through an NCD. This benefit is not limited only to blood tests.

Comment: One commenter recommended that we include a fasting blood glucose test as part of the CV screening blood benefit and that we cover this test every 2 years for beneficiaries over 45 and for younger beneficiaries who are obese or have a family history of diabetes. Fasting blood glucose is inherently a CV screening test because diabetes carries increased risk of CV disease.

Response: While some people who have diabetes exhibit other factors associated with CV disease, we do not see the necessity to adjust the CV screening benefit to include a fasting blood glucose test. The diabetes screening benefit should be able to identify these individuals. Medicare does not plan to duplicate tests when they are available through other screening programs.

Comment: One commenter requested the inclusion of V70.0 for routine examination to be added as one of the ICD–9-CM codes to be covered for screening for CV screening blood tests. They asked that the NCD on lipid panel be reviewed for any codes that were previously denied as routine screening in the past, and that these codes be considered for inclusion under this new benefit.

Response: We believe the majority of individuals who will seek care under this benefit will fit the V81.0, V81.1, or V 81.2 codes. We are willing to review a sample of claims and determine if V70.0 is an appropriate code for this benefit. At this time, we are unable to add V70.0 to the instructions being cleared. Codes that are to be considered for this new benefit must be brought to our attention through the national coverage determination process for laboratories.

Comment: One commenter suggested that the proposed § 410.17 include reference to whether beneficiaries will incur out-of-pocket costs for CV screening blood tests.

Response: Section § 410.17 is specific to coverage instructions for screening tests for the early detection of CV disease. We do not believe it is necessary to revise § 410.17 to include payment instructions. We have indicated that Medicare would pay for the tests under the clinical laboratory fee schedule. Currently under this payment system, beneficiaries do not incur copayments and deductibles in accordance with section 1833(a)(1)(D)(i) of the Act, and is included in

instructions at Medicare Claims Processing Manual, Pub. 100–04, chapter 16, § 30.2.

Comment: Two commenters asked us to clarify why we chose 5 years as the timeframe for the benefit, rather than the 2 years allowed by the statute.

Response: Our primary goal was to allow testing for the population that needed to be screened. In the preamble to the proposed rule, we stipulated that the Clinical Considerations of the USPSTF indicate, while screening may be appropriate in older people, repeated screening is less important because lipid levels are less likely to increase after age 65. Screening individuals more often than necessary might lead to unnecessary expenses and treatment. The scientific literature indicates that lipid levels in the elderly are fairly stable. Therefore, we proposed screening once every 5 years and have not received sufficient evidence to change this position.

Comment: Two commenters suggested that a two-tiered benefit be developed that would allow lipid profile screening tests at least every 5 years for beneficiaries when risk factors are not evident and a second group be screened at least every 2 years. The second group would include individuals who have modifiable risk factors (for example, tobacco smoking, high blood pressure, physical inactivity, obesity, and diabetes mellitus) and non-modifiable risk factors (such as age, gender, race, and family history).

Response: While the CV screening benefit could be expanded to include individuals other than those mentioned in the proposed rule, preventive benefits were added to the Medicare Program on a limited basis as science and technology permit them. Since some of the individuals in the second group already would be screened through the IPPE and the Diabetes Screening Benefit, we are not developing a second tier at this time. We believe expanding this to a second tier would waste precious resources of time and money and not contribute to lowering the risk factors for individuals with CV disease.

Comment: One commenter questioned why we proposed to use the NCD process as the method of making changes to the list of tests covered by the CV screening blood test benefit. The commenter wrote that the MMA does not require that the NCD process be utilized. They indicated that there is no need for us to conduct our own assessment since a thorough evaluation of the test was to be done by the USPSTF in determining that the test is one that it recommends. The commenter objected to the use of the NCD process for consideration of new tests because of the significant delays that mark this process. The commenter also stated that all that would be needed for us to approve the coverage of additional CV screening tests is the recommendation of the USPSTF.

Response: In establishing the benefit for CV screening blood tests, the Congress gave the Secretary the authority to determine which tests would be covered by this benefit. We do not believe it would be proper to delegate this function to USPSTF or any other entity. In the proposed rule, we proposed the tests to be covered for the new benefit when it becomes effective January 1, 2005 and at the same time, we offered the NCD process for changes to this benefit. We proposed that future tests would be added after reviewing the recommendations of the USPSTF and the use of the NCD process. The NCD process actually has several methods for evaluating which tests we may eventually cover. The NCD process includes an application for a new coverage issue, a reconsideration of an existing policy, or a coding change for laboratory tests. We believe the use of the NCD process is a worthwhile endeavor since it is a public process and less time consuming than rulemaking. The use of an NCD is authorized by Section 1871 of the Act.

Comment: One commenter suggested that we include triglycerides as a test for the CV screening blood test benefit since the 2001 USPSTF recommendations for screening for lipid disorders associated with CV disease only includes measurement of total cholesterol and high-density lipoprotein cholesterol (HDL–C).

Response: We have included the triglycerides test as one of the tests for screening for CV disease. For some individuals, triglycerides may detect a risk factor for CV disease. That is why it was more prudent to select a lipid profile that includes the three tests (total cholesterol, HDL-C, and the triglycerides) rather than to indicate the use of individual tests with different test intervals and different ordering patterns.

Comment: One commenter requested that the frequency limit for lipid testing of 5 years be waived if the patient develops a risk factor, such as diabetes, a marked weight gain, etc. in the interval.

Response: A patient screened for lipid testing could also meet the requirements for screening under the diabetes screening benefit. If a patient developed further risk factors which negate the need for continued screening under the CV screening blood test benefit, their additional signs or symptoms would probably cause the person to need to seek treatment which would be covered under other benefits including diagnostic clinical laboratory testing.

Comment: One commenter questioned whether § 410.16 that permits qualified nurse practitioners and others to order CV screening tests under the physical examination (section 611 of the MMA) is inconsistent with § 410.17 that requires that the laboratory tests be ordered by the treating physician (§ 410.32(a)).

Response: Section 410.16 addresses services by NPs because of conforming changes made in section 611(d) of the MMA. Section 410.32(a)(3) permits certain NPPs to furnish services that would be physicians' services if furnished by a physician and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit. We believe that the statute permits the use of NPPs to order tests described under § 410.17 without a change in the statute. The general rule for laboratory tests is that the tests must be ordered by the treating physician and in the instance of screening tests, the treating NPP may be regarded as a physician for this purpose.

Comment: One commenter believed that screening every 5 years was too long a period between tests and that the data we collect be used to allow more frequent testing.

Response: We have heard from commenters that the frequency limitation of keeping records for the 5 years is difficult because of storage, access and retrieval, and orders from multiple physicians. Change in the frequency (that is, the number of times a patient can be tested during a given timeframe) will be considered if the scientific literature supports it. We do not believe we are permitted to change the frequency based solely upon the logistical difficulties in collecting, consolidating, and maintaining administrative data. Modifying the benefit to permit more frequent testing will not resolve these administrative difficulties. However, we will take this recommendation under advisement as we continue to consider the associated clinical data, but will not make any changes for the final rule.

Comment: One commenter requested that blood be removed from the title of this benefit for the final rule. The commenter believed the narrow focus on blood would restrict the types of tests that would be administered for detecting CV disease.

Response: In developing the proposed rule, we included blood in the title of this benefit to be consistent with the

history of this benefit and to distinguish the tests in the benefit. We believe that noninvasive tests could be covered and this benefit is not limited only to blood tests.

Comment: One commenter suggested that the CV screening benefit include an appropriate screening instrument. As with depression, the examining physician has a test based on clinical practice guidelines to use as a tool for assessing the patient. Since the American Heart Association (AHA) and the ACC Guidelines for PAD are expected to be published in 2005, the commenter is requesting that we adapt the patient assessment and include these guidelines under the CV screening benefit.

Response: Since the publication of the AHA and ACC Guidelines has not taken place, it would be difficult to evaluate this document and how physicians would use this in the course of examining a patient. Physicians may use their best judgment for how they assess an individual patient and whether additional specific tests from the AHA and ACC guidelines would be more helpful than what is already included in the screening benefit for CV disease is not something we can conclude at this time. The NCD process is available when additional tests should be considered.

Result of Evaluation of Comments

After reviewing all the comments, we have plans to include the V codes (V81.0, V81.1 and V81.2) in the Laboratory Edit Module, and to release manual and transmittal instructions and information to smooth the transition for the new benefit. Providers who routinely give ABNs to beneficiaries must include in the ABN that the frequency limitation is the reason for which Medicare will deny coverage. A patient who has an ABN and exceeds the frequency limitation may incur out-of-pocket charges. We will finalize the changes to § 410.17 as proposed.

D. Section 413—Physician Scarcity Areas and Health Professional Shortage Areas Incentive Payments

[If you choose to comment on issues in this section, please include the caption ''HPSA Zip Code Areas'' at the beginning of your comments.]

Section 413(a) of the MMA provides a new 5 percent incentive payment to physicians furnishing services in physician scarcity areas (PSAs). The MMA added a new section 1833(u) of the Act that provides for paying primary care physicians furnishing services in a primary care scarcity county and specialty physicians furnishing services in a specialist care scarcity county an additional amount equal to 5 percent of the amount paid for these services.

Section 1833(u) of the Act defines the two measures of physician scarcity as follows:

1. Primary care scarcity areas—determined by the ratio of primary care physicians to Medicare beneficiaries. A primary care physician is a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist.

2. Specialist care scarcity areas—determined by the ratio of specialty care physicians to Medicare beneficiaries. The specialist care PSA ratio includes all physicians other than primary care physicians as defined in the definition of primary care scarcity areas.

To identify eligible primary care and specialist care scarcity areas, we ranked each county by its ratio of physicians to Medicare beneficiaries. In accordance with the statute, in the list of primary care and specialist care scarcity counties, only those counties with the lowest ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties were considered eligible for the 5 percent incentive payment. In accordance with the section 1833(u) of the Act, we also treated a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification) as an equivalent area (that is, equal to a full county).

Consistent with section 1833(u)(4)(C) of the Act, all PSAs were assigned their 5-digit zip code area so that we may automatically provide the 5 percent incentive payment to eligible physicians. For zip codes that cross county boundaries, we used the dominant county of the postal zip code (as determined by the U.S. Postal Service) to identify areas eligible to receive the 5 percent payment. Section 1833(u)(4)(C) of the Act also requires us to publish a list of eligible areas as part of the proposed and final physician fee schedule rules for the years for which PSAs are identified or revised and to post a list of PSAs on our Web site. *See* Addenda J and H for the zip codes of primary care and specialist care PSAs. The PSA lists by zip code and county are also available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment.* Since we are publishing these lists for the first time in this final rule with comment period, we are accepting comments for 60 days after the date of publication of this regulation on the zip codes and counties qualifying as physician scarcity areas and will address the comments in next year's fee schedule.

In addition to creating of the 5 percent PSA incentive payment, section 413 of the MMA amended section 1833(m) of the Act to mandate that we pay the 10 percent health professional shortage areas (HPSA) incentive payment to eligible physicians in full county HPSAs without any requirement that the physician identify the HPSA area. We can only achieve this result by assigning zip codes to eligible areas. *See* Addenda I and K for the lists of eligible primary care and mental health HPSAs by zip code. Consistent with the Act, we have also posted a list of links on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment* to assist those physicians located in eligible areas where automation is not feasible, that is, the eligible area could not be assigned a zip code.

In the August 5, 2004 proposed rule, we proposed conforming changes to our regulations to add § 414.66 to provide a 5 percent incentive payment to eligible physicians furnishing covered services in eligible PSAs. We also proposed conforming changes to our regulations to add § 414.67 to codify the 10 percent incentive payment to eligible physicians furnishing covered services in eligible HPSAs, established under the Omnibus Budget Reconciliation Act of 1987 (OBRA) (Pub. L. 100–203), previously implemented through manual issuance.

We received 23 letter comments on the bonus payment provisions of section 413 of the MMA. A summary of those comments and our responses follows:

Comment: One commenter questioned the rationale behind using zip codes for the purpose of identifying eligible areas for physician bonuses. The commenter believes that zip codes are less accurate than political boundaries (counties, census civil divisions, and census tracts).

Response: The statute requires the identification of PSAs on a county basis, except for rural areas (using the Goldsmith Modification). At this time, we can only determine physician scarcity for Goldsmith areas at the zip code level since the Medicare beneficiary data is currently unavailable at the census tract level.

Automation of physician bonus payments can only be achieved by assigning zip codes to eligible areas. That is, the zip code place of service is the only data element reported on the Medicare claim form that would allow automation.

Comment: A commenter believes that our proposal to identify qualified PSAs and HPSAs by zip code for automatic payment purposes is problematic

because zip codes cross county lines. The commenter suggested that a more user-friendly option would be to add a county identifier to the claim form.

Response: The addition of a county code would not resolve the issue of identifying the claims that would have a bonus because not all designated HPSAs and PSAs are full counties. We cannot identify, for an automated payment, services furnished in counties that are only partially designated and Goldsmith areas that are not full counties. In addition, there currently is no place on the standard electronic claims form to accommodate the entry of a county code.

Comment: A commenter requested clarification regarding circumstances when automation of bonus payments is not feasible.

Response: When the boundaries of zip code areas precisely overlay with the boundaries of eligible HPSAs and PSAs, automation of bonus payments is feasible. In other words, eligible physicians furnishing services to Medicare patients within these zip code areas will automatically receive their bonus payments. We can also automate bonus payments within zip code areas that cross outside of qualified county boundaries as long as the zip code, as determined by the U.S. Postal Service, is dominant to the qualified scarcity county. We cannot automate bonus payments when boundaries of zip code areas only partially coincide with the boundaries of HPSAs and PSAs.

Comment: One commenter requested clarification regarding the application of the billing modifier in determining physician eligibility. The commenter inferred from the proposed rule that, if the zip code is not posted as a qualified area, an eligible physician could still receive a bonus payment if a modifier is used.

Response: Eligible physicians furnishing covered services in a portion of an eligible PSA, which cannot be properly assigned a zip code to permit automation of the bonus payment, would need to include the new physician scarcity modifier on the Medicare claim in order to receive the bonus payment. Lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus are available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment.* If a service is provided in a zip code area that is not listed on the automated payment files, but is within a designated physician scarcity county, the physician must submit the ''AR'' billing modifier with the service in order to receive the bonus payment. Separate lists for the primary care PSAs and the specialty care PSAs are provided on our Web site for both the automated zip codes and the counties.

Comment: A commenter requested clarification on what ratios would be used to identify PSAs. The Health Resources and Services Administration (HRSA) uses a national ratio of 3,500:1, or 3,000:1 if high needs are shown. The commenter requested information on which ratios would be used to determine PSAs for specialty providers, and whether the ratios would be different for different specialty care providers.

Response: Only those counties with the lowest primary care ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties will be considered eligible for the 5 percent incentive payment. In other words, we ranked each county by its ratio of physicians to beneficiaries and then designated counties as scarcity areas with the lowest ratios until 20 percent of the Medicare population was reached. A separate specialist physician ratio was calculated to identify specialist care PSAs using the same methods stated. The statutory mandate precludes us from adopting a national physician-to-patient ratio similar to the HPSA designations. By statute, the 20 percent population threshold must serve as the qualifying condition for all counties/rural areas.

For calculating the ratios, section 1833(u)(6) of the Act, as added by the MMA, defines a primary care physician as a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist. In accordance with the statute, all other physicians were grouped together as specialists for purposes of determining the specialist care PSA list.

Comment: A commenter requested clarification regarding the frequency of updating the eligible zip code list for automatic HPSA bonus payments and its impact on otherwise eligible physicians.

Response: Determination of zip codes eligible for automatic HPSA bonus payment will be made on an annual basis, and there will not be any mid-year updates. We will effectuate revisions made to designations by HRSA the following year for purposes of automatic bonus payments. Consequently, if HRSA changes to the HPSA designations remove physicians in those areas from receiving automatic payment, the zip code areas will remain eligible until the next year when we remove the zip code from our approved list.

Eligible physicians furnishing covered services in newly-designated HPSAs are permitted to add a modifier to their Medicare claims to collect the HPSA incentive payment until our next annual posting of eligible zip codes for automation of bonus payments. In cases where a zip code cannot be properly assigned to the newly-qualified HPSA, physicians furnishing services in the area must continue to bill for the incentive payments using the appropriate modifier.

Comment: A commenter requested that we provide FQHCs with the 5 percent PSA incentive payment. Since the statute does not explicitly exclude other physicians' services (that are billed on an all-inclusive basis), such as those provided in FQHCs or RHCs, the commenter stated that we should extend the new 5 percent bonus payment to FQHC physicians.

Response: As defined in section 1861(aa) of the Act, FQHC and RHC services are not physicians' services, even though physicians' services are frequently a component of the services furnished in these facilities. The services are rather identified as FQHC services. Therefore, services furnished by these providers are not eligible for the incentive payment.

Comment: A commenter has questioned our proposal not to apply the new 5 percent physician incentive payment to the technical component of physicians' services. The commenter stated that extending the new bonus payment to both the professional and technical component of the physicians' services is consistent with Congressional intent and would simplify claims processing.

Response: Section 1833(u) of the Act provides for incentive payments for physicians' services furnished in PSAs. We note that the statute contains two definitions of physicians' services. The first, which appears at section 1861(q) of the Act, defines physicians' services as ''professional services performed by physicians including surgery, consultation, and home, office, and institutional calls.'' The second, which refers to services paid under the physician fee schedule, is found at section 1848(j)(3) of the Act and contains a broader definition of physician services. However, that definition applies only for purposes of section 1848 of the Act.

Since the incentive payment is not included in section 1848 of the Act, the definition of physicians' services specified in section 1861(q) of the Act is the definition that applies. Thus, we believe the best reading of the statute is that only *professional* services furnished

by physicians are eligible for incentive payments.

Comment: A commenter recommended that we extend the HPSA bonus payment to all physicians, regardless of their specialty, when their services are furnished within a mental health HPSA. The commenter believes there is no statutory basis to limit incentive payments just to psychiatrists within mental health HPSAs.

Response: We provide HPSA bonus payments in primary medical care HPSAs to all physicians regardless of specialty (including psychiatrists) in light of the fact that there is significant overlap between primary medical care HPSAs and mental health HPSAs. Furthermore, most primary medical HPSAs, especially in rural areas, also have shortages of specialists. Consequently, there is no apparent need to distinguish between physician specialties within primary medical care HPSAs for determining physician eligibility for bonus payment purposes. However, in the situation where the mental health HPSA does not overlap with a primary medical care HPSA, we allow only psychiatrists to collect the incentive payment. Within these stand-alone mental health HPSAs, there is an adequate supply of physicians for the provision of medical services and a shortage only of those providing mental health services. Therefore, it would be inconsistent with the HPSA incentive payment provisions, as well as an inappropriate use of the Medicare Trust Fund, to pay bonuses to physicians who furnish medical services in service areas without shortages of primary medical services.

Comment: A commenter requested that we count only those practicing physicians who treat Medicare patients when determining the ratio of beneficiaries to practicing physicians. To count all practicing physicians, including those who do not treat Medicare patients would undermine the intent of the provision.

Response: The statute does not permit us to count only Medicare participating physicians to determine PSAs. The statute explicitly requires that we calculate the primary and specialist care ratio by the number of physicians in the active practice of medicine or osteopathy within the county or rural area. Therefore, we must include in the physician tally all actively practicing physicians when determining PSAs.

Comment: A commenter asked that we clarify our methods for determining the number of primary care and specialty care physicians to calculate the physician-to-beneficiary ratio for identifying PSAs. The commenter suggested that we use only the number of practicing physicians when determining the beneficiary to physician ratio, that is, distinguish between licensed physicians and practicing physicians when determining ratios of primary care and specialty care since some physicians continue to be licensed after they retire.

Response: As required by section 413 of the MMA, the determination of eligible PSAs is based on the ratio of ''active practice'' physicians to Medicare beneficiaries within a county or rural area (using the Goldsmith Modification). The physician data source used in calculating scarcity areas is contained in the following:

- The 2001 Physician Characteristics file; and
- The 2001 Physician Address file.

These data are a compilation of:

- The December 2001 AMA Master file;
- The December 2001 American Osteopathic Association (AOA) Physician file; and
- The National Health Service Corps 2001 participant listing.

These physician data files allow for the identification of the physician's active status. Some of the key status indicators to identify practicing physicians include ''clinically active'' and ''Federal employment'' status. Clinically active status was determined using the type of practice, professional employment, and major professional activity fields from AMA and AOA. For example, determining non-active status is based on physicians who—

(1) Are involved in administration, medical teaching, research, and other non-patient care activities; or

(2) Have self-identified as fully retired or otherwise inactive.

We believe that the indicator field of ''fully retired or otherwise inactive'' addresses the specific issue of a physician maintaining his or her license after he or she retires.

Comment: A commenter expressed concern about our use of the AMA database to determine the number of licensed physicians engaged in direct patient care in each State. The commenter claims that the AMA database overstates the number of practicing physicians in the State of California by at least 10,000 physicians. In light of this concern, the commenter stated that we should use State medical board licensing information rather than the AMA database in determining the physician counts.

Response: The physician data source used in calculating scarcity areas is contained in the 2001 Physician Characteristics file and the 2001 Physician Address file. These data are a compilation of the December 2001 AMA Master file, the December 2001 AOA Physician file, and the National Health Service Corps 2001 participant listing. We made the decision to use the AMA Master file as well as the other files as the sources of physician data in scarcity calculations because there is no other adequate source of national physician data. It may be possible to obtain physician data from each individual State agency, but doing so would entail considerable administrative and technical difficulties. Furthermore, methods of gathering and compiling data may be inconsistent in different States. State agencies may vary greatly in terms of the methods used to update physician databases, the frequency of updates, how the data are stored, the type of information collected, and so forth. In addition, States may use their own classification systems for physician specialties, types of practice, and other key information, and these systems may change over time.

Comment: A commenter encouraged us to implement similar incentive payment programs for non-physician practitioners, for example, Certified Registered Nurse Anesthetists and physician assistants.

Response: We do not have the authority to provide bonus payments to non-physicians. Sections 1833(m) and 1833(u) of the Act authorize bonus payments only to physicians.

Comment: A commenter requested that we immediately publish the already identified PSAs by zip code and specify the specialties in short demand within each eligible PSA.

Response: Lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus, are now available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment.* See Addenda J and H for the zip code list of PSAs for primary care and specialist care.

We have forwarded to the Health Resources and Services Administration the request for identification of specialties in short supply within PSAs. That Agency has responsibility for physician manpower issues.

Comment: A commenter requested that the list of scarcity areas should be made interim in the final fee schedule rule in order to give physicians sufficient time to review and comment on the proposal.

Response: Although we made these lists public on our Web site on October 1, 2004, we will accept comments for 60 days after the date of publication of this regulation on the zip codes and counties

qualifying as physician scarcity areas and will address the comments in next year's fee schedule.

Comment: A commenter expressed appreciation for our effort to fairly implement the incentive payments to physicians in scarcity areas. As this new incentive payment program is implemented, physicians must be informed that this bonus is available, and it must be simple for them to receive the bonus.

Response: We have already made available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment* the lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus. We have also issued a *Medlearn* article to educate the physician community regarding Medicare physician incentive payment programs. For a copy of this provider education article go to: *http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SE0449.pd.* Lastly, Medicare's contractors have established their own Web site links for the HPSA incentive payment program to facilitate the payment of these bonuses to eligible physicians.

Comment: A commenter expressed support of our proposed changes relating to incentive payments for services provided in areas designated as HPSAs and PSAs. The commenter also commended us for our prompt implementation of section 413 of the MMA. Another commenter expressed appreciation that the new 5 percent incentive is available to specialists in counties with short supply of these physicians.

Response: We appreciate this positive feedback from the provider community.

Comment: A commenter has questioned the rationale for our policy of imposing, as a condition of eligibility, the requirement that the specific location at which the service is furnished must be considered a HPSA or PSA. Since physicians do not always reside in the county where they provide services, identifying PSAs on one basis and paying for them on another basis may be problematic.

Response: According to section 1833 of the Act, we make bonus payments for physicians' services furnished in an eligible HPSA or PSA. Thus, the place of service controls the availability of the bonus. A physician providing a service in his or her office, a patient's home, or in a hospital may receive the incentive payment only if the service occurs within an eligible shortage or scarcity area.

Comment: One commenter believes that podiatric physicians, who are considered specialists, should be among those eligible to receive the additional 5 percent incentive payment.

Response: Section 1833(u) of the Act, as added by the MMA, specifically defines ''physician'' as one described in section 1861(r)(1) of the Act. Therefore, we do not have authority to make bonus payments to podiatrists.

Commenter: A commenter expressed concern that our systems had trouble implementing the HPSA bonuses under Method II for Critical Access Hospital (CAH) participation, and some providers have waited more than two years for increased Medicare payments.

Response: Although some fiscal intermediaries may not have been accustomed to processing physician claims, these systems were updated and the problems resolved as of July 1, 2004.

Comment: A commenter from California requested that physicians who provide Medicare services only through managed care not be included in our calculations. The commenter believes that including physicians who only treat managed care patients in the count to determine physician scarcity areas will lead to a gross overstatement of the number of physicians available to provide care to fee-for-service Medicare patients.

Response: We do not believe that we have the legal authority to exclude managed care physicians from the ratio calculations. Moreover, excluding managed care physicians in the county-wide physician tally would not change PSAs in California based on our calculations. In fact, excluding the managed care physicians would make five eligible areas ineligible.

Result of Evaluation of Comments

We are finalizing § 414.66 and § 414.67 as proposed. We are accepting public comments on the zip code areas.

E. Section 303—Payment for Covered Outpatient Drugs and Biologicals

1. Average Sales Price (ASP) Payment Methodology

a. Background

Medicare Part B covers a limited number of prescription drugs and biologicals. For the purposes of this proposed rule, the term ''drugs'' will hereafter refer to both drugs and biologicals. Medicare Part B covered drugs generally fall into the following three categories:

- Drugs furnished incident to a physician's service.
- Durable medical equipment (DME) drugs.
- Drugs specifically covered by statute (for example, immunosuppressive drugs).

Section 303(c) of the MMA revises the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303(c) of the MMA amends Title XVIII of the Act by adding section 1847A, which establishes a new ASP drug payment system. In 2005, almost all Medicare Part B drugs not paid on a cost or prospective payment basis will be paid under this system.

The new ASP drug payment system is based on data submitted to us quarterly by manufacturers. Payment amounts will be updated quarterly based on the manufacturer's ASP calculated for the most recent calendar quarter for which data are available. We intend to implement the quarterly pricing changes through program instructions or otherwise, as permitted under Section 1847A(c)(5)(C). For calendar quarters beginning on or after January 1, 2004, the statute requires manufacturers to report their ASP data to us for almost all Medicare Part B drugs not paid on a cost or prospective payment basis. Manufacturers' submissions are due to us not later than 30 days after the last day of each calendar quarter.

The methodology for developing Medicare drug payment allowances based on the manufacturer's submitted ASP data is described in this final rule and reflected in final revisions to the regulations at § 405.517 and new Subpart K in part 414. Several comments discussed aspects of the manufacturers' calculation of ASP that are beyond the scope of this final rule. We did not propose any changes to the regulations concerning the manufacturer's calculation of ASP. We also received other comments regarding the use of the least costly alternative (LCA) methodology when pricing drugs, and requests for new HCPCS codes for drugs and coverage of compounded drugs. These comments are also outside the scope of this final rule. We did not propose any changes to the LCA policy, the HCPCS process, or coverage of compounded drugs.

b. Provisions of the Final Rule

i. The ASP Methodology

Effective 2005, payment for certain drugs and biologicals not paid on a cost or prospective payment basis furnished on or after January 1, 2005 will be based on an ASP methodology.

As described in section 1847A(b)(3)(A) of the Act for multiple source drugs and section 1847A(b)(4)(A) for single source drugs, the ASP for all

drug products included within the same billing and payment code [or HCPCS code] is the volume-weighted average of the manufacturers' average sales prices reported to us across all the NDCs assigned to the HCPCS code. Specifically, section 1847A(b)(3)(A) of the Act and section 1847A(b)(4)(A) of the Act require that this amount be determined by—

- Computing the sum of the products (for each National Drug Code assigned to those drug products) of the manufacturer's average sales price and the total number of units sold; and
- Dividing that sum by the sum of the total number of units sold for all NDCs assigned to those drug products.

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment allowance for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the HCPCS code. This payment allowance is subject to applicable deductible and coinsurance. The payment limit is also subject to the two limitations described below in section III.E.1.b.v of this preamble concerning widely available market prices and average manufacturer prices in the Medicaid drug rebate program. As described in section 1847A(e) of the Act, the payment limit may also be adjusted in response to a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and a concomitant increase in the price of the drug which is not reflected in the manufacturer's average sales price.

Section 1847A(b)(1)(B) of the Act requires that the Medicare payment allowance for a single source drug HCPCS code be equal to the lesser of 106 percent of the average sales price for the HCPCS code or 106 percent of the wholesale acquisition cost of the HCPCS code. This payment allowance is subject to applicable deductible and coinsurance. The payment limit is also subject to the two limitations described below in section III.E.1.b.v concerning widely available market prices and average manufacturer prices in the Medicaid drug rebate program. As described in section 1847A(e) of the Act, the payment limit may also be adjusted in response to a public health emergency under section 319 of the Public Health Service Act.

Comment: One commenter suggested that we implement the ASP methodology on a pilot basis prior to a national rollout. A physician interest group recommended that we delay the implementation of the ASP payment system for at least one year. The interest group stated that we should inform physicians of the ASP for all covered drugs before the final rule is issued and allow physicians to comment on the proposed rates after an informed and complete review process.

Response: The law requires that the new ASP-based drug pricing system be implemented January 1, 2005. The January 1, 2005 prices will be based on the data submitted to us no later than 30 days after the end of the third calendar year quarter of 2004. Given the requirements surrounding the timing of the promulgation of the physician fee schedule final rule, we will not have the January 1, 2005 prices available before the publication of the final rule. However, our goal is to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the January 1, 2005 effective date of those rates.

Comment: A provider asked that we earmark funds to enable physicians to transition from the AWP–15 percent payment system to the ASP + 6 percent payment system.

Response: We do not have statutory authority to create such a transition fund.

Comment: One commenter stated that the ASP plan does not account for price increases in a timely manner. Another commenter expressed concern that because ASP modifications lag by at least two calendar quarters, market prices would not be reflected in a drug's payment limit for at least six months after a pricing adjustment.

Response: The ASP methodology is based on average sales prices reported by manufacturers quarterly. Manufacturers must report to us no later than 30 days after the close of the quarter. We implement these new prices through program instructions or otherwise at the first opportunity after we receive the data, which is the calendar quarter after receipt.

Comment: Some commenters expressed concern that the ASP + 6 percent payment methodology would discourage providers from using generic drugs and would increase the tendency to use newer or more expensive agents.

Response: It is true that the higher the average sales price of a drug, the greater amount of money represented by 6 percent of that price. However, Section 1847A specifies that payment is at 106 percent of ASP. The law requires the use of the new ASP + 6 percent payment system except in the limited instances described below in Sections V and VI.

Comment: Several commenters suggested that we should establish a mechanism to provide the public with an opportunity to identify errors in the ASP-based payment rates before the start of the calendar quarter in which the rates are effective. They believe that this mechanism would minimize errors by permitting posting of the rates several weeks prior to the effective date.

Response: Our goal is to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the effective date of those rates.

Comment: A physician specialty group recommended that we use our inherent reasonableness authority to increase drug payments up to 15 percent where necessary to make the Medicare payment level sufficient to cover the price of drugs charged by specialty distributors that service the physician office market.

Response: We do not have sufficient data to determine whether our inherent reasonableness authority would apply in this instance. Even if our inherent reasonableness authority were triggered, our data are insufficient to determine whether the adjustment the commenters request would be appropriate.

Comment: Several commenters urged us to weigh the full range of potential consequences to patient care, especially in the oncology setting, with the implementation of the ASP payment methodology. They recommended that we take into consideration concerns such as the potential inability of providers to purchase drugs below the new reimbursement rate, the inability of oncologists to provide access to important under-reimbursed support services, and the disproportionate impact of these changes on rural providers necessitating a shift in care of sick cancer patient from community settings to the hospital. Some commenters suggested that we place a form on its Web site enabling beneficiaries to identify access problems. One commenter suggested that we perform a 1-year monitoring study to evaluate the quality of care issues and delay implementation until the results of the study are known.

Response: Although we do not expect access problems under the new ASP + 6 percent payment system, we will be monitoring patient access through our 1–800–MEDICARE line, regional office staff, claims analysis, and other environmental scanning activities. We will work with Congress if access issues arise. The law requires that the new ASP-based drug pricing system be implemented January 1, 2005.

Comment: Several commenters expressed concern regarding the statements on joining group purchasing organizations (GPOs) to improve their purchasing power. They indicate that

the size of the discount is based on the individual GPO member's purchases, not the combined purchases of the GPO members. Thus, membership in a GPO would not necessarily result in a greater discount. They also point out that retail pharmacies do not have access to GPO purchasing arrangements. One commenter requested that we offer more tangible suggestions for obtaining drugs at the ASP +6 percent price other than encouraging physicians to participate in purchasing groups.

Response: The law requires that the new ASP-based drug pricing system be implemented January 1, 2006. A recent survey of oncology practices performed by the American Society of Clinical Oncology indicated that the purchase price of drugs is not necessarily driven by practice size. It would appear that smaller purchasers are on average sometimes able to achieve similar drug pricing to larger purchasers. The OIG is conducting a study due not later than October 1, 2005, on the ability of different size physician practices in the specialties of hematology, hematology/oncology, and medical oncology to obtain drugs at 106 percent of the average sales price. We are currently conducting another MMA-mandated study of sales of drugs to large volume purchasers that is due not later than January 1, 2006. We will seek to work with physicians, providers, and suppliers on ways to encourage prudent purchasing, including to the extent practicable the dissemination of information on lower cost suppliers of Medicare Part B drugs. We would welcome suggestions on ways to accomplish this goal.

Comment: One commenter suggested that classes of trade should be taken into account when establishing ASP payment rates.

Response: The law does not permit the exclusion of or differentiation by classes of trade in the calculation of the ASP payment rates, except for the specific statutory exceptions described in the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act. The statute specifies a payment rate of 106 percent of ASP.

Comment: A drug manufacturer urges us to reject any requests to publish the NDC-specific ASPs as the publishing of the rates would facilitate inappropriate conduct.

Response: The law does not permit the disclosure of NDC level ASPs in a form that discloses the identity of a specific manufacturer or prices charged by the manufacturer except in accordance with Section 1927(b)(3)(D) of the Act. That provision permits the disclosure of such data as the Secretary determines to be necessary to effectuate the provisions of section 1847A of the Act.

v. Limitations on ASP

Section 1847A(d)(1) of the Act states that ''The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.'' Section 1847A(d)(2) of the Act states that ''Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

- The widely available market price for such drugs and biologicals (if any); and
- The average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.''

Section 1847A(d)(3) of the Act states that ''The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).'' Section 1847A(d)(3)(B) states that ''the term 'applicable threshold percentage' means—

- In 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and
- In 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.''

Section 1847A(d)(3)(C) of the Act states that ''If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

- The widely available market price for the drug or biological (if any); or
- 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.''

Comment: One commenter urged us to provide further guidance on the widely available market price (WAMP) methodology, specifically how the OIG will compare ASP to WAMP. The commenter also requested guidance on how WAMP will be determined in the case of multiple drugs represented by a single J-code. Other commenters stated that we should provide greater guidance for how it will substitute WAMP for ASP. These commenters also suggested that we provide guidance on how it will treat quarterly oscillations between ASP and WAMP.

Response: The OIG is developing its methodology regarding the widely available market price. Because the determination of WAMP is within OIG's purview, we believe it is premature to address the implementation issues prior to the OIG establishing its methodology and conducting its first review.

Comment: Several commenters recommend that we make adjustments where there is a disparity between the ASP-based payment limit and the physician acquisition cost. These commenters recommended that we raise the payment rate if the WAMP is higher than ASP.

Response: Section 1847A of the Act does not provide authority to increase the ASP-based payment system based on the review of the OIG.

vi. Payment Methodology in Cases Where the Average Sales Price During the First Quarter of Sales Is Unavailable

Section 1847A(c)(4) of the Act states that ''In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—

- The wholesale acquisition cost; or
- The methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.''

Comment: Several commenters requested that we provide guidance on how the payment rate for a new drug in its second calendar quarter will be determined. They recommend that we utilize the same methodology for the 2nd quarter payment as for the 1st quarter; that is, use the WAC or methodologies in effect on November 1, 2003.

Response: Pursuant to section 1847A(c)(4) of the Act, during an initial period (not to exceed a full calendar quarter) where data on prices for sales for a drug are not sufficiently available from the manufacturer to compute an ASP, we will pay based on WAC or the methodologies in effect on November 1, 2003 for a limited period. This time period will start on the date that sales of the drug begin and end at the beginning of the quarter after we receive information from the manufacturer regarding ASP for the first full quarter of sales.

c. Payment for Influenza, Pneumococcal, and Hepatitis B Vaccines

Section 1841(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of the average wholesale price (AWP) of the drug. The AWP payment rates for these vaccines will be updated quarterly. No commenters objected.

d. Payment for Drugs Furnished During 2005 in Connection With the Furnishing of Renal Dialysis Services if Separately Billed by Renal Dialysis Facilities

Section 1881(b)(13)(A)(ii) of the Act indicates that payment for a drug furnished during 2005 in connection with the furnishing of renal dialysis services, if separately billed by renal dialysis facilities, will be based on the acquisition cost of the drug as determined by the Inspector General(IG) report to the Secretary required by section 623(c) of the MMA or, insofar as the IG has not determined the acquisition cost with respect to a drug, the Secretary shall determine the payment amount for the drug. In the report, ''Medicare Reimbursement for Existing End-Stage Renal Disease Drugs,'' the IG found that, on average, in 2003 the four largest chains had drug acquisition costs that were 6 percent lower than the ASP of 10 of the top drugs, including erythropoietin. A sample of the remaining independent facilities had acquisition costs that were 4 percent above the ASP. Based on this information, the overall weighted average drug acquisition cost for renal dialysis facilities is 3 percent lower than the ASP. Therefore, we proposed that payment for a drug or biological furnished during 2005 in connection with renal dialysis services and separately billed by renal dialysis facilities will be based on the ASP of the drug minus 3 percent. We proposed to update this quarterly based on the ASP reported to us by drug manufacturers.

We received numerous comments regarding our proposed payments rate of ASP minus 3 percent. Those comments and responses are provided below.

Comment: Commenters questioned the basis for our decision to pay for separately reimbursed drugs at a rate of ASP minus three percent. These commenters stated that ASP minus 3 percent was not acquisition cost as determined by OIG and did not reflect the acquisition cost relationship between these drugs. Some commenters questioned the relationship between the ASP definition used by the OIG and the current definition. Commenters stated that we should base the payment rates on the acquisition cost of each drug as reported by the OIG updated to 2005 rather than an ASP-based formula. Some commenters indicated that the acquisition cost should be updated to 2005 and suggested an update using the same annual factor used for budget neutrality calculations. For drugs not included in the OIG report, some commenters suggested that we use the same methodology for most other Medicare Part B drugs, namely ASP plus 6 percent. Commenters indicated we should consider two tiers of payment based on provider size to minimize the discrepancy between large and small providers or in the absence of two tiers base the payment on the acquisition cost of the facilities not owned or managed by the four largest providers. Commenters also asked for clarification of the payment basis for separately billable ESRD drugs other than EPO billed by hospital based ESRD facilities since these drugs historically were not paid based on AWP but rather based on reasonable cost.

Response: We agree with the commenters who suggested we base the 2005 payment rates for separately billable ESRD drugs on the actual dollar value of the acquisition costs as determined by the IG rather than the acquisition costs relative to the ASP. We also agree that we should update the IG acquisition costs to calculate 2005 rates. After consideration of the available price data, we have determined that the Producer Price Index (PPI) for prescription preparations is the most appropriate price measure for updating EPO and other separately billable drugs from 2003 to 2005. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) for prescription drugs reflects price changes at the retail stage. Because EPO and many of the separately billable drugs used by dialysis facilities are purchased directly from the manufacturer, the use of a price index that measures wholesale rather than retail prices is more appropriate. The PPI for prescription drugs is the measure used in the various market baskets that update Medicare payments to hospitals, physicians, skilled nursing facilities, and home health agencies. In addition, the PPI for prescription drugs was recommended for use in the proposed composite rate market basket detailed in the 2003 Report to Congress.

Based on historical data through the second quarter of 2004, we used the Global Insight Inc. forecast of the PPI for prescription drugs to determine the update factors for 2004 and 2005. We feel the use of an independent forecast, in this case from Global Insight Inc., is superior to using the Naational Health Expenditure projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases for Medicare prospective payment systems.

We also agree with those commenters who suggested that the drugs not contained in the IG study should be paid at ASP plus 6 percent. We believe it is appropriate for the payment amount for these drugs when separately billed by ESRD facilities during 2005 to be the same as the payment amount for other entities that are paid by Medicare on other than a cost or prospective payment basis. We do not agree with commenters that we should establish separate drug payment rates for large and small providers. For reasons discussed in the section of this final rule on the ESRD composite rate, we believe it is appropriate to establish a single add-on payment to the composite rate and therefore appropriate to establish the same drug payment rates for both large and small providers. We do not believe it is appropriate to base the payment amount on only the higher acquisition cost of the facilities not owned or managed by the four largest providers and not take into account the acquisition costs of the largest four providers who represent the majority of the drug expenditures. Section 1881(b)(13)(A)(ii) of the Social Security Act refers to ''the acquisition cost of the drug or biological'' and not the acquisition costs of the drug or biological. In accordance with the statute and our understanding of Congressional intent for 2005, we believe it is more appropriate to base the 2005 payment amounts on a weighted average of the acquisition costs of the four largest providers and the other

facilities rather than base the 2005 payment amounts solely on the acquisition costs of the other facilities.

In response to the commenters who requested clarification of the payment basis for separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities, we did not propose changes to the reasonable cost payment basis for these drugs. The OIG did not study separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities and accordingly, we did not propose to change the payment basis for these drugs.

e. Payment for Infusion Drugs Furnished Through an Item of DME

In 2005, section 1841(o)(1)(D)(i) of the Act requires that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent of the average wholesale price for that drug in effect on October 1, 2003. No commenters objected.

2. Drug Administration Payment Policy and Coding Effective in 2005

Section 1848(c)(2)(J) of the Act (as added by section 303(a) of the MMA) requires the Secretary to promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for those services, taking into account levels of complexity of the administration and resource consumption. According to section 1848(c)(2)(B)(iv) of the Act (as amended by section 303(a) of the MMA), any changes in expenditures in 2005 or 2006 resulting from this review are exempt from the budget neutrality requirement of section 1848(c)(2)(B)(ii) of the Act. The statute further indicates that the Secretary shall use existing processes for the consideration of coding changes and, to the extent changes are made, shall use those processes to establish relative values for those services. The Secretary is also required to consult with physician specialties affected by the provisions that change Medicare payments for drugs and drug administration.

The AMA's CPT Editorial Panel established a workgroup, with representatives from affected specialties that met earlier this year to develop recommendations to the CPT Editorial Panel in August. Based on these recommendations, that panel adopted several new drug administration codes and revised several existing codes. Subsequently, the AMA's Relative Value Update Committee (RUC) met at the end of September to make recommendations to us on the practice expense resource inputs and work relative values for the new and revised drug administration codes.

We indicated in the proposed rule that we would consider whether it is necessary for us to make coding changes effective January 1, 2005 through the use of G-codes (because the 2005 CPT book will have already been published), and we requested public comment. As described in detail below, we are establishing new G-codes for 2005 that correspond with the new CPT codes that will become active in 2006. These new G-codes are interim until 2006.

The new CPT codes can be categorized into the following three categories of drug administration services: infusion for hydration; nonchemotherapy therapeutic/diagnostic injections and infusions other than hydration; and chemotherapy administration (other than hydration) which includes infusions/injections. There are some important changes in the new codes relative to current drug administration coding. The infusion of substances such as monoclonal antibody agents or other biologic response modifiers is reported under the chemotherapy codes, instead of the nonchemotherapy infusion codes, as is currently the case. There are also new codes in both the chemotherapy and nonchemotherapy sections for reporting the additional sequential infusion of different substances or drugs.

As we stated in the proposed rule, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue. We also note that the MMA requires the Medicare Payment Advisory Commission (MedPAC) to study how the changes in payments for drugs and drug administration affect other specialties.

We received many comments on various aspects of coding and payment for drug administration services in response to the proposed rule. We are also responding below to comments we received on the January 7, 2004 interim final rule with comment period that announced the provisions of section 303 of the MMA affecting drug administration services that took effect in 2004 (69 FR 1094). Specifically, section 303 of the MMA required the following changes in 2004: a transitional adjustment that increases payments for specific drug administration services by 32 percent in 2004 (and 3 percent in 2005); establishing work RVUs for certain drug administration services equal to the work RVUs for a level 1 office medical visit for an established patient; the incorporation of supplemental survey data in the calculation of the practice expense RVUs for drug administration codes; and allowing oncologists to bill for multiple drug administrations by the ''push'' technique on a single day.

Comment: Many commenters supported the efforts to promptly evaluate existing drug administration codes to ensure accurate reporting and billing for services. They support our proposal to use G-codes until the new CPT codes are active. They asked us to adopt the recommendations of the CPT Editorial Panel for new drug administration codes.

Response: We appreciate the support of the commenters of all of the efforts to expeditiously review and update these codes. We also would like to specifically recognize the efforts of the CPT Editorial Panel's Drug Administration Workgroup to develop the new CPT codes, the Editorial Panel for its consideration and approval of the new codes, and the RUC for its similar efforts to develop recommendations for the inputs for the new codes.

We have reviewed the recommendations of the CPT Editorial Panel and, with one exception noted below, agree with their new and revised codes for drug administration for 2005. Because the new CPT codes will not be included in the 2005 CPT, we have decided to establish G-codes, where applicable. At this time, we anticipate these new G-codes will be temporary until the new CPT codes become active January 1, 2006.

A listing of the old CPT codes and their corresponding G-codes are in the table below. Some of the old CPT codes will correspond to more than one G-code, and there are codes that will allow physicians to bill for services that previously did not have a code or were bundled into other services.

The drug administration codes are divided into three categories: infusion codes for hydration; codes for therapeutic/diagnostic injections; and chemotherapy administration codes. The descriptions of the codes below are taken primarily from the AMA CPT Editorial Panel. We are including these specific descriptions here in order to provide as much information as possible about the new G-codes prior to their implementation on January 1, 2005. However, we anticipate that we will issue further instructions regarding the appropriate use of these G-codes, including clarifications, interpretations, and other modifications to the following guidance (apart from the G-codes

themselves) as part of any instructions issued through a subregulatory process.

The codes for hydration (G0345 and G0346 in the table below) are for reporting hydration intravenous (IV) infusions consisting of a prepackaged fluid and electrolytes. These codes are not used to report infusion of drugs or other substances. The codes for chemotherapy administration are to be used for reporting the administration of non-radionuclide anti-neoplastic drugs, and anti-neoplastic agents provided for treatment of noncancer diagnoses, or substances such as monoclonal antibody agents and other biologic response modifiers. The remaining codes are for reporting injections and infusions for all drug administrations that were previously reported using CPT codes 90780–90788, 96400, and 96408–96414 (other than those described above as hydration or chemotherapy).

TABLE 8: Comparison of old CPT codes to G codes

Hydration

Old CPT	G Code	Descriptor
90780	G0345	Intravenous infusion, hydration; initial, up to one hour
90781	G0346	each additional hour, up to eight (8) hours

Injections and Infusions (Non-Chemotherapy, other than hydration)

Old CPT	G Code	Descriptor
90780	G0347	Intravenous infusion, for therapy/diagnosis, initial, up to one hour
90781	G0349	additional sequential infusion, up to one hour
90781	G0348	each additional hour, up to eight (8) hours
N/A	G0350	Concurrent infusion

Old CPT	G Code	Descriptor
90782	G0351	Therapeutic or diagnostic injection
90783	N/A	intra-arterial
90784	G0353	intravenous push, single or initial substance/drug
N/A	G0354	each additional sequential intravenous push
90788	N/A	Intramuscular injection of antibiotic
90799	N/A	Unlisted injection or infusion

Chemotherapy Administration

Old CPT	G Code	Descriptor
96400	G0355	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96400	G0356	hormonal anti-neoplastic
96405	N/A	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	N/A	intralesional, more than 7 lesions
96408	G0357	intravenous, push technique, single or initial substance/drug
96408	G0358	intravenous, push technique, each additional substance/drug
96410	G0359	Chemotherapy administration, intravenous infusion technique; Up to one hour, single or initial substance/drug
96412	G0360	each additional hour, one to eight (8) hours
96414	G0361	initiation of prolonged chemotherapy infusion
96412	G0362	each additional sequential infusion, up to one hour
96420	N/A	Chemotherapy administration, intra-arterial; push technique
96422	N/A	infusion technique, up to one hour
96423	N/A	infusion technique, each additional hour, one to eight hours

96425	N/A	infusion technique, initiation of prolonged infusion (more than eight hours)
96440	N/A	Chemotherapy administration into pleural cavity
96445	N/A	Chemotherapy administration into peritoneal cavity
96450	N/A	Chemotherapy administration into CNS
96520	N/A	Refilling and maintenance of portable pump
N/A	G0363	Irrigation of implanted venous access device for drug delivery systems
96530	N/A	Refilling and maintenance of implantable pump
96542	N/A	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents

The following coding guidance is based on the CPT Editorial Panel's explanatory language for the new CPT codes. As noted above, we plan to issue further guidance as needed.

Infusions that were previously reported under CPT code 90780 (non-chemotherapy infusion, 1st hour) will be billed under one of three G-codes beginning January 1, 2005. The first hour of a hydration infusion will be billed under G0345. The first hour of infusion of a nonchemotherapy drug other than hydration will be billed under G0347. The first hour of infusion of anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents and other biologic response modifiers is billed under G0359.

Similarly, services that were previously reported under CPT code 90781 (non-chemotherapy infusion, each additional hour) will be billed under one of four G-codes beginning January 1, 2005. Each additional hour of a hydration infusion will be billed under G0346. Each additional hour of a nonchemotherapy infusion will be billed under G0348. Currently, if a second (or other subsequent) nonchemotherapy drug is administered sequentially, the physician would bill code 90781 for the additional hour of infusion. Under the new G-codes, the physician will bill G0349, the sequential administration of a second or subsequent nonchemotherapy drug. In addition, each additional hour of the infusion of anti-neoplastic agents for the treatment of noncancer diagnoses or substances such as monoclonal antibodies and other biological modifiers is billed under G0360.

Injections that were previously billed under CPT code 90782 will now be billed under HCPCS code G0351. Physicians should use HCPCS code G0352 for injections previously billed under CPT code 90783. Nonchemotherapy drugs administered by IV push (currently using CPT code 90784) should now be billed under HCPCS code G0353. The CPT book does not currently contain a code for physicians to bill a second (or other subsequent) nonchemotherapy drug administered by IV push. The CPT Editorial Panel created a new code for each additional nonchemotherapy drug administered by IV push. For 2005, the physician should bill HCPCS code G0354.

The CPT coding system will be deleting code 90788 (Intramuscular injection of antibiotic) in 2006. We are maintaining CPT code 90788 as an active code until it is changed in the CPT coding system and instructions are provided on the code to bill in its place beginning January 1, 2006.

Chemotherapy injections, previously billed under the CPT code 96400, will now be billed using one of two new G-codes. For injection of nonhormonal anti-neoplastic drugs, the physician should bill HCPCS code G0355. For injection of hormonal anti-neoplastic drugs, the physician should bill HCPCS code G0356. CPT is not recommending any changes to CPT codes 96405 (Chemotherapy administration; intralesional, up to and including 7 lesions) and 96406 (more than 7 lesions), and these codes will remain active for Medicare in 2005.

Chemotherapy drugs administered by IV push (currently billed under CPT code 96408, or, if the drug meets the expanded definition of chemotherapy including monoclonal antibodies or other biologic response modifiers, currently billed under CPT code 90784) should be billed using G0357 for the initial drug administered. In 2004, Medicare paid for the second (or other subsequent) chemotherapy drug administered by IV push under CPT code 96408. CPT will be establishing a code that recognizes the resource inputs associated with each additional chemotherapy drug administered by IV push. For 2005, the analogous code to bill the second (or other subsequent) chemotherapy drug administered by IV push is G0358.

The first hour of chemotherapy administration, previously billed under CPT code 96410, should now be billed under CPT code G0359. Each additional hour of chemotherapy (previously billed under CPT code 96412) should now be billed under CPT code G0360. CPT is also recommending a new code for the first hour of a different chemotherapy drug administered sequentially by infusion. If a second chemotherapy drug is administered sequentially, the physician should bill for HCPCS G0362 for the first hour of infusion of the second drug. All additional hours (up to eight total hours) of chemotherapy infusion should be billed using HCPCS code G0360. Prolonged chemotherapy infusions (8 hours or more, previously billed under code 96414) should be billed in 2005 using HCPCS code G0361.

For three codes (G0350, G0354, G0363), the table above has an ''N/A'' listed in the ''Old CPT'' column, meaning there were no CPT codes that existed explicitly for these services. These services will now be billable under the new coding system. For instance, CPT will be establishing a code for a ''concurrent infusion.'' A concurrent infusion refers to the simultaneous infusion of two nonchemotherapy drugs. We are using temporary code G0350 for this service. Code G0350 is an add-on code. It must be reported as an ''add-on'' or with another code and our payment reflects the incremental resources associated with infusing the second drug. For example, if two nonchemotherapy drugs are infused concurrently, the physician bills G0347 for the initial drug infused and G0350 as an add-on.

As indicated above, HCPCS code G0354 is a new code for each additional sequentialnonchemotherapy drug administered by IV push. HCPCS code G0354 is also an add-on code. In general, G0354 will be an add-on to G0353. However, it is possible that a nonchemotherapy drug administered by IV push may follow the administration of a chemotherapy drug administered by IV push, and HCPCS code G0354 would then be an add-on to HCPCS code G0357.

HCPCS code G0363 is a new code for irrigation of an implanted venous access device. There is currently no code to describe this service. Medicare will pay for G0363 if it is the only service provided that day. If there is a visit or other drug administration service provided on the same day, payment for this service is bundled into payment for the other service.

We are creating the following new add-on G-codes: G0346, G0348, G0349, G0350, G0354, G0358, G0360 and G0362. As indicated above, add-on codes must be billed with other codes, and our payment reflects the incremental resources associated with providing the additional service. The initial codes that these add-on codes could potentially be billed with include: G0345, G0347, G0353, G0357 and G0359. If a combination of chemotherapy, nonchemotherapy drugs, and/or hydration is administered by infusion sequentially, the initial code that best describes the service should always be billed irrespective of the order in which the infusions occur.

Comment: In the January 7, 2004 interim final rule with comment, we revised our payment policy for pushes of chemotherapy drugs to allow for payment of multiple pushes of different chemotherapy agents in one day. A commenter asked that we revise our policy for multiple pushes of nonchemotherapy agents, to allow multiple billings on a single day.

Response: The CPT/RUC recommendations address this comment. New codes have been created to account for the resources associated with multiple chemotherapy and nonchemotherapy drugs administered by IV push. HCPCS code G0353 is used for the initial IV push of a nonchemotherapy drug, while HCPCS code G0354 is used for each additional push of a nonchemotherapy drug. For chemotherapy drugs administered by IV push, HCPCS code G0357 is used for the first drug administered, while HCPCS code G0358 is used for each additional drug.

We also note that existing CPT codes 90782–90788 (Therapeutic, prophylactic or diagnostic injections) currently have a status indicator of ''T'', which means that payment for the service is bundled unless it is the only service billed by the physician for the patient that day. However, based on the RUC recommendations and the resulting values for the injection services, we are making the status indicator on HCPCS codes G0351—G0354 an ''A'', which will allow them to be separately paid even if another physician fee schedule service is billed for the same patient that day.

Comment: A commenter stated that, given the increased work and practice expense RVUs for drug administration codes, it follows that both the work and practice expense RVUs for the immunization administration codes (90471, 90472, 90473, and 90474) should also be increased. The commenter argued that the service involved in administering vaccines is more intense/complex than the service involved in the drug infusion codes.

Response: We agree with the commenter that the physician work and practice expenses associated with administering injections are similar to immunizations. In addition, we would point out that we currently pay for vaccine administrations (G0008–G0010) based on crosswalking the RVUs to CPT code 90471. Therefore, any changes to the physician work and practice expense RVUs for code 90471 would also affect payments for vaccine administrations.

Because we agree these services should be similar in the amount of physician work involved, we are assigning the physician work value recommended by the RUC for code 90782 (G-code G0351) to code 90471 and HCPCS G-codes G0008–G0010. We are combining the utilization data for all of these codes to determine a single practice expense RVU that will be applied to each of these codes.

We are also assigning a work RVU of 0.15 to code 90472. Codes 90473 (Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)) and 90474 (Each additional vaccine (single or combination vaccine/toxoid)) are currently not covered. We are changing the status of these codes to ''R'', or restricted, meaning they are payable under some circumstances after carrier review. These codes will be carrier priced.

Comment: If a patient receives chemotherapy infusions, CPT code 96410 is used to report the infusion of the first drug up to one hour. Chemotherapy drugs are usually administered sequentially. Thus, if a patient receives the administration of a second chemotherapy drug at the same treatment session, CPT code 96412 is used to report the infusion of the second drug for each additional hour of infusion. In 2004, the national payment, including the transitional payment adjustment of 32 percent, for CPT code 96410 is $217. The comparable payment for CPT code 96412 is $48.

Commenters pointed out that this policy does not take into account the levels of complexity of administration and resource consumption. The administration of multiple drugs requires additional preparation time, supplies, and patient education, not currently accounted for in CPT code 96412.

Response: The CPT/RUC recommendations addressed this issue. We are implementing new code G0362, Chemotherapy administration, intravenous technique; each additional sequential infusion, up to one hour. This code will allow, effective January 1, 2005, physicians to begin to bill for the first hour of chemotherapy of the second chemotherapy drug administered.

Comment: Several commenters requested clarification that the changes to the drug administration codes resulting from the CPT changes and our G-codes would be exempted from budget neutrality by the provision at section 1848(c)(2)(B)(iv)(III), as added by MMA section 303(a)(1). This provision stipulates that the evaluation of the existing drug administration codes described above as leading to the interim G-codes and the new CPT codes for 2006, is to be exempt from budget neutrality.

Response: The commenters are correct that the additional expenditures that result from the interim G-code changes we are implementing in this rule are exempt from budget neutrality.

Comment: Several commenters asked that we continue payment for drug administration codes at the 2004 levels, which included the 32 percent transitional payment adjustment, instead of paying at the 3 percent transitional payment adjustment for 2005, or adopt other measures. For example, commenters suggested temporary codes to offset the large reductions that would otherwise go into effect in 2005.

Response: Section 303(a)(4) of the MMA is very specific on the application of the transitional payment adjustments in 2004 and 2005. We do not have the legal authority to continue payments based on the 2004 payment levels. In 2005, the transitional adjustment percentage for drug administration

decreases from 32 percent to 3 percent. No transitional percentage is applied in 2006 or subsequent years.

Comment: One commenter requested additional temporary G-codes to offset the payment reductions for oncologists that would otherwise go into effect in 2005. According to this commenter, the payment amount associated with each of these codes would be a percentage add-on amount sufficient to offset the reductions in drug margins and payments for drug administration services.

Response: We have worked extensively with the major associations representing oncologists and their patients to ensure that Medicare continues to pay appropriately for these extremely critical services. The payment changes we made for 2004, the new G-codes, and allowing additional payment for injections and additional infusions, either have already increased, or will increase, payments for drug administration services. The impacts of these changes are discussed extensively in the impact analysis section of this final rule.

In addition, as we indicated above, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue.

Comment: One commenter expressed concern that the reductions in payments to oncologists described in the proposed rule could make it difficult, if not impossible, for many patients to continue to access cancer care in nonhospital community settings.

Response: As noted above, we have taken several steps to increase payments for drug administration services in this final rule. We recognize that oncology patients in the Medicare population undergoing chemotherapy face serious and unique issues and problems related to quality of care throughout the life cycle of their disease process; from the time of first diagnosis, through treatment, until the patient experiences an end to medical (including hospice) care. Patients, national cancer organizations, and medical providers have identified certain factors that they believe affect the comfort and ultimately the care for cancer patients in the physician office setting.

We believe that the goals and objectives of optimal treatment include reviewing and analyzing pain control management, minimization of nausea and vomiting, explaining treatment options, outlining existing chemotherapy regimens, assessing quality of life, assessing patient symptoms and complaints, supporting and educating caregivers, and avoidance of unnecessary Emergency Department visits and inpatient hospitalizations. Further, we believe that clinicians armed with appropriate assessments can proactively intervene with medical treatment and nonmedical assistance to help ameliorate some of the distressing and unpleasant, but frequent and predictable, events that may accompany certain cancers and chemotherapeutic regimens used to combat cancer.

The Secretary has been given the authority under sections 402(a)(1)(B) and 402(a)(2) of the Social Security Act Amendments of 1967 (Pub. L. 90–248), as amended, to develop and engage in experiments and demonstration projects to provide incentives for economy, while maintaining or improving quality in provision of health services. In order to identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population, we will initiate a one-year demonstration project for CY 2005. While we encourage optimal care in all facets of treatment, the focus of the demonstration project will be on three areas of concern often cited by patients: pain control management, the minimization of nausea and vomiting, and the reduction of fatigue.

Practitioners participating in the project must provide and document specified services related to pain control management and minimization of nausea and vomiting, and the reduction of fatigue. To facilitate the collection of this information, we have established 12 new G-codes to be reported by program participants.

G-Codes for Assessment of Nausea and/or Vomiting

G9021: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level one: not at all (for use in a Medicare-approved demonstration project).

G9022: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level two: a little (for use in a Medicare-approved demonstration project).

G9023: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level three: quite a bit (for use in a Medicare-approved demonstration project).

G9024: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level four: very much (for use in a Medicare-approved demonstration project).

G-Codes for Assessment for Pain

G9025: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare-approved demonstration project).

G9026: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare-approved demonstration project).

G9027: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment level three: quite a bit (for use in a Medicare-approved demonstration project).

G9028: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project).

G-Codes for Assessment for Lack of Energy (Fatigue)

G9029: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare approved demonstration project).

G9030: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare approved demonstration project).

G9031: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level three: quite a bit (for use in a Medicare approved demonstration project).

G9032: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project).

The codes correspond to four patient assessment levels (''not at all,'' ''a little,'' ''quite a bit,'' or ''very much'') for each of the following three patient status factors: nausea and/or vomiting;

pain; and lack of energy (fatigue). These levels, based on the Rotterdam scale, were chosen since they appear to be less burdensome for the practitioner and more easily understood by the patient. Participating practitioners must bill the applicable G-codes for each patient status factor (that is, one G-code each for patient comfort assessment factors: nausea and/or vomiting; pain; and fatigue) assessed during a chemotherapy encounter in order to receive payment under the demonstration. A G-code for each patient status factor must appear on the claim for payment to be made under the demonstration project. A patient chemotherapy encounter is defined as chemotherapy administered through intravenous infusion or push, limited to once per day. During the course of the demonstration, an additional payment of $130 per encounter will be paid to participating practitioners for submitting the patient assessment data as described above.

Any office-based physician or nonphysician practitioner operating within the State scope of practice laws who takes care of and administers chemotherapy to oncology patients in an office setting is eligible to participate in this demonstration project. By billing the designated G-codes, the practitioner self-enrolls in the project and agrees to all of the terms and conditions of the demonstration project.

This information will help us to work with those who care for cancer patients to determine ways to improve the quality of care and quality of life for patients as demonstrated by measuring objective parameters and the medical response to those standardized measurements. The evaluation of the project will be based on data reported to us by the practitioners and the use of our administrative claims data to examine Emergency Department visits and inpatient hospitalizations.

We anticipate that further information regarding this demonstration project will be forthcoming after publication of this final rule.

Comment: Commenters pointed out that, under the MMA, we added physician work RVUs to specified drug administration codes equivalent to a level 1 established office visit. They indicated that we should also have increased the practice expense inputs for the same drug administration codes to account for the practice expense inputs associated with a level 1 established office visit.

Response: Section 1848(c)(2)(H)(iii) of the Act (as added by 303(a)(1)(B) of the MMA) specified that we increase the work RVUs for drug administration services equal to the work RVUs for a level 1 established patient office visit (CPT code 99211). As indicated in the January 7, 2004 **Federal Register** (69 FR 1093), we established work RVUs of 0.17 for specific CPT codes that met the statutory definition of ''drug administration services.''

However, the legislation did not direct us to also increase the practice expense RVUs of the drug administration codes to include the clinical staff time associated with a level 1 office visit. The practice expense inputs of the existing CPT codes for drug administration were refined in 2002. We believe the recommendations from the PEAC included the typical clinical staff time associated with each drug administration service.

The CPT Editorial Panel approved new and revised codes for drug administration services for 2005. Depending upon the service, the RUC is recommending work RVUs for the new drug administration codes that may equal, exceed or be less than 0.17. Although section 1848(c)(2)(H)(iii) of the Act requires that the work RVUs for drug administration services shall equal those of a level 1 office medical visit, new subparagraph (J) requires the Secretary to ''promptly evaluate existing drug administration codes for physicians' services''. The statute further indicates that the ''Secretary shall use existing processes for the consideration of coding changes and * * * in establishing relative values * * *''

Because we typically use the CPT and RUC processes to establish codes and relative values, we believe the statute gives us authority to establish work RVUs at a level other than those of a level 1 established patient office visit. Therefore, for 2005, we are accepting the RUC recommendations for the interim G-codes even though they result in work RVUs that are different than 0.17.

Comment: Several organizations and physicians commented that the Medicare payments for the chemotherapy codes do not include payment for many services provided by an oncology practice. These services include support services such as nutrition counseling, social work services, case management, psychosocial counseling, and educational services provided by an oncology nurse to the patient.

Response: Under certain circumstances, Medicare does make explicit payment for clinical social worker and medical nutrition therapy services. Medicare can pay separately for the services of clinical psychologists (CPs), clinical social workers (CSWs), and nurse practitioners (NPs), clinical nurse specialists (CNS) and physician assistants (PAs).

CPs can bill directly for services and supplies they are legally authorized by the State to perform that could also be furnished by a physician or incident to a physician's service. Payment for CP services is made at 100 percent of the physician fee schedule for services they are authorized to provide that are comparable to those of a physician.

CSWs can furnish services for the diagnosis and treatment of mental illnesses that they are legally authorized by the State to provide. Payment for CSW services is made at 75 percent of the CP fee schedule, which is 100 percent of the physician fee schedule.

NPs, CNSs and PAs can bill for mental health services consistent with their authority under law to furnish physician services. They may also bill for services furnished incident to their own professional services that fall under the State scopes of practice. Payment for these services is made at 85 percent of the physician fee schedule. Medicare will pay for medical nutrition therapy services provided by a registered dietitian or nutrition professional for a beneficiary with diabetes or renal disease. Based on a comment on our August 20, 2003 proposed rule (68 FR 50428), we understand that social worker services could involve different tasks (''helping patients with their health insurance, filling and refilling prescriptions'') than those that are explicitly paid for by Medicare. However, we believe Medicare does pay for these services indirectly through the practice expense RVUs for drug administration services. If these services are typically provided to cancer patients, we believe the RUC could consider whether it is possible for resource inputs for these types of staff to be incorporated into the new drug administration codes. We also believe that the RUC could consider whether these types of staff activities are unique to physicians who provide drug administration or if they apply to other physicians' services as well.

Comment: Current CPT code 96412 (infusion techniques, one to 8 hours, each additional hour) is an add-on code, billed in addition to the primary code, 96410 (the first hour of chemotherapy). There is no national coding policy that explains how this add-on code is to be reported if less than a full hour of chemotherapy infusion is provided. A commenter pointed out that the Medicare carriers have different policies for reporting this service. Some carriers require the infusion to extend at least 16 minutes into the subsequent hour before

an add-on code can be billed, and others impose a 31 minute requirement. The commenter asked that we establish a uniform policy for the carriers to follow.

Response: The CPT Editorial Panel addressed this issue as part of its review of the drug administration codes. Effective in 2006, the add-on code is to be used for ''infusion intervals of greater than thirty minutes beyond one hour increments''. We are adopting this policy for chemotherapy administration codes furnished on or after January 1, 2005.

Comment: The nonchemotherapy subcutaneous injection is currently reported and paid under CPT code 90782, while a chemotherapy subcutaneous injection is currently reported under CPT code 96400. Some commenters recommended that we permit billing for nonchemotherapy injections for cancer patients to be made under CPT code 96400. They believe this code more appropriately reflects the practice expenses related to supportive care for chemotherapy.

Response: The CPT Editorial Panel explicitly addressed this issue by creating separate drug administration codes for hydration, nonchemotherapy infusions and injections, and chemotherapy infusions and injections. It further expanded the definition of chemotherapy to include those drugs where the resource costs associated with the drug administration are similar to those administered as anti-neoplastics. Other drugs administered in support of chemotherapy, such as anti-emetics and drugs to prevent anemia, are billed using the injection code, G0351, which replaces CPT code 90782 (consistent with the CPT recommendations). We have reviewed the practice expense inputs for this code from the RUC and accepted their recommendation.

Comment: Some commenters asked that complex non-oncology infusions, such as Remicade, be paid at the same level as chemotherapy infusions. They indicate that these nonchemotherapy infusions have similar complexity and resource use as chemotherapy infusions.

Response: The CPT recommendations address this issue. The codes for chemotherapy administration are for reporting the administration of non-radionuclide, anti-neoplastic drugs, anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents, and other biologic response modifiers.

Comment: Some commenters inquired about the recognition of a severe drug reaction management code that could be used during the administration of high complexity biologic medications and less frequently during other drug administrations or chemotherapy services. While the CPT Drug Administration Workgroup supported the creation of a severe drug reaction management code, the CPT Editorial Panel did not approve this code.

Response: We recognize that considerable physician effort may be required to monitor and attend to patients who develop significant adverse reactions to chemotherapy drugs, or otherwise have complications in the course of chemotherapy treatment. Physicians may not be aware that these services can be billed using existing CPT codes. The following scenarios are examples where existing codes may be used in addition to the routine billing for the physician's care of a cancer patient:

- Bill for the Physician Visit. If a patient has a significant adverse reaction to drugs during a chemotherapy session and the physician intervenes, the physician could bill for a visit in addition to the chemotherapy administration services.
- Bill for the Higher-Level Physician Visit. If the patient had already seen the physician prior to a chemotherapy session for a problem that is unrelated to the supervision of the administration of chemotherapy drugs, the physician may bill a visit for a significant adverse drug reaction. The total time, resources, and complexity of the physician's interaction with the patient may justify a higher level of visit service.
- Bill for a Prolonged Service. If the patient had a physician visit prior to the chemotherapy session and experienced a significant adverse reaction to drugs on the same day, the physician can bill a prolonged service code in addition to the physician visit. There are several code combinations to use depending on the number of minutes involved. The physician must have a face-to-face encounter with the patient and must spend at least 30 minutes beyond the threshold or typical time for that level of visit for the physician to bill for the prolonged service code.
- Bill for Critical Care Service. If the patient had a physician visit prior to the chemotherapy session and experienced a life-threatening adverse reaction to the drugs, the physician could bill for a critical care service in addition to the visit if the physician's work involves at least 30 minutes of direct face-to-face involvement managing the patient's life-threatening condition. Examples of life-threatening conditions are: central nervous failure, circulatory failure, shock, renal, hepatic, metabolic, and/or respiratory failure.

These instructions are published here for informational purposes, and we anticipate that we will issue further instructions regarding the appropriate use of these G-codes including clarifications, interpretations and other modifications to the following guidance as part of any instructions issued through a subregulatory process.

Comment: The American Urological Association (AUA) commented in response to the January 7, 2004 interim final rule to ask us to include the following codes in the MMA-mandated evaluation of existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services: CPT codes 11980, 11981, 11982, 11983, 51700, 51720, 54200, 54231, and 54235. The AUA asked that we consider applying the transitional adjustment payment to these codes for 2005.

Response: We presented these codes to the CPT Drug Administration Workgroup. After subsequent discussion with representatives of the AUA, the AUA withdrew these codes from consideration by the workgroup.

These codes are not subject to the ''transitional adjustment payment provision'' because they are not included in the definition of ''drug administration codes.''

Comment: Ophthalmologists frequently perform the procedure photodynamic therapy (CPT code 67221 and 67225) by infusing the drug Visudyne. While separate payment is allowed for the drug, the infusion is considered an integral part of the photodynamic therapy code. Thus, the physician is not allowed to bill a separate code for the infusion of the drug.

According to one commenter, Visudyne is also a drug used in cancer chemotherapy. The commenter pointed out that when Visudyne is provided for photodynamic therapy, ophthalmologists incur drug administration costs similar to oncologists who use infused drugs.

The AAO asked why we did not include CPT codes 67221 and 67225 among the drug administration codes that benefited under the MMA.

Response: In this instance, the infusion of the drug is an integral part of the surgical procedure and it was valued by the RUC and CMS that way. The code of which it is a part is not considered a drug administration code under section 303 of the MMA.

3. Blood Clotting Factor

For clotting factors furnished on or after January 1, 2005, we proposed to establish a separate payment of $0.05

per unit to hemophilia treatment centers, homecare companies and other suppliers for the items and services associated with the furnishing of blood clotting factor. Section 303(e)(1) of the MMA requires the Secretary, after review of the January 2003 report to the Congress by the Comptroller General of the United States, to establish a furnishing fee for the items and services associated with the furnishing of blood clotting factor.

Based on a review of the Government Accountability Office (GAO) report and data received from various clotting factor providers, we proposed a furnishing fee in order to cover the administrative costs associated with supplying the clotting factor. As outlined in the MMA, any separate payment amount established may include the mixing and delivery of factors, including special inventory management and storage requirements, as well as ancillary supplies and patient training necessary for the self-administration of these factors. The MMA states that, in determining the separate payment, the total amount of payments and these separate payments must not exceed the total amount of payments that would have been made for the factors if the amendments in section 303 of the MMA had not been enacted.

As indicated in the GAO report, ''[w]hen Medicare's payment for clotting factor more closely reflects acquisition costs, we recommend that the Administrator establish a separate payment for providers based on the costs of delivering clotting factor to Medicare beneficiaries.'' Effective upon implementation of the ASP-based payment rates, payment for blood clotting factors will more closely reflect acquisition costs, since payment will be based on the average sales price as reported by drug manufacturers plus 6 percent.

Therefore, we stated in the August 5, 2004 proposed rule that in the absence of additional data we believe that a furnishing fee of $0.05 per unit for the cost of delivering clotting factor is an appropriate amount. However, we also sought updated data and comments on the GAO report, as well as information on the fixed and variable costs of furnishing clotting factor. We recognized that there may be alternatives to a fee, which varies entirely based on the number of units of clotting factor furnished. We indicated we would closely examine all data and information submitted in order to make a final determination with respect to the appropriateness of the $0.05 per unit amount.

We received comments from various sources including, but not limited to, hemophilia treatment centers, hemophilia coalitions, and other suppliers of clotting factors regarding our request for additional data and information on the appropriateness of our proposed fee. The comments and responses are provided below.

Comment: Many commenters recommended that we incorporate cost information received from homecare providers and any updated cost data from hemophilia treatment centers in determining the separate furnishing fee payment amount for 2005. The commenters cited an industry-sponsored survey of full-service hemophilia homecare companies that recommended a furnishing fee of $0.20 per unit. This survey collected CY 2003 data from three hemophilia homecare suppliers that the commenter indicated supplied 42 percent of all Medicare hemophilia patients. Commenters also stated that the GAO report was inadequate to serve as the basis for determining the separate payment for clinically appropriate items and services related to furnishing blood clotting factor. They questioned the accuracy of the recommended payment range in the GAO report, given what they viewed as an insufficient sample size; that is, the GAO report received data from only 4 hemophilia treatment centers and lacked any cost data from national or regional full-service hemophilia homecare providers. These commenters also indicated that the GAO survey may have included homecare companies that purchase clotting factor at a lower price through the Public Health Service's 340B program. More information on the 340B program is available on the Health Resources and Services Administration's Web site at *http://bphc.hrsa.gov/opa/howto.htm.* The commenters also stated that the GAO report focused solely on estimating providers' blood clotting factor delivery costs, which the GAO defined as inventory management, storage, shipping, and the provision of ancillary supplies. According to the commenters, the MMA directed us to establish a separate payment for items and services related to the furnishing of blood clotting factor that takes into consideration a wider range of items and services than the delivery costs addressed in the GAO report, for example patient education.

Response: We agree with the commenters that full-service hemophilia homecare companies provide services that may be of benefit to Medicare beneficiaries with hemophilia, such as disease and patient management activities. However, we do not believe that the scope of the furnishing fee includes these services. As noted above, Section 303(e) specifies the items and services that may be taken into consideration in setting the furnishing fee. Disease and patient management activities are not included in the items and services specified in Section 303(e). However, these activities may be more appropriately addressed through a future phase of the new Medicare Chronic Care Improvement Program.

The new Medicare Chronic Care Improvement Program is an important component of the MMA and demonstrates a commitment to improving and strengthening the traditional fee-for-service Medicare program. This program is the first large-scale chronic care improvement initiative under the Medicare fee-for-service program. We will select organizations that will offer self-care guidance and support to chronically ill beneficiaries. These organizations will help beneficiaries manage their health and adhere to their physicians' plans of care, and help ensure that they seek or obtain medical care that they need to reduce their health risks. More information regarding this program is available on the CMS Web site at *http://www.cms.hhs.gov/medicarereform/ccip/.*

With regard to the other costs identified in the comments and in the industry-sponsored survey, we also do not believe the scope of a furnishing fee includes costs associated with sales and marketing. We do not believe it is appropriate to build an explicit profit margin into the furnishing fee, but rather have the margin associated with the furnishing fee result from efficient furnishing of clotting factor. We agree with the commenters that the GAO report did not include amounts for education and that these are appropriate for the furnishing fee. Therefore, after removing the costs associated with sales and marketing, an explicit profit margin, and patient management, the resulting figure from the homecare survey is $0.14 per unit of clotting factor. We are establishing the furnishing fee for 2004 at $0.14 per unit of clotting factor. For years after 2005, the MMA specifies that the furnishing fee for clotting factor must be updated by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

Comment: One commenter recommended that the beneficiary's 20 percent coinsurance not be applicable to this separate payment. The commenter indicated that the additional financial

burden would limit many beneficiaries' access to this lifesaving product.

Response: Under provisions designed to protect the Medicare program from fraud and abuse, a broad waiver of beneficiary cost sharing of the type the commenter recommends would not be permitted. However, we make no statement regarding the applicability of existing statutory and regulatory provisions that may allow for the waiver of cost sharing in certain cases.

4. Supplying Fee

Section 1842(o)(6) of the Social Security Act requires the Secretary to pay a supplying fee (less applicable deductible and coinsurance) to pharmacies for immunosuppressive drugs described in section 1861(s)(2)(J) of the Act, oral anticancer chemotherapeutic drugs described in section 1861(s)(2)(Q) of the Act, and oral anti-emetic drugs used as part of an anticancer chemotherapeutic regimen described in section 1861(s)(2)(T) of the Act, as determined appropriate by the Secretary. In the interim final rule published on January 7, 2004 (69 FR 1084), we considered this fee to be bundled into the current payment for these drugs for 2004 and did not establish a separately billable supplying fee.

Effective January 1, 2005, we proposed to establish a separately billable supplying fee of $10 per prescription for immunosuppressive drugs, oral anti-cancer chemotherapeutic drugs and oral anti-emetic drugs. We based this proposed fee on information provided by retail chain pharmacies on the costs of supplying these drugs to non-Medicare patients combined with steps to reduce the administrative burden associated with billing Medicare.

We also sought data and information on the additional services pharmacies provide to Medicare beneficiaries, the extent to which oral drugs can be furnished without these additional services and the extent to which such services are covered under Medicare. Additionally, we requested comments concerning whether the supplying fee should be somewhat higher during the initial month following a Medicare beneficiary's transplant to the extent that additional resources are required for example, due to more frequent changes in prescriptions for immunosuppressive drugs.

Comment: Several commenters stated that they were not in a position to determine whether the proposed $10.00 supplying fee was adequate since they did not know the actual 2005 payment rates for Part B drugs. These commenters indicated that the supplying fee needed to cover return on investment, the costs of supplying the drugs, and make up for any differences between the product costs and the ASP based payment for the drug. Some commenters indicated that aside from the adequacy of the ASP-based payment for the drug, a $10.00 supplying fee appeared to be too low. These commenters indicated that the average cost to a retail pharmacy to dispense a non-Medicaid third party or cash paying prescription ranges anywhere from $7.50–$8.00. The commenters indicated that Medicare should pay at least $2.00–$2.50 more per prescription since costs associated with supplying Medicare prescriptions are higher.

We received a comment from a large retail pharmacy indicating that a supplying fee of $25 would be adequate to cover the higher costs of dispensing Medicare Part B oral drugs.

We received comments from specialty immunosuppressive pharmacies that included information from a recent survey of their supplying costs. The survey indicated that the cost for specialty pharmacies to dispense Medicare Part B immunosuppressants is $35.48 per prescription. The specialty immunosuppressive pharmacies indicated that they provide services not typically provided by retail chain drug stores or large mail-order pharmacy benefit management companies. These services include direct patient care through pro-active pharmacist contact, expeditious processing and turnaround of medication orders, direct billing of Medicare and coordination of benefits on behalf of transplant patients to reduce the costs to the patients, and maintaining expensive immunosuppressant in stock to ensure timely receipt when needed by beneficiaries. These pharmacies also indicated that the retail chains typically do not supply immunosuppressive drugs or file Medicare claims.

Several commenters indicated that the lack of on-line adjudication for Medicare claims was one of the major drivers, among other reasons, for the additional costs of supplying Medicare prescription.

Response: We agree that the cost of supplying Medicare Part B oral drugs is higher than many other payers because of the lack of on-line adjudication for Medicare Part B oral drug claims. Due to operational issues, we do not anticipate the establishment of an on-line adjudication system in the near future. Accordingly, we believe it is appropriate to establish a supplying fee higher than the fees paid by some other payers with on-line adjudication. We note that many other payers with on-line adjudication have fees in the range of $5–$10 per prescription. We note that this is consistent with the approximately $8 cost for non-Medicaid dispensing stated by some commenters and described earlier. Other than administrative costs associated with billing Medicare Part B for oral drugs, we do not agree with commenters that the supplying fee for these drugs should exceed the dispensing fees of other payers because we do not believe there are other significant differences between supplying Medicare Part B and other oral drugs. We also do not agree that the supplying fee should include product costs. Product costs are paid through the ASP + 6 percent drug payment system. For the additional burden associated with billing Medicare Part B for oral drugs, we note the commenters who suggested an additional fee of approximately $2 for Medicare billing costs. Added to the $8 non-Medicaid fee described above, this would result in a supplying fee of approximately $10. We also note the survey of the specialty immunosuppressive pharmacies that indicated Medicare claims processing costs of approximately $8. This same survey also indicated total personnel costs of approximately $9, a portion of which we assume is attributable to the additional work associated with Medicare billings because the comments indicated Medicare billing was labor-intensive. Using the $5 to $10 figures for payers with on-line adjudication described above, the specialty pharmacy data on Medicare claims processing costs and personnel costs, we developed a range of possible supplying fees based on the specialty pharmacy data. Depending upon the portion of the personnel costs associated with Medicare billings, this would result in a supplying fee between a minimum of $13 (= $5 + $8) and a maximum of $27 (= $10 + $8 + $9). The comment of the large chain pharmacy recommending a $25 supplying fee indicated that this amount would be adequate to cover the costs of supplying Medicare Part B drugs including the additional costs of processing Medicare claims; however, this amount included a margin for profit. We do not believe it is appropriate to build an explicit profit margin into the supplying fee, but rather have the margin associated with the supplying fee result from efficient supplying of these drugs. Although the profit margin included in the $25 was not explicitly stated in the comment, if we assume a 5 percent margin, then a supplying fee of approximately $24 would cover the large chain pharmacy's

costs of supplying Medicare Part B drugs. We are not indicating that 5 percent is an appropriate margin.

There was variability in the submitted comments with respect to an appropriate supplying fee. On the low end, analysis of the submitted comments would indicate a supplying fee of $10. On the high end, the analysis would indicate a supplying fee of $27. Given the variability in the values and assumptions included in various calculations, we do not think it is appropriate to simply take the rounded midpoint of this range, $19, as the supplying fee. However, we do not think it appropriate to take the maximum amount of this range, $27, given that it is unlikely that all of the personnel costs indicated in the specialty pharmacy survey are related to the costs of billing for oral Medicare Part B drugs. The amount in the comment from the large chain pharmacy, after adjusting for a possible profit margin, or $24, is consistent with our belief that not all of the additional personnel costs identified in the specialty pharmacy survey are related to the costs of billing for oral Medicare Part B drugs. We are therefore establishing a per prescription supplying fee of $24 as the value consistent with both the large retail pharmacy comment (after making an adjustment for built-in profit margins) and the higher end of the broad range of the specialty pharmacy survey. Although we believe that a $24 supplying fee coupled with the ASP-based drug payment will not result in any access problems for Medicare beneficiaries, we will monitor access as we implement the new ASP-based payment system.

Comment: Some commenters recommended that we update the supplying fee annually. Some commenters indicated this fee should be updated by the average annual increase in the costs of pharmacies supplying these drugs to Medicare beneficiaries (costs such as rent, utilities and salaries), but no less than the increase in the medical care inflation index for the most recent twelve months for which it can be calculated before the next calendar year.

Response: We will study the issue of appropriate future increases for the supplying fee and proceed, as necessary, through notice and comment rulemaking.

Comment: A specialty organization suggested that we develop a sliding supplying fee, which would be calculated as a percentage of the cost that the pharmacy incurred in acquiring a particular drug.

Response: We do not agree that the supplying fee should vary by product costs. Product costs are paid through the ASP-based drug payment system.

Comment: Several commenters agreed with our suggestion to increase the supplying fee in the first month following a transplant, but recommended that we extend this increase to at least the first 3 months following the transplant. One commenter suggested that extra resources are associated with frequent changes in prescriptions during the initial month following a beneficiary's organ transplant. One commenter recommended a fee of $50 for an initial prescription fill. However, one commenter advocated against a supplying fee that distinguished between new and refill prescriptions stating that it would be impractical, of questionable benefit and would discourage long-term pharmacy-patient relationships as pharmacy providers would only have an incentive to serve patients in the short term.

Response: We agree that additional costs are most likely to occur nearer the time when the beneficiary has a transplant. In order to recognize these costs, we are establishing a higher supplying fee of $50 for the supplying of the initial oral immunosuppressive prescription in the first month after a beneficiary has a transplant because the costs of supplying immunosuppressives are likely to be higher immediately following a transplant, when the practitioner is adjusting the dose of immunosuppressive drugs. With regard to the comment opposing higher supplying fees for new patients regardless of their transplant date, we agree with the commenter that it would result in inappropriate incentives and are not implementing any such fee.

Comment: Commenters recommended that the supplying fee should account for the different prices paid by pharmacies and physicians, recognizing that these are separate classes of trade that may not have access to comparable pricing. Thus, we should increase the supplying fee associated with providing and overseeing the use of oral anti-cancer drugs.

Response: We do not agree that the supplying fee should vary by product costs. Product costs are paid through the ASP based drug payment system.

Comment: Commenters recommended that we extend the supplying fee to physicians that directly supply covered oral anti-cancer, immunosuppressive and oral anti-emetic drugs to patients, as well as create a dose management and compliance fee for physicians that prescribe oral chemotherapy products. These commenters state that we could use the premise that the MMA does not provide a definition of the word ''pharmacy'' and we could permit payment of a supplying fee to include a physician acting in the capacity of a pharmacist. Alternatively, commenters suggested that we use its inherent reasonableness authority to extend the supplying fee to physicians.

Response: Given our current understanding of Congressional intent, we do not believe it would be appropriate to pay a supplying fee to physicians. Moreover, we do not have sufficient data to determine whether our inherent reasonableness authority would apply in this instance. However, we will study these issues further.

5. Billing Requirements

In the proposed rule, we proposed the following changes to certain billing requirements and clarified policy for other billing requirements in an effort to reduce a pharmacy's costs of supplying covered immunosuppressive and oral chemotherapy drugs to Medicare beneficiaries:

• *Original signed order.* We clarified Medicare's policy regarding the necessity of an original signed order before the filling of a prescription. According to the Medicare Program Integrity Manual (section 5.1 of Chapter 5), which addresses the ordering requirement for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), including drugs, most DMEPOS items can be dispensed based on a verbal order from a physician. A written order must be obtained before submitting a claim, but that written order may be faxed, photocopied, electronic, or pen and ink. The order for the drug must specify the name of the drug, the concentration (if applicable), the dosage, and the frequency of administration. The clarification of this requirement should reduce a pharmacy's costs of supplying covered immunosuppressive and oral drugs to Medicare beneficiaries to the extent that pharmacies are currently applying an original signed prescription requirement.

Comment: Commenters recommended that a prescription be filled and billed based solely on a verbal order from a physician and an actual signed written prescription should not be necessary before billing.

Response: The policy that allows dispensing based on a verbal order but requires a written order for billing applies to all DMEPOS items. This policy balances fraud and abuse concerns with prompt dispensing of DMEPOS items to beneficiaries. We

point out that the written order from the physician can be faxed, photocopied, electronic, or pen and ink. We currently allow pharmacies to accept electronic prescriptions from physicians.

• *Assignment of Benefits Form.* We proposed to eliminate use of the Assignment of Benefits form for Part B items and services, including drugs, where Medicare payment can only be made on an assigned basis. For Part B covered oral drugs, this would be a means of reducing a pharmacy's costs of supplying these drugs to Medicare beneficiaries. Currently, pharmacies must obtain a completed Assignment of Benefits form in order to receive payment from Medicare. This requirement increases a pharmacy's cost of supplying covered drugs to Medicare beneficiaries, as other payers do not impose this requirement. Thus, we do not believe that it is necessary for an assignment of benefits form to be filled out for drugs covered under Part B, since payment for them can only be made on an assignment-related basis.

Comment: Some commenters suggested that the Assignment of Benefits form be eliminated for diabetic supplies dispensed by pharmacy suppliers.

Response: Our proposal to eliminate the Assignment of Benefits form applied to services where Medicare payment can only be made on an assigned basis. That is not the case with diabetic supplies. Thus, we are not eliminating the AOB form for diabetic supplies.

• *DMERC Information Form (DIF).* The DIF is a form created by the DMERC Medical Directors that contains information regarding the dates of the beneficiary's transplant and other diagnosis information. This form is a one-time requirement that pharmacies must complete in order to receive payment. Since section 1861(s)(2)(J) of the Act no longer imposes limits on the period of time for coverage of immunosuppressive drugs, we believe that the information on transplant diagnosis can be captured through other means (for example, diagnosis codes on the Part B claim form).

Comment: Several commenters applauded our efforts to eliminate use of the DIF in an effort to reduce the cost that the billing requirements imposed. These commenters asked that we ensure that this requirement is applied uniformly by all the DMERCs.

Response: We appreciate the support regarding the elimination of the DIF form. Action is being taken to eliminate the DIF form, including accommodating systems issues and providing for notifications. We anticipate resolution of issues to occur soon and elimination would occur next year.

• *Other Billing Issues.* We also received other comments regarding other billing issues related to the supplying of immunosuppressive, oral anti-cancer, and oral anti-emetic drugs.

Comment: Commenters suggested that we allow physicians to bill the carrier when oral drugs are provided directly by the physician in his office rather than having the physician bill the DMERC for the oral anti-cancer drug. Others stated that we should allow for billing for pharmaceutical products to be conducted on current electronic platforms, because ''batch billing'' creates operational and patient care problems, and adds significant participation costs. Commenters also stated that we should eliminate the requirement for a diagnosis code to be present on the prescription; while, at the same time, adopt the usage of the physician's DEA number instead of the UPIN number when submitting claims.

Response: We thank the commenters for identifying these issues. We plan to examine these aspects of billing.

6. Shipping Time Frame

In the proposed rule, we highlighted the fact that the guidelines regarding the time frame for subsequent deliveries of refills of DMEPOS products had been revised. Effective February 2, 2004, the shipping of refills of DMEPOS products may occur ''approximately'' on the 25th day of the month in the case of a month's supply. In the proposed rule, we emphasized the word ''approximately''; while we indicated that normal ground service shipping would allow delivery in 5 days, if there were circumstances where ground service could not occur in 5 days, the guideline would still be met if the shipment occurs in 6 or 7 days. This change should eliminate the need for suppliers to utilize overnight shipping methods and would permit the shipping of drugs via less expensive ground service.

F. Section 952—Revision to Reassignment Provisions

As discussed in the August 5, 2004 proposed rule, section 1842(b)(6)(A)(ii) of the Act, as amended by section 952 of the MMA, allows, in many circumstances, a physician or NPP to reassign payment for Medicare-covered services, regardless of the site of service, providing there is a contractual arrangement between the physician or NPP and the entity through which the entity submits the bill for those services. Thus, the services may be provided on or off the premises of the entity receiving the reassigned payments. The MMA Conference Agreement states that entities that retain independent contractors may enroll in the Medicare program. The expanded exception created by section 952 of the MMA applies to those situations when an entity seeks to obtain the medical services of a physician or NPP.

Section 952 of the MMA states that reassignment is permissible if the contractual arrangement between the entity that submits the bill for the service and the physician or NPP who performs the service meets the program integrity and other safeguards as the Secretary may determine to be appropriate. The Conference Agreement supports appropriate program integrity efforts for entities with independent contractors that bill the Medicare program, including joint and several liability (that is, both the entity accepting reassignment and the physician or NPP providing a service are both liable for any Medicare overpayments). The Conference Agreement also recommends that physicians or NPPs have unrestricted access to the billings submitted on their behalf by entities with which they contract. We incorporated these recommended safeguards in a change to the Medicare Manual, implementing section 952 of the MMA that was published on February 27, 2004. In the August 5, 2004 rule, we proposed to revise § 424.71 and § 424.80 to reflect these safeguards, as well as the expanded exception established by section 952 of the MMA.

Section 952 of the MMA revises only the statutory reassignment exceptions relevant to services provided in facilities and clinics (section 1842(b)(6)(A)(ii) of the Act). Section 952 of the MMA does not alter an individual or entity's obligations under any other applicable Medicare statutes or regulations governing billing or claims submission.

In addition, physician group practices should be mindful that compliance with the physicians' services exception and the in-office ancillary services exception to the physician self-referral prohibition in section 1877 of the Act requires that a physician or NPP who is engaged by a group practice as an independent contractor may provide ''designated health services'' to the group practice's patients only in the group's facilities. See the definition of physician in the group at 42 CFR 411.351.

We also cautioned that parties must be mindful that contractual arrangements involving reassignment may not be used to camouflage inappropriate fee-splitting arrangements

or payments for referrals. In the August 5, 2004 proposed rule, we solicited comments on potential program vulnerabilities and on possible additional program integrity safeguards to guard against those vulnerabilities.

Comment: We received positive comments for the proposed changes to the reassignment rules from two physician associations and one association representing non-physician practitioners.

Response: We are pleased to receive positive feedback to the changes to the reassignment rules. We believe these changes balance the need to respond to the changing business arrangements in the delivery of health care services with the need to protect the Medicare trust funds from fraudulent and abusive billing practices.

Comment: An association representing emergency medicine physicians and numerous members of that association commented that requiring independent contractor physicians to have unrestricted access to the billings submitted on their behalf is not sufficient to ensure such access. The commenters requested that we revise our regulations to require the entity submitting the bills to provide duplicates of the Medicare remittance notices (which indicate the services billed and the amounts paid for those services) to the independent contractor physicians. Some of the commenters requested that we require independent contractor physicians to receive itemized monthly reports of the claims submitted and remittances received on their behalf.

Response: We believe that requiring independent contractors to have unrestricted access to the billings submitted on their behalf is sufficient to satisfy the independent contractors' need to review the claims information.

We recognize that some independent contractors may not wish to receive copies of all bills submitted on their behalf. It would place an unnecessary burden on entities if we require them to furnish duplicate remittance notices to independent contractors on a routine basis. Similarly, it would place a significant burden on our claims processing systems if we were obligated to provide duplicate remittance notices to those who have reassigned their payments. We note that the method and frequency of obtaining access to billing records is an issue that the independent contractor and the entity to which the independent contractor is reassigning payments can resolve in their written contract.

Comment: A commenter asked whether or not the new reassignment exception (which essentially expanded or revised the previous exceptions pertaining to independent contractors), established by section 952 of the MMA, is available when one entity contracts with a second entity, which in turn contracts with a physician or non-physician practitioner to furnish services for the first entity.

Response: We refer to this situation as an indirect contractual arrangement between the independent contractor furnishing the service and the entity doing the billing and receiving payment (excluding billing agents). Thus, the reassignment is between the individual furnishing the service and the entity receiving the reassigned benefits. Indirect contractual arrangements were permissible prior to passage of section 952 of the MMA and remain permissible. The CMS–855–R enrollment form would need to be completed by the entity receiving the reassigned benefits and the person furnishing the service. In accordance with section 952 of the MMA, the contractual arrangement and any program integrity safeguard requirements deemed appropriate by the Secretary are between the independent contractor and the entity receiving the reassigned payments, with the program integrity safeguards applying to both parties. If the parties involved also wish to include the intermediary entity in a similar contract, and apply standards identical or similar to the program integrity safeguards to their arrangement, they have that option; but, it is not required or necessary to comply with the exception to the reassignment prohibition for contractual arrangements.

Comment: Several members of the Congress urged us not to delay the enrollment process of providers or suppliers while implementing section 952 of the MMA.

Response: We do not expect any delays in provider or supplier enrollment to result from implementing the reassignment provisions of this regulation. We are sensitive to the need for an efficient and timely enrollment process. If the new reassignment exception results in the submission of a particularly high volume of claims, or if a Medicare contractor has to process a large number of new enrollment applications, it is possible that delays may occur in some cases. A provider or supplier whose enrollment was delayed must contact the appropriate Medicare contractor's provider or supplier enrollment office to discuss the reasons for the delay.

Comment: A trade association of physician specialists asked that we clarify our definitions of onsite and off-site services. This trade association also requested that we further describe the potential program vulnerabilities that the revised Medicare reassignment exception might create.

Response: We consider onsite services to be services of an independent contractor that are performed in space owned or leased by the entity billing and receiving the reassigned payments. We consider offsite services to be services of an independent contractor that are performed in space that is not owned or leased by the entity billing and receiving the reassigned payments, that is, services performed off the premises.

The Congress originally passed the prohibition on reassignment provision due to experience with fraudulent and abusive billing practices. As we discussed in the preamble to the August 5, 2004 proposed rule, the new reassignment exception for contractual arrangements will potentially permit myriad relationships and financial arrangements. Some of these relationships may have the potential to increase fraudulent and abusive billing practices that the reassignment rules were designed to prevent. We also stated in the proposed rule that the new reassignment exception does not alter an individual's or entity's obligations under existing Medicare statutes and regulations (for example, the physician self-referral prohibition, the anti-kickback statute, purchased diagnostic test rules, incident to rules, etc.).

Comment: Several commenters expressed concern over the recent growth of so-called pod, salon, turnkey, mini-mall, or condo labs, especially since section 952 of the MMA appears to liberalize the Medicare reassignment rules.

As we understand the situation, some entities have created a building or a floor of a building that contains a number of cubicles, each of which is equipped with a microscope and other supplies that enable a pathologist to go to a particular cubicle or pod to analyze any tissue sample that is submitted by the group practice that rents pod space on a full-time basis. Apparently, some of the owners of these anatomical laboratories assert that each pod is a centralized location for a laboratory that is owned by a group practice. Other owners assert that each pod serves as an offsite office of a pathologist who works for a group practice as an independent contractor.

These entities market their services to specialists in certain disciplines, such as gastroenterology, urology, and dermatology, which rely on a high

volume of anatomic pathology services. The commenters stated that these lab arrangements are subject to excess, waste, and abuse, including, but not limited to: (a) Generation of medically unnecessary biopsies; (b) kickbacks; (c) fee-splitting; and, (d) referrals that would otherwise be prohibited under the physician self-referral statute.

The commenters agree with us that safeguards are necessary to prevent the increased incidence of fraudulent and abusive billing practices resulting from the new reassignment exception for contractual arrangements. To reach the goal of closing any loophole for excess, waste, and abuse opened by the new independent contractor reassignment exception, the commenters provided several suggestions. One commenter recommends that we add language to proposed § 424.80(d) that would prohibit a physician from making a reassignment to another physician, under the independent contractor exception, if the physicians do not practice in substantially the same medical specialty. This limitation would not apply if the entity accepting the assignment is a bona fide multi-specialty physician practice, meaning that it employs (on a W–2 basis) physicians who regularly practice in two or more specialties of medicine.

The commenters believe that the regulations need to state more clearly that all requirements of the purchased diagnostic test rules and purchased test interpretation rules need to be met. In other words, the commenters want to prevent the new reassignment exception from applying to services furnished by independent contractor pathologists.

These commenters are urging us to review these practices to see if they fail to meet existing obligations under the physician self-referral prohibition or anti-kickback statute. The commenters believe that these business arrangements are exploiting the in-office ancillary services exception and other exceptions to the physician self-referral prohibition.

Response: We appreciate comments that specify situations where fraud and abuse may occur and propose solutions to prevent such occurrences. While we decline to incorporate the commenters' suggested regulatory revisions at this time, we share the commenters' concerns. We will be paying close attention to this issue, and may initiate future rulemaking to address arrangements that are fraudulent or abusive.

To respond to commenters' concerns, we are amending the regulations governing reassignment at § 424.80(a) to clarify that nothing in § 424.80 alters an individual or entity's obligations under other Medicare statutes or rules, including, but not limited to, the physician self-referral prohibition (section 1877 of the Act), the anti-kickback statute (section 1128(B)(b)(1) of the Act), the regulations regarding purchased diagnostic tests, and regulations regarding services and supplies provided incident to a physician's services.

In response to the concerns expressed by the commenters, we wish to further expand on the fact that section 952 of the MMA did not affect the obligation of an individual or entity to comply with the physician self-referral prohibition (section 1877 of the Act and the corresponding regulations). As stated in the proposed rule, ''physician group practices should be mindful that compliance with the in-office ancillary services exception to the physician self-referral prohibition requires that a physician who is engaged by a group practice on an independent contractor basis must provide services to the group practice's patients in the group's facilities. As noted in the Phase I physician self-referral final rule (66 FR 887), ''we consider an independent contractor physician to be 'in the group practice' if: (1) He or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities; (2) the contract contains compensation terms that are the same as those that apply to group members under section 1877(h)(4)(iv) of the Act or the contract fits in the personal services exception; and, (3) the contract complies with the reassignment rules * * * '' See also 66 FR 886.'' This test is specified at § 411.351 in the definition of physician in the group practice, which contains a premises requirement independent of the reassignment rules.

In addition, the use of independent contractors at off-premises locations may impact the ability of a group practice to meet the definition of a group practice at § 411.352 for purposes of complying with section 1877 of the Act. Accordingly, some group practices may need to be careful about the number of physician-patient encounters that independent contractors perform off-premises to ensure that they meet the 75 percent patient-physician encounters test as set forth in § 411.352(h).

We will continue to monitor compliance with the reassignment rules and we will analyze the impact of the physician self-referral prohibition on ''pod'' labs. If we determine that changes to the physician self-referral prohibition are necessary, these changes will be made in a separate rulemaking document.

Comment: We received a number of comments and recommendations from three organizations that utilize the services of independent contractor emergency department physicians. One of the three organizations represents management companies that employ independent contractor emergency department physicians. The commenters believe that the changes to the reassignment rules necessitated by section 952 of the MMA should be implemented in a manner that does not impose additional burdens on the Medicare enrollment process. They believe that implementation of the proposed regulations could impede the enrollment process. They expressed concern that amendments to current contracts might be necessary to incorporate the program integrity safeguards included in the proposed regulations. Since they believe requiring contract amendments would be burdensome and costly to hospitals, they are urging us not to require parties to amend their contracts to reflect the program integrity safeguards that we proposed.

Response: We do not believe that implementation of the proposed regulations will impede the enrollment process. Our proposed regulations would not require parties to amend their contracts to reflect the program integrity safeguards. We plan to include the program integrity safeguard requirements on the CMS–855–R enrollment form. The program integrity safeguards will apply to arrangements entered into pursuant to the new reassignment exception for contractual arrangements, regardless of whether the parties reference the safeguards in their contracts.

Comment: Three commenters representing groups that utilize independent contractor emergency physicians strongly oppose our implementation of the two proposed program integrity safeguard requirements: (1) Joint and several liability/responsibility for Medicare overpayments; and (2) unrestricted access to the billings for services provided by independent contractors. The commenters believe that establishing program integrity safeguards is premature and that we should first formally assess the need for such safeguards. These commenters also ask us to clearly define joint and several liability/responsibility. They express concern over our attempt to impose joint and several liability/responsibility on both the contracting entity and practitioner furnishing the services and

note that the CMS–855–R enrollment form certification holds the enrolling provider or supplier responsible for any Medicare overpayments. The commenters argue that we should impose these program integrity safeguards on employer/employee relationships if we are going to impose them on contractual arrangements. The commenters ask how we would monitor compliance with joint and several liability/responsibility. The commenters also have concerns about regulating access to claims submitted by an entity for services furnished by an independent contractor. In their view, this type of requirement should be part of the compliance programs of entities and employers rather than mandated as part of the reassignment rules.

Response: We disagree with the commenters' assertion that it is premature to implement the proposed program integrity safeguards. Section 952 of the MMA specifically authorizes the Secretary to implement program integrity safeguards. Further, in the Conference Report to the MMA, the Congress specifically highlighted the two program integrity safeguards that we have proposed.

Our assessment of the need for program integrity safeguards is based upon prior experience with certain types of entities and their subsidiary billing companies. For example, on April 6, 2000, Lewis Morris, Assistant Inspector General for Legal Affairs, Office of Inspector General (OIG), U.S. Department of Health and Human Services, testified before the House Committee on Commerce, Subcommittee on Oversight and Investigations regarding Medicare and third-party billing companies. Mr. Morris of the OIG detailed the upcoding activities of two firms that provided billing services for entities contracting with emergency department physicians. One firm paid $15 million and the other paid $15.5 million to settle their respective liabilities. Moreover, as we have noted, we have received numerous comments from physicians stating that they have been prevented from seeing the Medicare remittance notices for services they furnished, on penalty of termination.

In addition, we understand the commenters' concerns that if the Agency plans to implement the two proposed program integrity safeguards, we should apply these same program integrity safeguards to employees, as well as to independent contractors. Joint and several responsibility/liability and unrestricted access to billings may or may not be appropriate for employees and employers as it is for the parties involved in contractual arrangements. CMS will study this issue further, and if necessary will address it in a separate rulemaking document.

We use the words responsibility and liability interchangeably, and in the context of claims filing and payment, they both have the same meaning. We define joint and several liability/responsibility to mean that both the person furnishing a service and the entity billing for that service (and to which payments have been reassigned) can be held liable or responsible for any errors in billing that result in a Medicare overpayment, including, but not limited to, upcoding and billing for services never rendered.

We will monitor the program integrity safeguards as we monitor all other program integrity requirements. We also believe that entities and independent contractors will report violations to us, since both may be held responsible for any Medicare overpayments. If an independent contractor is refused access to the billings submitted on his or her behalf, the independent contractor may report this to the appropriate Medicare contractor.

Comment: An organization representing entities that use independent contactor emergency department physicians believes if we retain the proposed program integrity requirements, then these requirements should be clarified and included in other reassignment exceptions and in other Medicare conditions of participation.

Response: It is our goal to have the program integrity requirements identified and included on the appropriate CMS–855–R enrollment form. As we have discussed above, while we will study whether it is appropriate to extend the program integrity safeguards to employer/employee relationships, we do not believe it is necessary to include the program integrity requirements in other reassignment exceptions (or in other Medicare conditions of participation) at this time.

Comment: Three commenters representing organizations that use independent contractor emergency physicians recommend that we revise our definition of entity to specifically identify the types of entities that are listed in the Conference Report to section 952 of the MMA. They believe that our existing definition which defines entity as a person, group or facility enrolled in the Medicare program is ambiguous and inconsistent with Congressional intent. Therefore, they are recommending that we add the language to the definition that specifies that an entity includes but is not limited to, a hospital, clinic, medical group, a physician practice management organization, or a staffing company. One of the commenters opposes stating that entities need to be enrolled in Medicare in the definition of entity because the commenter believes it is not necessary to include such information in the regulations on reassignment. This commenter believes that instructions on enrollment should be addressed in an enrollment regulation. The commenter also states that our current reassignment regulation does not define facility as a hospital or other institution enrolled in the Medicare program. These groups believe that their proposed definition of entity more accurately reflects the language from the Statement of the Managers filed by the MMA Conference Committee and is included in the Conference Report (Conference Agreement). Finally, these groups do not believe that a definition of entity is necessary, since we do not define employer in the reassignment regulations definition section.

Response: We continue to believe that our definition of entity in the proposed rule is appropriate. We believe that defining entity as a person, group, or facility that is enrolled in Medicare encompasses all entities that are allowed to bill and receive payment from Medicare, and does not prevent those entities that were specifically identified in the Conference Report from benefiting from the new contractual arrangement reassignment exception. We will not specifically include a staffing company in the definition of entity because a staffing company cannot enroll in Medicare as a staffing company. Staffing companies can enroll as either a group practice or clinic, depending on how they are licensed or allowed to do business in the state where they are located. We further believe that a definition of entity is necessary to distinguish between entities that are allowed to reassign their right to payment and to receive reassigned payments from entities that are not allowed to reassign their right to payment or to receive reassigned payments (for example, billing agents, entities that provide services under arrangements, and substitute physicians, (for example, locum tenens physicians or physicians working on a reciprocal basis) all of which are not required to enroll in Medicare).

Comment: Three commenters representing organizations that use independent contractor emergency physicians found our use of the term supplier confusing when denoting the physician or non-physician practitioner

that contracts with an entity and reassigns his or her right to bill and receive payment. Specifically, the commenters found the proposed revision to § 424.80(c) (Prohibition on reassignment of claims by suppliers) confusing because it refers to a hospital or facility as the supplier of services for purposes of the reassignment revision when Medicare already has regulations that separately define provider and supplier. The commenters recommend that we clarify our intent regarding the use of the term supplier.

Response: In instances of reassignment, the supplier is the person furnishing the service and reassigning his or her right to bill and receive payment to another entity. This is consistent with our definition of supplier in § 400.202. In our proposed revision to § 424.80(c), we state that the employer or entity is considered to be the supplier of the services for subparts C, D, and E of this part, subject to the provisions of paragraph (d) of the section. Once a supplier reassigns his or her right to receive Medicare payments, the entity receiving the reassigned payments essentially takes the place of the supplier. We have revised § 424.80(c) to reflect the new contractual arrangement reassignment exception. The existing § 424.80(c) includes the same formulation and we have simply proposed to replace the words ''facility'' and ''system'' with ''entity,'' because the new exception for payment to an entity under a contractual arrangement now replaces the previous exceptions for payment to a facility or health care delivery system.

Comment: Three commenters that use independent contractor emergency physicians expressed concern about our statement in the preamble to the proposed rule that the new reassignment exception may create fraud and abuse vulnerabilities, which may not become apparent until the program has experience with the range of contractual arrangements permitted by the new reassignment exception. These groups do not believe that the new reassignment exception will result in an increase in violations of the types addressed in the preamble to the proposed rule. The groups also disagree with our statement in the preamble to the proposed rule that contractual arrangements with independent contractor physicians may be used to camouflage inappropriate fee-splitting arrangements or payment for referrals. These groups state that Medicare does not govern fee-splitting arrangements, that policing such arrangements is a matter of State law, and that Medicare reassignment policy has no direct effect on this issue. They question why we have expressed concern over potential violations of the physician self-referral prohibition, because section 952 of the MMA does not affect or otherwise change the obligation of providers and suppliers to comply with the physician self-referral prohibition and its accompanying regulations.

Response: The Congress originally passed the prohibition on reassignment provision because of increasing fraud and abuse in billing practices. Since the new reassignment exception has expanded the circumstances under which suppliers can reassign their right to receive Medicare payments, we are concerned that the potential exists for an increased incidence of fraud and abuse, which may not become apparent until the program has experience with the range of contractual arrangements permitted by the new reassignment exception. Fee-splitting arrangements may violate the physician self-referral prohibition and the anti-kickback statute. Preventing fraudulent and abusive billing practices continues to be the primary purpose of the reassignment rules, even as they are amended to reflect changing practices in the delivery of health care.

We agree that section 952 of the MMA does not change the obligations of providers and suppliers under the physician self-referral prohibition, and all other Medicare statutes and regulations. We are incorporating this clarification in § 424.80(a).

Comment: Three organizations that use independent contractor emergency physicians raised procedural concerns regarding the timing of the final rule, which is effective January 1, 2005. The commenters claim that providers and suppliers do not have time to comply with the new program integrity safeguards. They are asking us to provide providers and suppliers with an additional time frame of at least six months for compliance with the program integrity safeguards, if they are finalized. They recommend that we make the new safeguards applicable to enrollment applications submitted on or after the effective date of the final rule.

Response: We do not believe additional time is necessary for compliance with the program integrity safeguards. Providers and suppliers will not have to amend contracts to include the proposed program integrity requirements. Thus, enrollment applications are not affected by this regulation. The program integrity safeguards will be effective on the effective date of this final rule and these requirements will be applicable to all Medicare providers and suppliers affected by the section 952 change to the reassignment rules.

Comment: One commenter believes that the public comment period for this rule was shortened to 50 days instead of the 60-day comment period required by statute. The proposed rule was published in the **Federal Register** on August 5, 2004 and the public comment period ended at 5 p.m. on September 24, 2004.

Response: While the law requires that we provide a 60-day public comment period and that the notice of proposed rulemaking be published in the **Federal Register**, it does not require that the date of **Federal Register** publication be the first day of the comment period. The two requirements are independent. We post the proposed rule on our Web site on the date of display of the proposed rule at the Office of the Federal Register, satisfying the requirement for a 60-day comment period. By making the proposed rule available on the CMS Web site (as well as at the Office of the Federal Register), we provided the public with access to not only the proposed rule, but also to all of the supporting files and documents cited in the proposed rule in a manner that can be used for analysis. We note that the computer files posted on the Web site can be used for independent analysis. Therefore, we believe that beginning the comment period for the proposed rule with the display date at the Office of the Federal Register, and posting the proposed rule and data files on the CMS Web site on the display date, fully complies with the statute and provides a far better opportunity for the public to have meaningful input than the past practice under which the comment period began with the publication date in the **Federal Register**, a week or longer after the display date and no other data in any other form was furnished.

G. Section 642—Extension of Coverage of IVIG for the Treatment of Primary Immune Deficiency Diseases in the Home

In the August 5, 2004 proposed rule, we stated that for dates of service beginning on or after January 1, 2004, Medicare would pay for IVIG administered in the home. The benefit is for the drug and not for the items or services related to the administration of the drug when administered in the home, if deemed medically appropriate. The implementing instructions for this benefit were provided in a transmittal released on January 23, 2004. We received several comments regarding this new benefit. The comments and our responses are provided below.

Comment: Several commenters expressed concern regarding the lack of coverage for the items and services needed to administer IVIG. These commenters urged us to use our authority to pay for the items that are necessary for the effective use of IVIG.

Response: The MMA provided coverage for the approved pool plasma derivative for treatment in the home; however, new section 1861(zz) of the Act specifically precludes coverage for the items and services related to the administration of the derivative.

Comment: The commenter stated that on January 23, 2004, we released a transmittal implementing the new IVIG coverage. The transmittal contained the following language: ''for coverage of IVIG under this benefit, it is not necessary for the derivative (IVIG) to be administered through a piece of durable medical equipment.'' Commenters stated that this language has resulted in the denial of coverage of IVIG for patients because providers are using the rationale that it is medically unnecessary to infuse IVIG through an infusion pump and therefore IVIG is medically unnecessary. The commenters recommended that we issue a new transmittal stating that IVIG is to be covered even when administered through durable medical equipment (DME), as determined necessary by a physician.

Response: It was not our intention to deny any beneficiary the coverage of IVIG in the home. It appears that the sentence that references the use of DME for the administration of IVIG is both confusing and misleading. Therefore, we will issue a new transmittal removing the apparent DME restriction.

Result of Evaluation of Comments

We are finalizing the proposed revisions to § 410.10 without alteration.

H. Section 623—Payment for Renal Dialysis Services

Section 623 of the MMA amended section 1881(b) of the Act and directed the Secretary to revise the current renal dialysis composite rate payment system. The MMA included several major provisions that require the development of revised composite payment rates for ESRD facilities.

The following is a summary of the proposed revisions to the composite payments rate methodology implementing provisions in section 623 of the MMA that are required to be effective January 1, 2005.

- The proposed rule provides for a 1.6 percent increase to the current composite payment rates effective January 1, 2005.
- The proposed rule included an add-on to the composite rate for the difference between current payments for separately billable drugs and payments based on a revised drug pricing methodology using acquisition costs. For purposes of this adjustment, in the proposed rule, we defined acquisition costs as the ASP minus 3 percent. We proposed a single adjustment to the composite payment rates for both hospital-based and independent facilities, equal to 11.3 percent.
- In the proposed rule, we discussed the reinstatement of the ESRD exceptions process for pediatric facilities as provided in section 623(b) of MMA. The statute defines pediatric ESRD facilities as renal facilities at least 50 percent of whose patients are under age 18. Since April 1, 2004, we have accepted ESRD composite rate exception requests from ESRD facilities that believe they qualify for exceptions as pediatric ESRD facilities.
- Section 1881(b)(12)(D) of the Act, added by section 623(d)(1) of the MMA gives the Secretary discretionary authority to revise the current wage indexes and the urban and rural definitions used to develop them. In the proposed rule, we proposed to take no action at this time to revise the current composite rate wage indexes. Because of the potential payment implications of recently revised definitions of urban areas, we believe further study is required.
- The proposed rule described the proposed methodology for a case-mix adjustment to a facility's composite payment rate based on the statutorily required limited number of patient characteristics. We used co-morbidity data for all Medicare ESRD patients obtained from the Form CMS–2728, supplemented with co-morbidity information obtained from Medicare claims. We measured the degree of the relationship between specified co-morbidities and ESRD facility per treatment costs, controlling for the effects of other variables, using standard least square regression. The source of the per treatment costs was the Medicare cost report. The result, after all necessary statistical adjustments, was a set of eight case-mix adjustment factors based on age, gender, AIDS, and peripheral vascular disease (PVD). Section 623(d)(1) of the MMA requires that aggregate payments under the case-mix adjusted composite payment system be budget neutral. Therefore, the proposed rule provided an adjustment 0.8390 to be applied to a facility's composite payment rate to account for the effects of the case-mix adjustments.

A. Composite Rate Increase

The current composite payment rates applicable to urban and rural hospital-based and independent ESRD facilities were effective January 1, 2002. Section 623(a)(3) of the MMA requires that the composite rates in effect on December 31, 2004 be increased by 1.6 percent. The updated wage adjusted rates were published in Tables 18 and 19 of the proposed notice.

The tables reflected the updated hospital-based and independent facility composite rate of $132.41 and $128.35, respectively, adjusted by the current wage index. The rates shown in the tables do not include any of the basic case-mix adjustments required under section 623 of the MMA.

Comment: Although there were no specific comments on the 1.6 percent adjustment, several commenters wanted to emphasize the importance of providing an annual adjustment to the composite rate in order to recognize the increased costs that face renal dialysis facilities. They stated that failure to increase the composite rate on a regular basis has caused dialysis providers to suffer a significant loss of income from their Medicare reimbursement and that dialysis facilities are the only Medicare entities that do not receive a statutorily mandated annual increase in their reimbursement rates.

Response: We do not have the authority to establish an annual update to the composite payment rates. Section 4201(a)(2) of Pub. L. 101–508 effectively froze the methodology for calculation of the rates, including the data and definitions used as of January 1, 1991. Since that time, the Congress has set the composite payment rate for ESRD services furnished to Medicare beneficiaries. As a result, we do not have the authority to update the composite payment rate.

B. Composite Rate Adjustments To Account for Changes in Pricing of Separately Billable Drugs and Biologicals

Section 623(d) of MMA provides for an add-on to the composite rate for thedifference between current payments for separately billable drugs and payments based on a revised drug pricing methodology using acquisition costs.

In the proposed notice we proposed to pay for separately billable ESRD drugs using ASP minus 3 percent based on the average relationship of acquisition costs to average sales prices from the drug manufacturers as outlined in the OIG report. We developed the proposed drug add-on adjustment using the ASP minus

3 percent drug prices. As discussed below, the drug add-on adjustment for this final rule is based on average acquisition costs for the top ten ESRD drugs updated to 2005 and ASP plus 6 percent for the remaining separately billable ESRD drugs. *See* section III.E, Payment for Covered Outpatient Drugs and Biologicals, for a discussion of the final payment methodology for ESRD separately billable drugs.

In the proposed notice, we outlined the methodology and data used to develop the proposed drug add-on adjustment to the composite rate of 11.3 percent for both hospital-based and independent ESRD facilities. Since the composite rate payment for hospital-based facilities is higher than the composite rate for independent facilities, the proposed adjustment results in a higher payment rate for hospital-based facilities. The 2005 composite rates (including the 1.6 percent increase) would be $132.41 for hospital-based facilities and $128.35 for independent facilities with the hospital-based facilities' rate higher by $4.06. We found this result consistent with section 1881(b)(7) of the Act, which requires that our payment methods differentiate between hospital-based facilities and others. We also indicated that the proposed methodology for making this drug add-on adjustment to the composite rate is designed to ensure that the aggregate payments to ESRD facilities for separately billable drugs would be budget neutral with what would have been paid absent the MMA provisions.

The proposed rule also discussed an alternative approach that produced separate adjustments to the composite rate of 2.7 percent for hospital-based and 12.8 percent for independent facilities. In contrast to a single add-on, separate add-on adjustments would result in a significantly higher composite payment rate for independent facilities than hospital-based facilities, of $8.79 more per treatment.

Comment: We received many comments from independent facilities, chain organizations and groups objecting to our proposal to establish a single add-on adjustment to the composite payment rate. Several commenters expressed concern that since hospital-based facilities are paid reasonable cost for their separately billed drugs other than EPO, those facilities should receive an adjustment based only on the spread related to EPO payments. They stated that our proposal to spread the drug savings to all facilities does not comply with the provision in the statute that they believe is intended to hold facilities harmless with respect to their drug payment profit margins. The commenters also contend that since hospital-based facilities already receive about $4.00 per treatment more than independent facilities, they should not share in the drug add-on adjustment for other than their specific EPO usage.

Response: As we indicated in the proposed rule, we believe that the statutory language supports one uniform drug add-on adjustment to composite payment rates set forth in section 1881(b)(7) of the Act after updating by 1.6 percent. The provision speaks of one ''difference between payment amounts'' and ''acquisition costs * * * as determined by the Inspector General.'' It is reasonable to infer that the Congress intended us to compute one ''difference'' based only on the payment amounts under sections 1842(o) and 1881(b)(11) of the Act.

Although the language of section 1881(b)(7) contemplates differential composite rates for hospital-based facilities and 623(d) contemplates existing composite rates as the starting point for application of the new rate adjustments prescribed under section 1881(b)(12)(A) of the Act, the MMA language does not suggest that these adjustments would be applied differentially across facilities. Otherwise, all of the adjustments, including case-mix and budget neutrality would have to be developed separately based on facility type.

We note that the amount of the drug add-on has decreased significantly from the proposed rule as a result of our revised policy of paying for ESRD drugs for 2005. Since the drug payment amounts increased, the amount of the drug add-on to the composite rate decreased. The resulting drug add-on amount is now 8.7 percent.

We also note that there is not a significant difference in composite rates for independent facilities under single and separate add-ons. With a single add-on of 8.7 percent, the 2005 composite rate for independent facilities would be $139.52. Under a separate add-on approach, the 2005 composite rate for independent facilities would be $140.93, a difference of $1.41 or about 1 percent before taking other considerations into account. This difference is about 27 percent less than the difference based on the approach and figures in the proposed rule.

While a composite rate difference of $1.41 is important, such difference does not take into account two other factors: (1) Since Medicare's 2005 payments for ESRD drugs will be a weighted average of the acquisition costs determined by the Inspector General, the payment amounts for the most utilized ESRD drugs (such as EPO) will be significantly higher than payment based on ASP–3 percent; and (2) Beginning with 2005, Medicare will pay separately for syringes that are currently included in the EPO payments.

With separate add-ons, the composite rate for the independent facilities would be $7.33 higher than the composite rate for hospital-based facilities. However, the composite rate for hospital-based facilities would be $10.33 lower under separate add-ons than under a single add-on approach. We believe the current difference in composite rates where the hospital-based rate is about $4.00 higher than the independent facility rate would effectively be preserved with a single add-on and significantly reversed with separate add-ons.

Finally, we note that a key purpose of the MMA legislation was to eliminate the cross-subsidization of composite rate payments by drug payments. If the composite rate was inadequate before the MMA provision, it was inadequate for both hospital-based and independent facilities. As such, increasing the composite rate by relatively greater amounts for independent facilities than hospital-based facilities would place the latter facilities at a competitive disadvantage relative to the former facilities.

Comment: One comment from a drug manufacturer suggested that in order to preserve high quality care to ESRD patients and prevent cost shifting behavior, we should require a facility to provide the full range of separately reimbursable drugs and biologicals in order to receive the drug add-on adjustment.

Response: We do not believe the statute permits imposing such a requirement as a condition for receiving the add-on adjustment to the composite rate. However, other regulations require that ESRD facilities provide appropriate care to each patient based on a plan of care that would include the administration of medically necessary drugs as prescribed by the patient's dialysis physician.

1. Growth Factors Used To Update Drug Expenditures and Prices

Comment: One commenter noted that, in the proposed rule, we updated the 2004 ASP drug prices to 2005 prices by using the projected annual growth factor for National Health Expenditures prescription drugs of 3.39 percent. This commenter wanted to know why we did not use the actual growth factors for separately billable drugs that are furnished by ESRD facilities to ESRD

patients. The commenter states that this factor is currently running about 39 percent.

Response: After consideration of the available price data, as discussed in the section on payment for ESRD separately billable drugs, we have determined that the Producer Price Index (PPI) for prescription preparations is the most appropriate price measure for updating EPO and other separately billable drugs from 2003 to 2005. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) for prescription drugs reflects price changes at the retail stage. Because EPO and many of the separately billable drugs used by dialysis facilities are purchased directly from the manufacturer, the use of a price index that measures wholesale rather than retail prices is more appropriate. The PPI for prescription drugs is the measure used in the various market baskets that update Medicare payments to hospitals, physicians, and skilled nursing facilities, and home health agencies. In addition, the PPI for prescription drugs was recommended for use in the proposed composite rate market basket detailed in the 2003 Report to the Congress.

Based on historical data through the second quarter of 2004, we used the Global Insight Inc. forecast of the PPI for prescription drugs to determine the update factors for 2004 and 2005. We feel the use of an independent forecast, in this case from Global Insight Inc., is superior to using the NHE projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases for Medicare prospective payment systems.

Comment: One comment questioned the 3 percent growth rate that we used in the proposed rule to estimate 2005 Medicare AWP payment amounts for purposes of calculating the drug add-on amount. Specifically, the commenter asked whether the 3 percent figure represented the AWP growth trends for all drugs as opposed to the AWP growth trends for only ESRD separately billable drugs and biologicals. The commenter also asked for clarification of the timeframe used to establish the historical trend.

Several comments also expressed concern that we used a 10-quarter average as an approximation for 2002 expenditures, and as a result, the projected 2005 drug expenditures were understated. These comments strongly recommended that we establish an accurate baseline using actual 2002 expenditures. A study performed for commenters by an industry consultant was cited as confirming that our base year estimate is materially below actual drug spending computed using CMS's 2002 Outpatient Five Percent Standard Analytic File (SAF). Commenters were also concerned that the drug add-on does not reflect the true difference between payments under the current system and acquisition costs described by the OIG.

Response: We have taken all these comments into consideration and have re-evaluated our 2005 projection of aggregate ESRD facility drug expenditures. We did not use an average over 10 quarters to determine aggregate drug payments. The 10 quarters of data were used only to establish historical growth trends. However, we determined that our estimates of aggregate drug payment amounts were in fact understated because they did not include deductibles and coinsurance. Since drug payment rates are set at 100 percent of the allowable payment, we incorrectly calculated the aggregate drug payment for 2005. We revised our calculation to ensure that we capture the allowable payment before deductible and coinsurance are removed. In addition, we updated our estimates to incorporate the June 2004 update to the 2003 standard analytical file. The 3 percent growth represents our best estimate of the expected growth rate in AWP prices. In addition, due to numerous coding changes for the various ESRD drugs, we were unable to do direct comparisons for each of the AWP prices from year-to-year. Therefore, we believe the 3 percent inflation factor we used to update the AWP prices is appropriate.

Comment: One comment expressed concern that the projected number of dialysis treatments in 2005 would be overstated if home peritoneal dialysis (PD) treatments for home patients are included because facilities do not bill for non-EPO drugs in that setting.

Response: Since ESRD facilities also receive composite rate payments for their Method I home patients, the drug add-on would also apply to composite rate payments for those patients. Therefore, it is appropriate for us to count those treatments in projecting the number of dialysis treatments for computation of the drug add-on amount. We did not, however, count treatments attributable to Method II home patients since payment for these patients is made based on reasonable charges as opposed to the composite rate.

Comment: One comment from a patient organization raised concern that the add-on provision would remove any incentives the current payment policy creates for facilities to provide separately billable drugs and biologicals to dialysis patients. This comment suggested that we establish new clinical guidelines or indicators to ensure that dialysis patients receive necessary drugs and biologicals. This commenter also asked whether we have longer term plans to revise payment for dialysis treatment and ancillary services.

Response: We share this commenters concern that changes in payments to dialysis facilities could produce perverse incentives for dialysis facilities to skimp on care to ESRD patients. In order to ensure that patients continue to receive quality care, we are revising the ESRD facility conditions for coverage so that they are more patient-centered and outcome-oriented. We will publish proposed ESRD conditions by the end of 2004. We note that section 623 of MMA also requires us to develop a bundled, case-mix adjusted payment system and report to the Congress by October 1, 2005. This section also requires the establishment of a demonstration to test the revised payment system over a 3-year period beginning January 1, 2006.

2. Update Methodology for Drug Add-on Adjustment in 2006

Comment: Several commenters recommended that we publish the methodology that we intend to use to update the drug add-on component of the basic case-mix adjusted payment amounts, beginning in 2006, and that we provide the opportunity for public comment.

Response: We did not propose a mechanism for updating the 2006 payments in this document since this rule addresses payment for 2005. It is our intent to publish a proposed rule in mid-2005 to address payment changes for 2006. The public will be given an opportunity to comment on those proposals at that time.

3. Computation of Final Drug Add-On Adjustment to the Composite Payment Rate

To develop the final drug add-on adjustment we used historical total aggregate payments for separately billed ESRD drugs for half of 2000 and all of 2001, 2002 and 2003. For EPO, these payments were broken down according to type of ESRD facility (hospital-based versus independent). We also used the 2003 data on dialysis treatments performed by these two types of facilities over the same period.

I. 2005 Average Acquisition Payment (AAP) Amounts

The OIG report contained 2003 average acquisition costs for the top ten drugs supplied by the four largest dialysis chain organizations and by a sample of those facilities not managed by the four largest chain organizations. According to the OIG report, these ten drugs accounted for about 98 percent of total expenditures for separately billed drugs furnished by ESRD facilities. The report also indicated that payment to the four largest dialysis chains accounted for 73 percent of Medicare drug reimbursement in 2002. Therefore, we weighted the average acquisition costs using a 73–27 split. As discussed earlier, we then updated the 2003 weighted average acquisition costs to arrive at the 2005 AAP amounts by using the PPI for prescription drugs. These factors were 4.81 percent and 3.72 percent for 2004 and 2005, respectively.

TABLE 9:

	2003 Average Acquisition Costs	2005 Average Acquisition Payment Amounts
Epogen	$8.98	$9.76
Calcitriol	0.88	0.96
Doxercalciferol	2.39	2.60
Iron dextran	10.07	10.94
Iron sucrose	0.34	0.37
Levocarnitine	12.53	13.63
Paricalcitol	3.68	4.00
Sodium ferric glut	4.55	4.95
Alteplase, Recombinant	29.19	31.74
Vancomycin	2.74	2.98

II. Estimated 2005 Medicare Payment Amounts Based on 95 Percent of AWP

We estimated what Medicare would pay for ESRD drugs in 2005 if the MMA had not been enacted. We adjusted the first quarter 2004 Medicare payment amounts (95 percent of AWP), based on the prices from the January 2004 Single Drug Pricer, for drugs other than EPO, to estimate 2005 prices by using an estimated AWP growth of 3 percent. As discussed earlier, these growth factors are based on historical trends of AWP pricing over years. We did not increase the price for Epogen since payment was maintained at $10.00 per thousand units prior to MMA.

TABLE 10:

Drugs	Estimated 2005 Pre-MMA Medicare Payment Amounts
Epogen	$10.00
Calcitriol	1.42
Doxercalciferol	5.67
Iron dextran	18.45
Iron sucrose	0.68
Levocarnitine	35.23
Paricalcitol	5.49
Sodium ferric glut	8.42
Alteplase, Recombinant	37.80
Vancomycin	7.24

III. Dialysis Treatments

We updated the number of dialysis treatments based on 2003 data by actuarial projected growth in the number of ESRD beneficiaries. Since Medicare covers a maximum of three treatments per week, utilization growth is limited, and therefore any increase in the number of treatments will be due to enrollment. In 2005, we project there will be a total of 34.8 million treatments performed.

IV. Estimated Drug Spending

We updated the total aggregate 2003 Epogen drug spending for hospital-based and independent facilities using historical trend factors. For 2004 and 2005, we increased the 2003 spending levels by trend factors of 1.0 percent for hospital-based facilities and by 10.0 percent for independent facilities based on historical growth from 2000 to 2003.

We also updated the aggregate AWP based spending for separately billed drugs, other than EPO, for independent facilities by using the 10 percent growth factor for Epogen. Since aggregate spending in this category show extremely varied growth in recent history, we could not establish a clear growth trend. For this reason we decided to apply the Epogen growth rate to the other separately billed drugs. Given the problems establishing growth trends for the other drugs, plus the fact the expenditures for Epogen account for about 70 percent of the total spending for the top ten ESRD drugs, we believe this approach to updating all of the separately billed drugs is appropriate.

Additionally, we deducted 50 cents for each administration of Epogen from the total Epogen spending for both hospital based and independent facilities, to account for payment for syringes that is currently included in the EPO payments. Payment for syringes used in administering EPO will be made separately beginning January 1, 2005. In 2005, we estimate that the total spending for syringes associated with the administration of Epogen will amount to $1.6 million for hospital-based facilities and $27 million for independent facilities. For 2005, we estimate that the total spending for Epogen provided in hospital-based facilities will be $210 million, and $2.913 billion for drugs provided in independent facilities ($2.003 billion for Epogen and $910 million for other drugs).

V. Add-On Calculation and Budget Neutrality

For each of the ten drugs in the previous tables, we calculated the percent by which 2005 AAP amounts are projected to be different from the payment amounts under the pre-MMA system. For Epogen, this amount is 2 percent. We applied this 2 percent figure to the total aggregate drug payments for Epogen in hospital-based facilities, resulting in a difference of $5 million.

Since the top 10 ESRD drugs will be paid at 2005 AAP amounts and the remainder will be paid at ASP plus six percent, we then calculated a weighted average of the percentages by which AAP amounts would be below current Medicare prices, for the top 10 drugs, and the percentage by which ASP plus 6 percent would be below current Medicare payment amounts. For other than the top ten drugs, we do not have detailed data on expenditures for drugs billed by ESRD facilities. Therefore, we computed the percentage by which ASP plus 6 percent is below the estimated 2005 pre-MMA payment amounts for those drugs, using the average of the comparable ASP prices for the top 10 ESRD drugs. This procedure resulted in a weighted average of 13 percent by which the overall revised 2005 drug payment amounts applicable to independent facilities is projected to be less than the 2005 estimated pre-MMA system (that is, 95 percent of AWP). We then applied the 13 percent weighted average to total aggregate drug spending projections for independent facilities, producing a projected difference of $385 million.

Combining the 2005 estimates of $5 million and $385 million, for a total of $390 million and then distributing this over a total projected 34.8 million treatments would result in an add-on to the per treatment composite rate of 8.7 percent. We estimate that an 8.7 percent adjustment to the ESRD composite payment rate would be needed to achieve budget neutrality with respect to drug expenditures for ESRD facilities.

A. Patient Characteristic Adjustments

As explained in the proposed rule, the current ESRD composite payment rates are not adjusted for variation in patient characteristics or case-mix. Section 623(d)(1) of the MMA added section 1881(b)(12)(A) of the Act to require that the outpatient dialysis services included in the composite rate be case-mix adjusted. Specifically, the statute requires us to establish a basic case-mix adjusted prospective payment system for dialysis services. Also, the statute requires adjustments under this system for a limited number of patient characteristics. In the proposed notice, we described the development of the methodology for the proposed patient characteristic case-mix adjusters required under the MMA.

In summary, we proposed to use a limited number of patient characteristics that explain variation in reported costs for composite rate services, consistent with the legislative requirement. The proposed adjustment factors are as follows:

TABLE 11:

	Age	Adjustment factor
Female	<65 years	1.11
	65-79 years	1.00
	>79 years	1.16
Male	<65 years	1.21
	65-79 years	1.17
	>79 years	1.23
AIDS		1.15
PVD		1.07

Although the magnitude of some of the patient-specific case-mix adjustments appears to be significant, facility level variation in case-mix is limited because of the overall similarity of the distribution of patients among the eight case-mix classification categories across facility classification groups.

We received a significant number of comments regarding the case-mix adjustment factors, which are summarized in this section with our corresponding responses.

1. Sample Data Used To Develop the Basic Case-Mix System

Comment: Comments regarding the sample or universe used to derive the proposed basic case-mix adjustments in the proposed rule expressed concerns about the size of the sample, the number of hospitals and freestanding facilities included, as well as the number of facilities excluded from the data.

Response: We used the database established by our contractor to develop the basic case-mix system in the proposed rule. Facility cost report data were matched to the corresponding facility billing data to insure that the sample reflected the most valid and reliable data available. The specific methodology used to develop the database is discussed in Kidney Epidemiology and Cost Center's (KECC's) Phase I report. The Phase I report entitled: ''An Expanded Medicare Outpatient End Stage Renal Disease PPS—Phase I'' is available on the University of Michigan Web site: *http://www.sph.umich.edu/kecc.* The contractor has been updating the data files for subsequent phases of their research and is beginning to analyze these data for the bundled prospective payment system. The data used for the basic case-mix proposed system were also assessed in terms of consistency. Data from 2000, 2001, and 2002 were examined separately as well as combined to determine if there were consistent trends over the 3-year period. The data were updated to include the latest 2002 data that was available as of September 2004. The updated data reflect an increase of approximately 10 percent in the number of facilities represented in the database.

Comment: Several comments expressed concerns regarding the timeliness of the data used to develop the proposed case-mix measures. These concerns focused on the availability of cost reports for 2002. In the proposed notice we acknowledged we were delayed in obtaining cost reports for 2002 and that the final rule would reflect the most recent data on the number of cost reports available.

Response: Table 12 indicates the number of dialysis facilities with at least one cost report for 2000 to 2002. This table also reflects the availability of the most recent cost reports data for 2002 and reflects an increase from the proposed rule of an additional 564 cost reports for the independent facilities in 2002.

TABLE 12:

	2000	2001	2002
Independent Facilities	3034	3067	3072
Hospital-based Facilities	476	470	456

The availability of cost reporting data may be delayed because of a number of factors including late submissions by facilities and necessary reconciliation and verification of data by fiscal intermediaries prior to submission to our data systems. The comment on delays and availability of data is also related to concerns expressed by other comments regarding the reporting of co-morbid conditions. Several comments addressed potential inconsistencies in

facility reporting of co-morbid conditions, specifically with the impact of the variation of the reporting of AIDs noted in the 2000 data compared to other years. This variation, coupled with the potential incompleteness of the 2002 data, led us to examine options for selecting the time period to be used for determining the case-mix adjustments.

In this final rule, we have decided to use combined data for the 3-year period 2000–2002, to determine the case-mix adjustment factors. The use of combined data enables us to eliminate any impact caused by annual variation in reporting, delays in the availability of administrative files, and overemphasizing the predictive significance of selected variables, because case-mix variables are combined and averaged over a 3-year period, thus representing a more stable database.

Comment: Several comments focused on the number of facilities that were excluded from the study sample in the development of the proposed case-mix adjustments. For the proposed regulation, we excluded from our sample facilities where cost report data could not be matched to claims data and vice versa, or where key data elements were missing. In addition we excluded outlier facilities (those with high or low average costs, or high or low proportions of co-morbid conditions.) Data from small facilities (fewer than 20 patients) and those with existing composite rate exceptions were also excluded.

Response: We concurred with the recommendation to reassess the sample. For the final rule, we are including, within the sample, data for facilities with existing exceptions. However, we have continued to exclude data for small facilities, outliers, and facilities with missing or unusable data. Missing data excluded approximately 11 percent of the sample, and not including small facilities or outlier facilities eliminated approximately 9 percent of the study sample.

We did not accept the suggestion that smaller sized facilities were proxies for rural facilities, however, and we will continue to study the rural and urban issue in future research and in updates to the wage index.

Overall, including those facilities with exceptions provides a more robust study sample. In this way any effects on the case-mix values due to fluctuations in the data from year to year are greatly diminished.

Comment: Several commenters objected that the database used to develop the basic case mix was not available. One commenter indicated that not having the data made it difficult to evaluate the impact of the proposed case-mix variables on specific facilities.

Response: The database developed for the basic case-mix system is the same database that was developed by the University of Michigan for the ongoing research project to develop a bundled payment system. This database was compiled using our administrative data. We make available for purchase data available in the form of public use files or standard analytic files. Commenters can use the same data files that were used by the University of Michigan to develop the database used. The proposed rule provides the factors necessary to determine impact on individual facilities based on the case-mix within that facility. In addition, we have expanded our discussion of the impact of the case-mix adjustments and have provided a more detailed example to assist facilities in evaluating the impact of the case mix on their specific facilities.

2. Including Co-Morbid Conditions in the Case-Mix Adjustment

Comment: A number of comments expressed concerns regarding the coding of co-morbid conditions. Some comments acknowledged that limited time has been spent by ESRD facilities in coding multiple conditions. Some stressed that training should be provided to ensure that facilities understand this reporting requirement. One commenter attributed the proposed delay in implementation of the case-mix adjustments to potential difficulties in coding co-morbid conditions and in integrating these coded conditions into the payment.

Response: We considered the commenters concerns regarding incorporating co-morbid conditions and the findings from analyzing more recent data. Although our regression modeling suggests that the inclusion of co-morbidities in the case-mix system would be appropriate, we are concerned that the data available to determine patient level co-morbidities may not accurately reflect diagnoses relevant to the dialysis patient population. Therefore, in this final rule we are not including co-morbidities as case-mix adjustments. As discussed later in this section, we are establishing the case-mix adjustments based on the following variables: age, body mass index (BMI) and body surface area (BSA). More recent analysis of the data and clinical concerns expressed regarding the inclusion of AIDs and selected PVD diagnoses support this decision. However, while co-morbid conditions are not currently part of the basic case-mix system, we encourage all facilities to more thoroughly report and code co-morbid conditions on their claims. This will enable appropriate refinements to the basic case-mix adjustments and also provide a better database from which we can develop case-mix measures for a bundled payment system.

Comment: One commenter representing a chain of ESRD facilities stated that we overstated the prevalence of patients with peripheral vascular disease (PVD). The commenter maintained that overstating the incidence of PVD in the ESRD outpatient population results in an overstatement of the offset for budget neutrality because of the proposed 1.07 case-mix adjuster for PVD patients, thereby decreasing the otherwise applicable composite payment rate prior to case-mix adjustments. The commenter identified 51 diagnoses from the list of PVD diagnosis codes included in the proposed rule that he believed were either not reflective of PVD in ESRD patients, were not usually considered as a cause of PVD in ESRD patients, or were poorly differentiated clinically and could occur even in the absence of PVD. The commenter believed that these 51 diagnoses should be excluded from our list of PVD diagnoses for purposes of determining the case-mix and budget neutrality adjustments to the composite payment rates. Another commenter pointed out that there is substantial clinical disagreement about the definition of PVD and that the ESRD claims data presently do not contain sufficient information to implement the proposed PVD adjustor.

Response: The selection of specific co-morbid conditions for purposes of adjusting the composite payment rates to reflect the patient characteristics associated with cost differences across facilities is an important issue, and we appreciate the commenter's suggestions. However, we disagree with the recommendation that we exclude certain diagnoses because they are not usually considered a cause of ESRD in patients. We believe that whether a particular co-morbid condition caused the onset of ESRD is irrelevant. The important factor is whether a particular co-morbid condition is associated with facility differences in composite rate costs, regardless of their role in the etiology of ESRD.

We agree with the commenter's suggestion that diagnoses which can occur in the absence of PVD will be excluded for purposes of applying a case mix adjustment based on PVD. In addition, there is apparent disagreement among clinicians as to whether certain

diagnoses are reflective of PVD in ESRD patients, and we will try to achieve as much consensus as possible before proceeding to implement a case mix adjuster which purports to reflect PVD. Accordingly, we are eliminating the case mix adjustment for PVD as set forth in the proposed rule. We point out that further analyses with more restricted sets of diagnostic codes revealed that the omitted codes were still strong predictors of costs. We intend to revisit the issue of appropriate co-morbidity adjustments as we continue our research to develop the bundled ESRD payment system.

We point out that our case mix model that included PVD explained about 35.7 percent of the variation in facility composite rate costs. By comparison, our model using five age groups without co-morbidities explains about 35.6 percent of the cost variations. Although PVD was a statistically significant case mix variable, its contribution to the model's performance overall in explaining facility differences in costs was minimal. While co-morbidity adjustments will be excluded under the basic case mix adjusted composite payment system, accuracy in the reporting of co-morbid conditions on the bills will become increasingly important because of the likelihood that a bundled ESRD payment system will include co-morbidities associated with differences in patient resource consumption.

Comment: Two commenters recommended that we exclude AIDS as a co-morbidity warranting case-mix adjustment. These commenters stated that because of State laws requiring that a patient's AIDS status be kept confidential, most facilities do not know whether their patients have AIDS. This does not pose a risk to other patients or caregivers because of the universal precautions which dialysis facilities are required to use in order to prevent exposure and infection.

Response: Because the claims data contain primarily the patient's primary diagnosis, AIDS is not likely to be recorded as a claims diagnosis for outpatient dialysis patients. Requiring the recording of the AIDS diagnosis on the bills would create powerful incentives for ESRD facilities to circumvent confidentiality restrictions. In those States with AIDS confidentiality requirements, the diagnosis is not likely to be recorded at all. Given the relatively low incidence of AIDS patients in the outpatient dialysis population, the fact that facilities in States with AIDS confidentiality requirements would be potentially disadvantaged if AIDS were included as a payment adjuster, and the fact that the relationship between AIDS and dialysis costs was not stable from year to year, we have decided to eliminate AIDS as a basis for case-mix adjustment to the composite payment rates at the present time.

3. Case-Mix Adjustment for Gender

Comment: One commenter suggested that we eliminate gender as one of the patient characteristic variables used to case-mix adjust the composite payment rates. The commenter stated that gender was essentially a surrogate for differences in height and weight measures that would yield a superior case-mix adjustment.

Response: Although height and weight are much better predictors of facility variation in composite rate costs, these data were only available on the Form CMS 2728, not on the bills submitted for payment. Accordingly, we used gender as a surrogate measure in proposing adjustments, because gender is reported on the outpatient bill (for example, UB92 or the equivalent electronic form). However, the National Uniform Billing Committee has approved the use of two new value codes for reporting weight and height (A8—weight in kilograms, A9—height in centimeters) on the billing forms effective January 1, 2005.

The mandatory reporting of height and weight permits the development of case mix measures that reflect both variables, such as BMI and BSA, each of which are superior to weight alone as predictors of resource use. Given the impending availability of height and weight data on the outpatient dialysis bill, we examined the predictive power of weight, BMI, and BSA in lieu of gender based on data reported on the Form 2728 from 2000 through 2002. We found that both BMI and BSA are superior predictors to weight alone and that BSA, coupled with a variable for low BMI, is the best predictor of facility differences in composite rate costs. Accordingly, we have eliminated gender in this final rule as a patient classification variable for purposes of case mix adjustment. Instead we are substituting BSA, and a variable for low BMI, each of which are explained in another section of this final rule.

4. Age Groupings Used in Proposed Case-Mix Adjustment

Comment: Several comments indicated that the proposed age groups were too broad. Some of the comments recommended that we create more age categories for purposes of the case-mix adjustments.

Response: In the proposed rule we established three age categories for example: less than 65, 65–79, and greater than 79. In reassessing the study sample and the proposed case mix adjusters, we also explored the age categories. We concur with the comments to expand the number of age categories. For the final rule, there will be five age groupings. These are: 18–44, 45–59, 60–69, 70–79, and 80+. Patients under 18 are discussed in the following section on pediatrics. We believe that the revisions to the age groupings more accurately describe the distribution of the patient population and reflect more refined predictors of age for payment purposes.

Comment: One commenter asked what would happens under our proposed adjustment if during the course of a month, an ESRD patient's age changed and they cross the line into another case-mix adjustment factor. For example, on August 15 a 64-year-old ESRD patient turns 65. They questioned how is this situation is handled and is the age used as of the last day of the month.

Response: We believe it is appropriate to handle this situation as it is handled for enrollment. Thus, for a month when the patient has a birthday that puts him or her into another age category, the first of the month would be the effective date of the patient's new age category.

5. Case-Mix Adjustment for Pediatric Patients

Comment: Several commenters expressed concern over the lack of a case-mix adjustment for pediatric ESRD patients. The commenters stated that although section 623(b) of the MMA provided for an exception process for pediatric ESRD facilities, qualification for a pediatric exception is limited to those facilities where pediatric patients (those under age 18), comprise at least 50 percent of the caseload. The commenters pointed out that ESRD pediatric patients are unusually resource intensive and costly and are widely scattered among facilities, most of which would not qualify as pediatric facilities under the definition set forth in the statute. The commenters recommended that we develop a case-mix adjuster for pediatric ESRD patients using other data sources.

Response: Using the same regression methodology described in the proposed rule, we attempted to develop a case-mix adjuster for outpatient ESRD patients under age 18. However, based on the approximately 600 Medicare patients for whom bills were available each year from 2000 through 2002, the results were highly variable, statistically

unstable, and therefore inappropriate for development of a case-mix adjuster in accordance with the proposed rule's methodology. However, because of the costliness of pediatric ESRD patients, we believe that an alternative case-mix adjustment is warranted, particularly for those facilities, which do not meet the definition of a pediatric facility under section 623(b) of the MMA.

As the commenter correctly pointed out, some facilities would not qualify for consideration for the pediatric exception provided in the law because their pediatric caseload does not constitute 50 percent of their patients. These facilities may still incur substantial costs for the treatment of pediatric ESRD patients. Pending the development of more refined case-mix adjustments that are more sensitive to individual variation in treatment costs under a fully bundled ESRD PPS, we are providing for a single adjustment to a facility's otherwise applicable composite payment rate, developed based on the methodology described below, for outpatient ESRD pediatric treatments. We want to emphasize that the pediatric adjustment factor resulting from this methodology is intended to be a temporary measure. It will only apply until we can develop an adjustor under the bundled ESRD PPS that is more similar with the case-mix adjustments that would apply to non-pediatric ESRD patients.

During the period from November 1, 1993 to the present time, we identified 19 hospital-based and one freestanding ESRD facility, each of which sought and received an atypical services exception based on the higher costs incurred for the treatment of outpatient pediatric patients. For each of these facilities we obtained the number of treatments at the time the exception was submitted and determined the unadjusted composite payment rate that would have applied beginning January 1, 2005 without regard to any exception amount, that is, each facility's unadjusted composite payment rate was inflated to January 1, 2005 to reflect the statutory increases of 1.2 percent effective January 1, 2000, 2.4 percent effective January 1, 2001, and 1.6 percent effective January 1, 2005.

We then subtracted the inflated January 1, 2005 unadjusted composite rate from each facility's composite payment rate, including the exception amount granted, to obtain the estimated amount of the exception projected to 2005. This amount was multiplied by the number of treatments previously provided, summed for all 20 facilities, and then divided by the number of treatments for all 20 providers to yield an average atypical services exception amount per treatment. The average exception amount for ESRD facilities that received exceptions due to their pediatric caseload, adjusted to 2005, was $86.79 per treatment. The average unadjusted composite payment rate for these same 20 facilities projected to 2005, similarly weighted by the number of treatments, was $139.32. Thus, the average composite payment rate adjusted to January 1, 2005, including the average exception amount of $86.79, was $139.32 + $86.79 or $226.11. Because the average exception amount was calculated from facilities located in areas with differing wage levels, we converted the average pediatric exception amount to a ratio, $226.11/$139.32 or 1.62.

This is the case-mix adjustment factor that will be applied to each facility's composite payment rate per treatment for outpatient maintenance dialysis services furnished to pediatric patients. This includes both in-facility and home dialysis. Applying the adjuster multiplicatively in this manner recognizes the wage index variation in labor costs among urban and rural areas built into the composite rates. Notwithstanding this case-mix adjustment per treatment for ESRD pediatric patients, facilities who otherwise qualify as a pediatric facility under section 623(b) of the MMA will be permitted to seek an exception to this rate if they believe their circumstances warrant a higher payment rate under the atypical services exception provisions set forth in the regulations. We intend the pediatric adjustment factor of 1.62 to be a temporary measure. We anticipate its elimination once the case-mix methodology that will apply in the context of the bundled ESRD PPS is developed. We want the same methodology to apply to both pediatric and non-pediatric ESRD patients.

6. Facility Level Control Variables Used in the Proposed Regression Model

In developing the regression model used to derive the case-mix adjustments, we included variables reflective of facility characteristics. Because facility characteristics do account for differences in facility composite rate costs, we included them in the regression model through the use of facility control variables, so that the patient characteristic case-mix adjusters are not distorted. The facility control variables included the wage index, facility size (based on the annual number of treatments), facility status as hospital-based or freestanding, percent of patients with urea reduction ratios greater than or equal to 65 percent, chain ownership, year of cost report, and percent of pediatric patients treatments. These variables were not used to calculate the basic case-mix adjustment factors.

Comment: One comment questioned the inclusion of the proportion of patients with urea reduction ratios (URRs) greater than 65 as a facility control variable in the least squares regression model used to develop the case-mix adjustment factors. The comment maintained that because a patient's URR may be correlated with other co-morbid conditions, the coefficients for the variables tested in the model might be distorted. The comment recommended an evaluation of the degree of association between URR and the main co-morbid conditions to determine the extent of any multicolinearity. The comment further stated that if URR is appropriate as a facility control variable, then other surrogates of dialysis efficiency, such as standardized mortality ratio and proportion of patients with hemoglobin readings above specified target levels, should also be considered as control variables.

Response: We believe that case-mix adjustments to the composite payment rate must be determined by patient and not by facility characteristics. To the extent that facility differences in costs are statistically explained by facility and not patient characteristics, we account for them in the regression model through the use of control variables, so that the potential case-mix adjusters are not distorted. Facility control variables were not used to develop the adjustment factors to the composite payment rates.

For example, chain affiliation, facility size, and status as a hospital-based or freestanding facility were associated with statistically significant differences in facility costs. However, it would be inappropriate to object to the payment rates based on a facility belonging to a particular chain, or based on the number of annual treatments.

To test for multicolinearity, that is, to ensure that each co-morbidity tested for inclusion in the regression model was not correlated with other variables, we ran a correlation matrix. The correlation matrix included URR. URR was found not to correlate with any of the co-morbidities tested; in statistical parlance, it was orthogonal. Accordingly, low URR was not a surrogate of co-morbidity. Therefore, we believe it was appropriate to treat URR as a quality of care outcome measure at each facility. The effect of using URR as a facility control variable was to ensure that the case-mix adjustment factors were not distorted for facilities with similar URR outcomes. For example, if

larger patients receive lower doses of dialysis, not controlling for URR could impart a downward bias on the coefficient for patient size. The comment also suggested the use of other variables as facility control variables such as standardized mortality ratio (SMR) and hemoglobin count. Because SMR standardizes or controls for the effect of case mix on the ratio, we would have to ensure consistency in the reporting of specified co-morbidities on the bills in order to ensure the validity of each facility's SMR. That consistency currently does not exist. Facilities are only required to report hematocrit/hemoglobin on the claims available for those patients receiving erythropoeitin (EPO). However, because the proportion of patients receiving EPO is high, the use of hematocrit/hemoglobin as another outcome facility control variable is feasible, but mainly in the context of the bundled payment system. Since the drugs and lab tests associated with anemia management are paid outside the composite payment rate, hematocrit/hemoglobin level would not be appropriate as a control variable applicable to composite rate costs.

7. Propriety of Case-Mix Adjustment

Comment: Several commenters expressed reservations about our proceeding with the implementation of a case-mix adjustment to the composite payment rates using the methodology set forth in the proposed rule. One commenter cited the May 19, 2004 report prepared by the KECC of the University of Michigan, which pointed out that the proposed case-mix variables collectively explained less than 1 percent of the facility variation in composite rate costs, although the addition of facility control variables increased this proportion to about 33 percent. One commenter stated that the low explanatory power of the proposed case-mix variables indicated that they do not accurately predict cost variation and are flawed. The commenter suggested that we defer applying a case-mix model until the results of the demonstration project mandated under section 623(e) of the MMA are available.

Response: We would have preferred to develop a case-mix adjustment in the context of a bundled outpatient ESRD PPS. In a fully bundled PPS, which section 623(f) of the MMA anticipates, routine and separately billable dialysis related services, drugs, and clinical laboratory tests would be included in the payment bundle. KECC's previous research revealed that, for separately billable services, case-mix explained about 23 percent of the variation in cost across dialysis facilities. (*See* Hirth, *et al.*, Is Case-Mix Adjustment Necessary for an Expanded Dialysis Bundle?, Health Care Financing Review, 2003, 24, pages 77–88).

However, the enactment of Pub. L. No. 108–173 foreclosed the option of deferring implementation of a casemix adjusted composite rate based on a limited number of patient characteristics effective January 1, 2005. We do not believe that the statutory directive set forth in section 623(d) of the MMA permits us to defer the development of a basic case-mix measure, one based on a ''limited number of patient characteristics.''

We do not agree with the statement that, because the proposed case-mix adjusters collectively account for about 1 percent of the facility variation in composite rate costs, the variables used are fundamentally flawed. In fact, when data is combined over three years, each of the proposed case-mix variables is highly significant statistically, despite the low proportion of facility variation in costs explained. A more important indicator of the importance of the case mix factors identified is the size of the adjustments. If the identified case mix variables did not have a meaningful relationship with costs, the magnitude of the adjustment factors would be insignificant or trivial. They are not. As explained in this final rule, based on our analysis of the comments we received, we have revised the case-mix variables used to adjust the composite payment rates. Our research to develop a statistically robust clinically coherent case-mix measure in the context of the fully bundled ESRD PPS will continue.

8. Alternative Case-Mix Variables

Comment: Several commenters suggested alternative case-mix variables which they believe account for patient differences in resource consumption and would better distinguish facility differences in composite rate costs. The patient characteristics proposed by commenters included quarterly serum albumin values, cancer, limb amputation, gastrointestinal disorders, body mass index, weight, revised age groupings, hypertension, duration of dialysis treatment, and others. The commenters indicated that, based on their clinical judgment, the suggested factors were more likely to be predictors of variability in the cost of care than the proposed AIDS and PVD co-morbidities. A few commenters recommended a delay in the implementation of the case-mix adjusted composite payment rates pending evaluation of the suggested variables. A number of comments indicated that BMI was a significant predictor of cost and recommended that BMI be included in the case-mix adjustment. Another commenter recommended BSA be examined as a potential case-mix predictor.

Response: We appreciate all of the comments we received proposing alternative case-mix variables. We welcome suggestions for case-mix refinement based on sound clinical judgment, especially when analyses including separately billable ESRD services are performed as our research for development of the bundled ESRD payment system progresses. However, we point out, that unless the existence of a suggested co-morbidity or patient characteristic could be determined from either the Form CMS 2728 or claims data which could be linked to a specific ESRD dialysis patient, we were unable to evaluate its potential to predict facility differences in composite rate costs. Furthermore, unless a patient characteristic can be reported on the UB 92 claim form (or the equivalent electronic version), it cannot be used to adjust a facility's composite payment rate. These limitations eliminate for consideration many of the commenters' suggested alternative patient characteristic variables.

Nonetheless, our regression model evaluated 35 patient characteristics including weight, BMI, BSA, seven types of cancer, diabetes, chronic obstructive pulmonary disease, four types of heart disease, and race. Co-morbidities selected for inclusion in the model with significant negative coefficients were removed from subsequent iterations of the stepwise regression model. The inclusion of such co-morbidities would have resulted in reductions in the otherwise applicable composite rate payments. Because we can now require the reporting of height and weight on the claim form beginning January 1, 2005, we have adopted the commenters' suggestions to use either BMI or BSA as a predictor variable. We selected BSA and low BMI because they improve the model's ability to predict the costs of composite rate service compared to using BMI or weight alone. In addition, we have increased the number of age groups from three to five and eliminated gender as a payment variable entirely.

As explained later in the ''Implementation Date'' section, we do not believe it would be appropriate to further delay the implementation of the basic case-mix adjustment. We proposed delaying implementation of the case-mix payments until April 1, 2005 in order to ensure all systems, programming, and other operational requirements are in place. Between publication of this final rule and the

implementation date, we will conduct training programs to ensure that facilities understand both the payment methodology and reporting requirements necessary to ensure appropriate payment to ESRD facilities.

9. Continuing Research To Develop a More Fully Bundled Case-Mix System

Comment: Several comments requested additional detail regarding the continuing research for the development of a more fully bundled system.

Response: The research activities for the fully bundled system have focused on updating the database. Research efforts since the passage of MMA have focused on supporting the Congressional mandate for the development of a limited number of case-mix variables. Following the publication of this rule, we anticipate that the emphasis will return to the development of a bundled prospective payment system that includes bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. This research will be reflected in an October 1, 2005 Report to the Congress.

In addition, the MMA requires us to establish the fully case-mix adjusted demonstration which will bundle into the payments both separately billable drugs and biologicals and clinical labs. Both the Report to the Congress and the demonstration will be supported by continuing research.

10. Body Measurements as Case-Mix Adjusters

In the proposed rule, we had discussed the importance of the BMI as a measure of resource consumption related to the composite payment rate. At that time, our analysis indicated that patients with very low or high BMI were more costly to treat. At the time of the publication of the proposed rule, we had no mechanism to obtain indicators for height and weight on the claims form. We had indicated that we would be exploring adding height and weight to the bills.

Comment: A number of commenters endorsed the use of low BMI as an appropriate surrogate for the severity of morbid conditions associated with malnourishment in the dialysis population, and some suggested that a BMI below 20.0 kg/m^2 is generally considered in the underweight range. In addition, we also received comments regarding the inclusion of a measure of BSA.

Response: We concur with the comments to include BMI and BSA as case-mix adjusters reflecting patient characteristics that explain variation in the reported costs for composite rate services. We have obtained approval to collect both height and weight on the bill through the use of two new value codes. ESRD facilities will be required to report height and weight using these value codes, so that payment can be based on the case-mix adjusted composite rate payment system on April 1, 2005.

For the implementation of the basic case-mix payments, we are providing an adjustment for low BMI, that is, any patient with a BMI less than 18.5 kg/m^2. We included this variable because our regression analysis indicated that those patients who are underweight and malnourished consume more resources than other patients. Although we received one comment suggesting defining low BMI as 20 kg/m^2, we chose the measure of low BMI that is consistent with the CDC and NIH definition for malnourishment. Furthermore, our exploration of alternative BMI thresholds did not improve the model's ability to predict the costs of composite rate services.

In addition, we are providing case-mix adjustments based on BSA. Our research into this body measurement indicated that BSA (meters^2) is a good predictor of composite rate resource consumption. We examined all of the formulas for BSA. While we found very little differences between the formulas in predictive power, we are adopting the Dubois and Dubois formula for BSA since our literature search revealed that this particular formula was the most widely known and accepted. This formula is: $BSA=W^{0.425} * H^{0.725} * 0.007184$ (DuBois D. and DuBois, EF. ''A Formula to Estimate the Approximate Surface Area if Height and Weight be Known'': Arch. Int. Med. 1916 17:863–71.), where w and h represent weight in kilograms and height in centimeters, respectively.

In addition, we explored a number of options for setting the reference values for the BSA. We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on this analysis, we are setting the reference point at a BSA of 1.84 (the average BSA among dialysis patients in 2002). By setting the reference point at the average BSA, the adjusters will reflect the relationship of a specific patient's BSA to the average BSA of all patients. Therefore, some adjusters will be greater than 1.0 and some will be less than 1.0. In this way, we are able to minimize the magnitude of the budget neutrality offset to the composite payment rate.

The following presents an example of the method for calculating patient level multipliers that were derived from the coefficients resulting from the regression model that includes control variables, expanded age groups, BSA, and an indicator for low BMI (<18.5 kg/m^2). The model excluded small facilities, and outliers.

Case-mix adjuster = Age factor * low BMI factor * BSA factor

Although we could have selected any increment, we believed an increment of 0,1 provided and appropriate degree of precision of the calculation of the exponent used to compute the BSA case-mix adjustment. The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.84 divided by 0.1. The BSA adjustment factor of 1.037 is then exponentiated based on the calculated BSA factor as 1.037 ((BSA - 1.84)/0.1)

For Example: The case-mix adjuster for a 47-year old person who is underweight (BMI<18.5 kg/m^2) and has a body surface area of 2.0 m^2 is calculated by using the 1.84 BSA reference point:

Age Factor = 1.055
Low BMI Factor = 1.112
BSA Factor = $1.037\ ((2.0-1.84)/0.1) = 1.037^{(1.6)} = 1.060$
Case-Mix Adjuster = 1.055 * 1.112 * 1.06 = 1.244

The resulting case-mix adjustment factor of 1.244 for this patient would be applied to the facility's composite payment rate that is adjusted for area wage index, drug add-on, and budget neutrality.

11. Budget Neutrality for Case-Mix Adjustment

Section 1881(b)(12)(E)(i) of the Act, as added by section 623(d)(1) of the MMA, requires that the basic case-mix adjusted composite rate system be designed to result in the same aggregate amount of expenditure for such services, as estimated by the Secretary, as would have been make for 2005 if that paragraph did not apply. Therefore, the patient characteristics case-mix adjustment required by section 623(d)(1) of the MMA must result in the same aggregate expenditures for 2005 as if these adjustments were not made.

In order to account for the payment effect related to the case-mix adjustment, we proposed to standardize the composite rate by dividing by the average case-mix modifier of 1.1919. The proposed budget neutrality adjustment to the composite rate was 0.8390. However, we were not able to simulate case-mix effects at the bill level

because co-morbidities are generally not reported on the ESRD bill. We still intend to refine our case-mix adjustments once we have more complete patient data on the ESRD bill. In this final rule, we have refined our adjustment for budget neutrality related to the case-mix factor. We simulated payment for each ESRD provider by applying a facility-specific case-mix multiplier to the composite rate applicable for that facility. Since the pediatric case-mix adjustment was developed outside the regression model, we simulated payments separately for those treatments. The results of these tow computations were then combined to arrive at the total case-mix adjusted payments. We also simulated payment for each provider as if they did not receive any case-mix adjustments. We then compared the total simulated payments with case-mix adjustment to total simulated payments without case-mix adjustment. The resulting budget neutrality adjustment to the composite rate is 0.9116.

B. Revised Patient Characteristic Adjustments

The following section discusses in detail the final case-mix adjustments to the ESRD composite rate payment.

In summary, based on the comments that we received on the proposed case-mix and additional analyses prepared by our contractor, KECC, in this final rule, we are modifying the proposed case-mix adjustments. We have broadened the number of age groups to include five age categories and added low BMI and BSA as measures. We have also included a specific case-mix adjustment for pediatric patients under age 18. We excluded the proposed categories gender and co-morbid conditions. We will be using a limited number of patient characteristics for the basic case mix system; however, we believe that these adjustments adequately explain variation in the reported costs per treatment for the composite rate services consistent with the legislative requirement. The adjustment factors for the basic case mix are listed in Table 13 below.

TABLE 13:

Variable		Multiplier
Age	Pediatrics <18 **	1.62
	18-44	1.223
	45-59	1.055
	60-69	1.000
	70-79	1.094
	80+	1.174
Body Surface Area (per 0.1 Δ BSA of 1.84)		1.037
Low BMI (<18.5 kg/m^2)		1.112

** BSA and BMI adjustment do not apply to pediatric patients.

The following table illustrates the average case-mix adjustment by type of provider based on the 2002 data that was used to develop the adjustment factors.

Table 14:

Facility Type	Average Case-Mix Adjustment
All	1.0967
Independent	1.0963
Hospital-Based	1.0990
Urban	1.0957
Rural	1.1009
Small (<5k treatments/yr.)	1.1027
Medium (<5-10k treatments/yr.)	1.0995
Large (>10k treatments/yr.)	1.0947
Non-Profit	1.1004
For-Profit	1.0957

As illustrated in table 14, regardless of the type of provider, the projected average case-mix adjustments for patient characteristics do not vary significantly.

C. Rural Facilities

Comments: Some commenters focused on the potential impact the revised composite rate payment system could have on rural facilities. They were initially concerned that excluding small facilities from the overall sample actually reflected the elimination of rural facilities from the sample. As a means of resolving this issue, they suggested that a rural facility exception be restored.

Response: The MMA provision for composite rate exceptions limited the availability of exceptions only to pediatric facilities. To the extent that a qualifying pediatric facility is located in a rural area, it would be able to apply for an exception to its composite payment rate.

D. Dual Eligible Dialysis Population

Comment: One commenter expressed concerns regarding potential impact on the dual eligible population, specifically with respect to coverage of deductibles and coinsurance amounts. Concern was expressed regarding the impact of this proposal on the Medicaid population on a state-by-state basis.

Response: We recognize that this is an important issue for ESRD facilities and can be particularly problematic for chain organizations that own facilities in multiple States. While we cannot direct States for payment for dual eligible beneficiaries, we will take appropriate action to ensure that States are aware of the changes we are implementing so they can take steps to adjust their payments for dual eligible dialysis patients.

E. Budget Neutrality

Section 623(d)(1) of the MMA added section 1881(b)(12)(E)(i) of the Act, which requires that the basic case-mix adjusted composite rate system be designed to result in the same aggregate amount of expenditure for services, as estimated by the Secretary, as would have been made for 2005 if that paragraph did not apply. Therefore, the drug add-on adjustment and the patient characteristics case-mix adjustment required by section 623(d)(1) of the MMA must result in the same aggregate expenditures for 2005 as if these adjustments were not made.

For the proposed drug payment add-on adjustment, we indicated in the proposed rule that the methodology we used to estimate the difference between the current and proposed drug payments was designed so that aggregate payments would be budget neutral.

In addition, the proposed rule provided for a budget neutrality adjustment to the composite payment rate of 0.8390 to account for the effects of the proposed case-mix adjustments on aggregate expenditures.

Comment: We received a number of comments concerning our application of the budget neutrality provision of section 623 of MMA. Specifically, many comments suggested that we did not comply with Congressional intent that facilities would be held harmless by this provision, that is, that facilities would not receive lower payments then they otherwise would have.

Response: Section 623 of MMA requires that aggregate payments in 2005 not exceed payments that would otherwise be paid. The budget neutrality provision is to ensure that total aggregate payments from the Medicare trust fund will not increase or decrease as a result of changes in the payment methodology. As with other Medicare payment systems, changes in the payment mechanism will result in the redistribution of Medicare dollars across facilities. There is no provision (nor any implication) in section 623 of the MMA that guarantees that individual facilities would receive the same amount of payment under a case-mix adjusted system as they did previously.

The final budget neutrality adjustment to the ESRD composite payment rate applicable to the case mix adjustments (including the pediatric adjustment) is 0.9116. Also in the proposed rule, the calculation of the drug add-on adjustment was designed to ensure budget neutrality with respect to aggregate drug payments.

F. Geographic Index

Comment: Several comments expressed disappointment that we did not propose revisions to the current outdated wage indexes reflected in the composite payment rates, despite the discretionary authority set forth in section 623(d)(1) of the MMA to replace them. These comments stated that this decision likely would have the greatest impact on facilities located in high cost and high wage areas, where competitive labor market pressures are more

pronounced. Comments generally were in favor of using the most up-to-date information available for developing a revised composite rate wage index.

Response: The wage index currently used in the composite rates is a blend of two wage index values, one based on hospital wage data from fiscal year 1986 and the other developed from 1980 data from the Bureau of Labor Statistics. The wage index is calculated for each urban and rural area based on 1980 U.S. Census definitions of metropolitan statistical areas (MSAs) and areas outside of MSAs. Restrictions apply to the wage index values used to develop the composite payment rates. Payments to facilities in areas where labor costs fall below 90 percent of the national average, or exceed 130 percent of that average, are not adjusted below the 90 percent or above the 130 percent level. This effectively means that facilities located in areas with wage index values less than 0.90 are paid more than they would receive if we fully adjusted for area wage differences. Conversely, facilities in locales with wage index values greater than 1.30 are paid less than they would receive if we fully adjusted payment for these higher wage levels.

We agree that the current ESRD composite rate wage indexes, and the definitions of the geographic areas on which they are based, need to be updated. On June 6, 2003, OMB issued Bulletin 03–04, which announced new geographic areas based on the 2000 Census. The extent to which we use the new OMB geographic definitions, incorporate them into the various prospective payment systems (PPSs) we administer, and whether we rely on hospital wage and employment data to develop new composite rate wage index values will have the potential to significantly redistribute payments among ESRD facilities.

In the August 11, 2004 **Federal Register** (69 FR 48916), we announced how we were revising the hospital wage index used in connection with inpatient PPS. Although one comment stated that we should adopt the same wage index used in connection with the inpatient PPS, several of the hospital wage index revisions stem from specific provisions of law (for example, geographic reclassification of hospitals) and would not necessarily be appropriate to apply to a revised ESRD wage index for the composite payment rates. Because of the discretion afforded the Secretary in developing a new wage index for ESRD payment purposes, we are carefully assessing the propriety and payment implications of policy options before recommending revisions to the current measure. We will not take action to replace the current composite rate wage index at this time. We point out that, in accordance with section 623(d)(1) of the MMA, any revisions to the wage index ultimately adopted must be phased in over a multiyear period.

G. Payment Exceptions and the Revised Composite Payment Rate

1. Application of Statutory Increases to Exception Amounts

Comment: Several comments were critical of our policy of not applying increases to composite rates, mandated by the Congress, to amounts paid under exceptions. The comments maintained that this policy is inequitable, precludes the proper application of inflation updates to costs that we had recognized as appropriate in granting the exception, and over time erodes the value of the exception because of the cumulative impact of an effective ''historical freeze.''

Response: The commenters are correct that we have only applied the Congressionally mandated statutory increases to the basic wage index adjusted composite payment rates, not to exception payments. For example, a provider which was authorized a $12.00 atypical services exception amount per treatment in addition to its otherwise applicable composite payment rate of $125.00 effective August 12, 2000 would not be entitled to the 2.4 percent increase applicable to composite rate payments on January 1, 2001, because its exception rate of $137.00 exceeded its basic rate of $125.00 increased by 2.4 percent or $128.00. While the commenter believes that our policy of not applying the Congressional mandated increases to exception amounts is unfair, we believe that the policy is consistent with the law. Section 422(a)(2)(C) of SCHIP, enacted December 21, 2000, states as follows in pertinent part:

> Any exception rate under such section in effect on December 31, 2000 * * * shall continue in effect so long as such rate is greater than the composite rate as updated * * *.

Thus, the statute seems to distinguish between an exception rate and the composite rate, as ''updated'' by the Congress. The clear implication of the text is that the exception rate is not so updated. Accordingly, we believe that our policy of not applying mandated composite rate increases to exception amounts is consistent with the statute. Moreover, we point out that section 422(a)(2) of SCHIP prohibited the granting of new exceptions and that we are providing facilities the option of either retaining their exception rates, or at any time, electing payment under the case-mix adjusted composite payment rates. We do not believe providers, given this option, will be disadvantaged.

2. Home Dialysis Training Exceptions

Comment: We received comments asking for clarification concerning home dialysis training exceptions since the proposed rule only addressed exceptions in a very general way. They stated that the rule proposes that each facility with an exception rate would compare their exception rate to the new basic case-mix adjusted prospective payment and then decide if it wishes to withdraw the exception rate and be subject to the basic case-mix adjusted composite rate. The commenters stated that this language does not consider a facility that would choose to accept the basic case-mix adjusted prospective payment for its chronic treatments, but continue its exception rates for the training of home patients. The home training exception is the most widely used exception and provides a higher rate for the higher cost of training a patient in fewer than the maximum number of allowed treatments.

Response: We agree and are providing that a home training exception rate may be continued. Facilities with home training exceptions will be able to retain their current exception training rates as well as take advantage of the case-mix adjusted rate for non-training dialysis.

3. New Exception Window

Comment: One commenter requests that a new ''exceptions window'' for pediatric facilities be opened in early 2005. It will not be until after this rule is final that its members will be able to determine the exact impact of this new methodology on their operations.

Response: Section 623(b) of MMA reinstated exceptions for qualifying pediatric facilities defined as facilities with at least 50 percent of their patients under 18 years of age. The current exception window for pediatric facilities closed on September 27, 2004. At this time, future exception windows will be open only for pediatric facilities. The exceptions process is opened each time there is a legislative change in the composite payment rate or when we open the exception window. The fiscal intermediary will notify the ESRD pediatric facilities when a new exception window opens. However, it is our intent to open pediatric exception windows on an annual basis.

4. Home Dialysis Training Rates

Comment: One commenter asked if the training rate add-on to the composite rate would still be applied.

Response: Yes, the following rates will apply for self-dialysis or home dialysis training sessions:

- For intermittent peritoneal dialysis (IPD), continuous cycling peritoneal dialysis (CCPD) and hemodialysis training, the facility's case-mix adjusted payment excluding any approved exception rates will be increased by $20 per training session, furnished up to three times per week.
- For continuous ambulatory peritoneal dialysis (CAPD), the facility's case-mix adjusted payment excluding any approved exception rates will be increased by $12 per training session, furnished up to three times per week.

Based on the example for John Smith in section L (Example of Payment Calculation Under the Case-Mix Adjusted Composite Rate System), the hemodialysis (IPD & CCPD) training rate would be his case-mix adjusted rate of $170.80, increased by the training add-on of $20 for a total training rate of $190.80. For CAPD training, the training rate would be $182.80 ($170.80+$12)

H. Implementation Date

Comment: We received a number of comments supporting our proposed delay in implementing the case-mix portion of the revised composite payment methodology. Many comments maintained that the proposed April 1, 2005 effective date was overly ambitious, and some suggested that a July 1, 2005 implementation date would be more realistic given the need for facility and fiscal intermediary training and education.

Response: The MMA requires that the basic case-mix adjusted composite payment rates be effective for services beginning January 1, 2005. Despite the statute's specificity, we pointed out in the proposed rule that all of the numerous systems, programming, and operational changes necessary to implement the case-mix adjusted payments cannot be completed in time for a January 1, 2005 implementation date.

As presented in the proposed rule, we considered two options that we believed effectively complied with the statute's January 1, 2005 implementation date. While we stated in the proposed rule that either of these options substantively complies with the January 1, 2005 implementation date requirement of the statute, we rejected both alternatives.

The likelihood of payment error, potential disruption of facility payments, and the cost of reprocessing bills militated against either option. We proposed instead an April 1, 2005 implementation date for the basic case-mix adjustments to the composite payment rates, including the budget neutrality reduction. This option avoids the need for reprocessing of bills and applies the budget neutrality adjustment applicable to the case-mix adjustments effective April 1, 2005. Although we agree with the comment that a July 1, 2005 effective date would be ideal in light of the systems and operational changes required to implement the case-mix provisions, we believe that an April 1, 2005 effective date for the case-mix adjustments is feasible, and have decided not to revise that date. We have concluded based on our evaluation of ESRD claims processing systems that the April 1, 2005 implementation date is achievable. As we stated in the proposed rule, the 1.6 percent increase to the composite payment rates and drug add-on will be effective January 1, 2005.

I. Summary of Final Rule Implementing Changes to the ESRD Composite Payment Rate (Section 623 of MMA)

As set forth in this final rule, we will increase the ESRD composite payment rates by 1.6 percent effective January 1, 2005 in accordance with section 623(a) of the MMA. Also, the composite payment rates will be increased January 1, 2005 by 8.7 percent to reflect revisions to the drug pricing methodology for separately billable drugs, as discussed previously in this rule (Composite Rate Adjustments to Account for Changes in Pricing of Separately Billable Drugs and Biologicals). This section explains the development and computation of the revised drug add-on, which differs from the 11.3 percent amount described in the proposed rule, and our response to comments which advocated separate add-on amounts for hospital-based and independent facilities.

Despite the discretionary authority set forth in section 623(d)(1) of the MMA to replace the current outdated wage index used in the composite payment rates, we are taking no action to revise the wage index at the present time. A revised wage index will potentially significantly redistribute ESRD payments. We believe that further study is warranted before we revised the current index. Those assessments are presently underway.

We have also adopted a revised basic case-mix methodology for adjusting the composite payment rates based on a limited number of patient characteristics, as prescribed in section 623(d) of the MMA. The development and application of the revised case-mix adjusters were previously explained in the ''Revised Patient Characteristic Adjustments'' section of this final rule. The variables for which adjustments will be applied to each facility's composite payment rate include age, BSA, and low BMI. In response to comments, we eliminated gender in this final rule as a patient classification variable for purposes of case-mix adjustment, substituting BSA and a low BMI variable instead. We have also increased the number of age categories from three to five, and eliminated co-morbidities pending further study. Because height and weight are necessary to compute each patient's BSA and BMI, those measurements, in centimeters and kilograms, respectively, will be required on the UB 92 for outpatient ESRD services furnished on and after January 1, 2005. This final rule also provides for a case-mix adjustment of 1.62 to a facility's composite payment rate for pediatric ESRD patients (that is, under age 18). The methodology used to develop the pediatric case-mix adjustment factor of 1.62 is described in the ''Case-Mix Adjustment for Pediatrics Patients'' section of this rule. Although the MMA requires that the basic case-mix adjusted composite payment rates be effective for services beginning January 1, 2005, the systems and operational changes necessary to implement them cannot be completed in time for a prospective January 1, 2005 effective date. The case-mix adjustments and the applicable budget neutrality adjustment of 0.9116 will be effective April 1, 2005.

Example of Payment Calculation Under the Case-Mix

Example 1

Adjusted Composite Rate System

The following example presents 2 patients dialyzing at Neighbor Dialysis, an independent ESRD facility located in Baltimore, MD.

Calculation of Basic Composite Rate for Neighbor Dialysis

Wage adjusted composite rate for independent facilities in Baltimore, MD: $134.93

Wage adjusted composite rate increased by drug add-on adjustment $134.93 × 1.087: $146.67

Adjusted Facility Composite Rate after budget neutrality adjustment ($146.67 × 0.9116): $133.70

Patient #1

John Smith attains age 18 on April 10, 2005 and undergoes hemodialysis. John

weighs 75.5 kg. and is 181.5 cm. in height. Because John Smith attains age 18 April 10, he is considered age 18 for the entire month of April, and would not be classified as a pediatric patient.

Calculation of Case Mix Adjusted Payment

The BSA and BMI for John Smith will be calculated by the PRICER program used to compute the composite payment for each patient based on the height and weight reported on the UB 92. However, the computations of the BSA and BMI for John Smith are shown below:

BSA = $0.007184 \times (\text{height})^{0.725} \times (\text{weight})^{0.425}$

BSA = $0.007184 \times 181.5^{0.725} \times 75.5^{0.425}$

BSA = $0.007184 \times 43.4196 \times 6.2824 = 1.960$

BMI = $\text{weight}/\text{height(m)}^2$

John Smith is 181.5 cm. in height, which converts to 1.815 meters.

BMI = $75.5/1.815^2 = 22.919$

The case mix adjustment factor for John Smith, an 18 year old whose BMI exceeds 18.5 kg/m^2 and has a BSA of 1.960 is calculated as follows:

Age adjustment factor (age 18–44) 1.223

BMI adjustment factor (BMI ≥ 18.5 kg/m^2) 1.000

BSA adjustment factor ($1.037^{1.960-1.84/0.1}$) 1.0446

Case mix adjustment factor ($1.223 \times 1.000 \times 1.0446$) 1.2775

Basic case mix adjusted composite payment ($133.70 \times 1.2775) $170.80

Patient 2

Jane Doe is a 82 year old malnourished patient who undergoes hemodialysis. Jane is 158.0 cm. in height.

Calculation of Case Mix Adjusted Payment

The BSA and BMI for Jane Doe, which will be automatically computed by the PRICER program, are calculated as follows:

BSA = $0.007184 \times (\text{height})^{0.725} \times (\text{weight})^{0.425}$

BSA = $0.007184 \times 158.0^{0.725} \times 31.25^{0.425}$

BSA = $0.007184 \times 39.2669 \times 4.3183 = 1.2182$

BMI = $\text{weight}/\text{height(m)}^2$

Jane Doe is 158 cm. in height, which converts to 1.580 meters.

BMI = $31.25/1.580^2 = 12.5180$

The case mix adjustment factor for Jane Doe, an 82 year old whose BMI is less than 18.5 kg/m^2 and has a BSA of 1.2182, is calculated as follows:

Age adjustment factor (age 80+) 1.174

BMI adjustment factor (BMI ≤ 18.5 kg./m^2) 1.112

BSA adjustment factor ($1.037^{1.2182-1.84/0.1}$) 0.7978

Case-mix adjustment factor ($1.174 \times 1.112 \times 0.7978$) 1.0415

Basic case mix adjusted composite payment ($133.70 \times 1.0415) $139.24

Example 2

Linda Jones is age 16 and undergoes peritoneal dialysis at Community Hospital, a hospital-based facility in New York City. Linda weighs 35 kg and is 160.0 cm in height. The basic composite rate for Linda Jones is calculated as follows:

Wage adjusted composite rate for hospital-based facilities in New York, New York: $146.35

Wage adjusted composite rate increased by drug adjustment factor ($146.35 × 1.087): $159.08

Adjusted Facility Composite Rate after budget neutrality adjustment ($159.08 × 0.9116) $145.02

Because Linda is a pediatric ESRD patient, the automatic pediatric adjustment factor of 1.62 applies. Neither the age, BMI, nor BSA adjustments are applicable because Linda is less than age 18.

Pediatric adjusted composite rate ($145.02 × 1.62) $234.93

If Community Hospital were entitled to a composite rate exception, then the provider could elect to retain its exception rate in lieu of receiving the otherwise applicable pediatric payment rate of $234.93.

Impact Analysis

Comment: One commenter observed that the budgetary impact on the Medicare program of proposed section 623 changes (impact table) generally indicates an ''overall'' neutral or modest reimbursement increase for all types of dialysis facilities (independent and rural, for profit and non-profit, urban and rural). This commenter requested data that indicate the number of dialysis facilities that are operating at a loss in the U.S., by corresponding facility characteristics shown in the impact table.

Response: The purpose of the impact table is to simulate what ESRD facilities will receive in payments under the MMA section 623 changes compared to what ESRD facilities would receive without any changes to the current composite payment rates. We do not have data to determine whether or not a facility may operate at a loss under MMA section 623.

J. Section 731—Coverage of Routine Costs for Category A Clinical Trials

Before the enactment of the MMA, Medicare did not cover services related to a noncovered Category A device. The MMA authorizes Medicare to cover the routine costs associated with certain Category A clinical trials for services furnished on or after January 1, 2005. For a trial to qualify for payment, it must meet certain criteria to ensure that the trial conforms to appropriate scientific and ethical standards. In addition, the MMA established additional criteria for trials initiated before January 1, 2010 to ensure that the devices involved in these trials are intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Seven commenters were in favor of this provision. Of them, four had additional comments. One commenter was against the provision.

Comment: One commenter stated that this provision would result in money being taken away from the pool of money for physician payments of non-experimental procedures.

Response: We considered this issue in determining the SGR for 2005. Since we have made a regulatory change to allow for coverage of routine costs associated with Category A clinical trials, we are required by statute to reflect any increased costs of this policy in the 2005 SGR. At this time, we are estimating that the costs associated with coverage of routine costs of Category A clinical trials will increase Medicare spending for physicians' services by less than 0.1 percent. However, we are reviewing this issue and we will adjust our estimates once we have actual spending data for 2005.

Comment: One commenter specifically requested that we define routine costs.

Response: We discuss and define routine costs in section 310.1 of the Medicare National Coverage Determination Manual (pub 100.3). We will take this comment into consideration if we decide to revise section 310.1 in the future.

Comment: Two commenters recommended that we adopt a definition of ''immediately life-threatening'' that would allow contractors some level of flexibility when they apply this criteria to evaluate trials.

Response: We will consider the importance of some level of flexibility in defining ''immediately life-threatening.'' Although we are not defining this term in our regulation, we intend to provide guidance through implementing instructions.

Comment: Another commenter suggested that contractors determine in advance if trials satisfy the immediately life threatening requirement.