Response: We are considering implementation requirements and will take this suggestion under advisement.

Result of Evaluation of Comments

We are finalizing the changes to § 405.207 as proposed.

K. Section 629—Part B Deductible

Section 629 of the MMA provides for regular updates to the Medicare Part B deductible in consideration of inflationary changes in the nation's economy. Since 1991, the Medicare Part B deductible has been $100 per year. The MMA stipulates that the Medicare Part B deductible will be $110 for calendar year 2005, and, for a subsequent year, the deductible will be the previous year's deductible increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) of the Act, ending with that subsequent year (rounded to the nearest dollar). Section 1839(a)(1) of the Act requires the Secretary of Health and Human Services to calculate the monthly actuarial rate for Medicare enrollees age 65 and over.

We proposed to update § 410.160(f), ''Amount of the Part B annual deductible,'' to conform to the MMA and to reflect that the Medicare Part B deductible is $100 for calendar years 1991 through 2004.

Comment: Commenters stated that they understand that we are following the statute in implementing this provision, but encouraged us to educate Medicare beneficiaries regarding this change.

Response: We agree that it is important to educate beneficiaries about the deductible, as well as the other provisions of the MMA, such as the new screening benefits, and we will be using publications such as the ''Medicare and You Handbook'' for this purpose.

Result of Evaluation of Comments

We are finalizing the proposed changes to § 410.160(f).

L. Section 512—Hospice Consultation

1. Coverage of Hospice Consultation Services

As discussed in the proposed rule published August 5, 2004, effective January 1, 2005, section 512 of the MMA provides for payment to a hospice for specified services furnished by a physician who is either the medical director of, or an employee of, a hospice agency. Payment would be made on behalf of a beneficiary who is terminally ill (which is defined as having a prognosis of 6 months or less if the disease or illness runs its normal course), has not made a hospice election, and has not previously received the pre-election hospice services specified in section 1812(a)(1)(5) of the Act as added by section 512 of the MMA. These services comprise an evaluation of an individual's need for pain and symptom management, counseling the individual regarding hospice and other care options, and may include advising the individual regarding advanced care planning.

We believe that most individuals will seek this type of service from their own physicians. Thus, we do not expect that the services of a hospice physician would be necessary for all individuals who elect hospice. However, a beneficiary, or his or her physician, may seek the expertise of a hospice medical director or physician employee of a hospice to assure that a beneficiary's end-of-life options for care and pain management are discussed and evaluated.

Currently, beneficiaries are able to receive this evaluation, pain management, counseling, and advice through other Medicare benefits. For example, physicians who determine the beneficiary's terminal diagnoses can provide for these E/M services as well as for pain and symptom management under the physician fee schedule. Beneficiaries may also obtain assistance with decisions pertaining to end-of-life issues through discharge planning by social workers, case managers, and other health care professionals. To the extent that beneficiaries have already received Medicare-covered evaluation and counseling for end-of-life care, the hospice evaluation and counseling would seem duplicative. We plan to monitor data regarding these services to assess whether Medicare is paying for duplicative services.

In the proposed rule, we proposed to cover the services described above for a terminally ill beneficiary when the services are requested by a beneficiary or the beneficiary's physician. The service would, in accordance with the statute, be available on a one-time basis to a beneficiary who has not elected or previously used the hospice benefit, but who might benefit from evaluation and counseling with a hospice physician regarding the beneficiary's decision-making process or to provide recommendations for pain and symptom management. The beneficiary or his or her physician decides to obtain this service from the hospice medical director or physician employee. Thus, the evaluation and counseling service may not be initiated by the hospice, that is, the entity receiving payment for the service.

The statute specifies that payment be made to the hospice when the physician providing the service is an employee physician or medical director of a hospice. Therefore, other hospice personnel, such as nurse practitioners, nurses, or social workers, cannot furnish the service. The statute requires that the physician be employed by a hospice; therefore, the service cannot be furnished by a physician under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice. Moreover, if the beneficiary's physician is also the medical director or physician employee of a hospice, that physician already possesses the expertise necessary to furnish end-of-life evaluation, management, and counseling services and is providing these services to the beneficiary and receiving payment for these services under the physician fee schedule through the use of E/M codes.

In the event that the individual's physician initiates the request for services of the hospice medical director or physician, we indicated in the proposed rule that we would expect that appropriate documentation guidelines would be followed. The request or referral would be in writing, and the hospice medical director or employee physician would be expected to provide a written note on the patient's medical chart. The hospice employee physician providing these services would be required to maintain a written record of this service. If the beneficiary initiates the services, we would expect that the hospice agency would maintain a written record of the service and that communication between the hospice medical director or physician and the beneficiary's physician would occur, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

We proposed to add new § 418.205 and § 418.304(d) to implement section 512 of the MMA.

Comment: Several commenters requested that this provision be extended to contracted physicians and nurse practitioners.

Response: Section 1812(a)(5) of the Act explicitly indicates that a physician employed by a hospice agency must provide the services under this provision. We recognize that contractual relationships are permitted by hospice agencies for medical director and physicians' services under the hospice benefit as described in section 1861(dd) of the Act. However, the plain language of section 1812(a)(5) provides only for employees of the hospice to furnish the service.

Section 1812(a)(5) of the Act also requires that this service be provided by a physician as defined in section 1861(r)(1) of the Act. While nurse practitioners may serve as attending physicians for beneficiaries who have elected the hospice benefit, this provision does not permit non-physicians to provide this pre-hospice service.

Comment: We received several comments that supported this provision as beneficial for end-of-life care.

Response: We believe that this provision supports and supplements options available to beneficiaries as they make end-of-life decisions when the individual's health care provider and community resources are not able to provide the expertise and information.

Comment: We received a comment suggesting that the certification of a terminal illness, with a 6-month prognosis if the disease runs its normal course, be eliminated and that this service should be available to any individual deemed to be terminal.

Response: Section 1812(a)(5) of the Act explicitly indicates that this one-time service is available to Medicare beneficiaries who are terminally ill and have not previously elected the hospice benefit. Section 1861(dd)(3)(A) of the Act defines the phrase ''terminally ill'' as denoting a medical prognosis that the individual's life expectancy is 6 months or less. Since section 1812(a)(5) of the Act specifies that the beneficiary must have a terminal illness, which includes the 6-month prognosis, we have no authority to eliminate this definition.

Since the benefit is a pre-hospice one, we have not required that a certification be completed before this service is provided. Nonetheless, in the judgment of the individual's physician, the individual must be terminally ill, that is, having a 6-month or less life expectancy if the disease or illness runs its normal course.

2. Payment for Hospice Consultation Services

Section 512(b) of the MMA amends section 1814(i) of the Act and establishes payment for this service at an amount equal to an amount established for an office or other outpatient visit for E/M associated with presenting problems of moderate severity and requiring medical decision-making of low complexity under the physician fee schedule, other than the portion of such amount attributable to the practice expense component. No existing CPT or HCPCS code specifically represents these services. We proposed establishing a new HCPCS code, G0337 (proposed as G0xx4) *Hospice—evaluation and counseling services, pre-election.* The hospice would use this new HCPCS code to submit claims to the Regional Home Health Intermediary (RHHI) for payment for this service. Utilization of the code would allow us to provide payment for the service, as well as enable us to monitor the frequency with which the code is used and assess its appropriate use. Payments by hospices to physicians or others in a position to refer patients for services furnished under this provision may implicate the Federal anti-kickback statute.

In accordance with the statute, we proposed that the payment amount for this service would be based on the work and malpractice expense RVUs for CPT code 99203 multiplied by the CF (1.34 Work RVU + 0.10 Malpractice RVU) * (CF). The CPT code for an office or outpatient visit for the E/M of a new patient represents a detailed history, detailed examination and medical decision making of low complexity. We believe that this E/M service is quite similar to the components of the new service provided by a medical director or physician employed by the hospice agency. Assuming that there are no changes in RVUs for CPT code 99203, and that the CY 2005 update to the physician fee schedule is the 1.5 percent specified in the MMA, the national payment amount for this service would be $54.57 for this service (1.44 * $37.8975).

Comment: We received several comments indicating that CPT Code 99203, a mid-level office visit with a new patient, does not accurately reflect the complexity associated with the hospice consultation. One commenter suggested using CPT code 99205. In addition, commenters stated that payment for this benefit should reflect the length and intensity of each consultation.

Response: Section 1814(i)(4) of the Act explicitly states that the payment for this service be equal to an amount established for an office or outpatient visit with presenting problems of moderate severity and requiring low complexity medical decision-making. We believe that CPT code 99203, rather than CPT code 99205, most closely conforms to the statutory language. However, in order to establish a payment rate that excludes the practice expense component and to ensure that we pay for the service only once, we established a G code.

Comment: We received one comment that indicated that existing consultation codes coupled with a place of service should be used.

Response: We appreciate the concern about introducing another code into a complex system of codes. While the title of the provision indicates that this is a consultative service, we believe that, unlike other consultations, beneficiaries are able to seek this service without a referral. Moreover, we need to be able to distinguish this service so that we can ensure that it is furnished only once to an individual. In addition, existing E&M codes are billed by physicians. This provision is billed by the hospice agency and is not a result of reassignment of payment by a physician to a hospice agency. Finally, the G code will allow us to track utilization of this new benefit.

Result of Evaluation of Comments

We are adopting our proposed policy and revising the regulations at § 418.205 and § 418.304(d). We are also finalizing our proposal to pay for this service using a G code (G0337) *Hospice—evaluation and counseling services, pre-election,* with the payment based on the work and malpractice expense RVUs for CPT code 99203.

M. Section 302—Clinical Conditions for Coverage of Durable Medical Equipment (DME)

Section 1832(a)(1)(E) of the Act, as added by section 302(a)(2) of the MMA, requires the Secretary to establish clinical conditions of coverage standards for items of DME. The statute requires the Secretary to establish types or classes of covered items that require a face-to-face examination of the individual by a physician or specified practitioner. Due to the timeframe and the extensive number of public comments received, we will implement this provision at a later date. We will address all public comments in a future **Federal Register** document.

N. Section 614—Payment for Certain Mammography Services

Medicare covers an annual screening mammogram for all beneficiaries who are women age 40 and older and one baseline mammogram for beneficiaries who are women age 35 through 39. Medicare also covers medically necessary diagnostic mammograms. Payment for screening mammography, regardless of setting, is paid under the physician fee schedule, but diagnostic mammography performed in the hospital outpatient department is currently paid under the hospital outpatient prospective payment system (OPPS).

As stated in the August 5, 2004 proposed rule, section 614 of the MMA amended section 1833(t)(1)(B)(iv) of the

Act to exclude payment for screening and diagnostic mammograms from the OPPS. Beginning January 1, 2005, we will pay for diagnostic mammograms under the OPPS based on the payments established under the physician fee schedule. Thus, both diagnostic and screening mammography services provided in the OPPS setting will now be paid based on the physician fee schedule.

Comment: Commenters expressed support for this proposed change in payment and believe it will assist in ensuring that these services are available to women at risk for breast cancer.

Response: We agree that it is important to ensure access to these services. Additional discussion of the MMA provision can also be found in the OPPS final rule, ''Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2005 Payment Rates'' currently under development.

O. Section 305—Payment for Inhalation Drugs

The August 5, 2004 proposed rule contained the ASP plus 6 percent payment amounts based on data received from manufacturers' ASP for the first quarter of 2004 for albuterol sulphate and ipratropium bromide. We indicated that such payment amounts were not the payment rates for 2005 and specified that Medicare payment rates for the first quarter of 2005 would be based on data submitted by manufacturers from the third quarter of 2004.

We proposed to establish a separate dispensing fee for inhalation drugs. We noted that Medicare currently pays a monthly dispensing fee of $5 for each inhalation drug used in a nebulizer. We requested information about an appropriate dispensing fee amount.

We also proposed to make several changes related to billing for inhalation drugs. We proposed to allow a prescription for inhalation drugs written by a physician and filled by a pharmacy to be increased from 30-day to a 90-day period. We indicated that we had recently revised the guidelines regarding the time frame for delivery of refills of DMEPOS products to occur no sooner than ''approximately five days'' prior to the end of usage for the current product. We emphasized the word ''approximately'' in this time frame. The change allows shipping of inhalation drug refills on ''approximately'' the 25th day of the month in the case of a 30-day supply and on ''approximately'' the 85th day in the case of a 90-day supply. We indicated our belief that such revision eliminates the need for suppliers to use overnight shipping of inhalation drugs and allows shipping of inhalation drugs by less expensive ground service.

We also clarified the ordering requirements for DMEPOS items, including drugs. Drugs, including, inhalation drugs, can be dispensed with a verbal physician order and without a written prescription. Although a written prescription must be obtained before submitting a claim, we reiterated that we allowed photocopied, electronic, or pen and ink prescriptions. We pointed out the recent revision to the Program Integrity Manual of acceptable proof of delivery requirements for DMEPOS items. Finally, we proposed to eliminate the requirement that pharmacies have a signed Assignment of Benefits (AOB) form from a beneficiary in order for Medicare to make a payment. Our proposal would eliminate a billing requirement for all drugs, including inhalation drugs and other items where Medicare payment is only made on an assigned basis.

Comment: A number of commenters, particularly retail pharmacies, indicated that they are not able to obtain albuterol sulfate at the $0.04 per milligram and ipratropium bromide at the $0.30 per milligram rates specified in the proposed rule based on manufacturer submissions of data for the first quarter of 2004. A large company indicated that the ASPs stated in the proposed rule for albuterol sulfate and ipratropium bromide were extremely close to its own acquisition costs and inferred that the payment amount would be below smaller providers' purchase prices. A commenter questioned the suggestion in the proposed rule that because albuterol sulfate and ipratropium bromide are generic drugs with multiple manufacturers a pharmacy might be able to obtain them at a price below the average. The commenter suggested that this is highly speculative because we have not yet received the information from manufacturers to set the ASP for the first quarter of 2005.

Response: The ASP plus 6 percent prices for drugs in the proposed rule were calculated based on manufacturer submissions of data covering the first quarter of 2004. We indicated that such ASP plus 6 percent figures were not actual payment rates for the first quarter of 2005. ASP data submitted by manufacturers for the second quarter of 2004 show some significant changes for inhalation drugs. The data show that the ASP plus 6 percent would be $0.05 per milligram for albuterol sulfate, a 25 percent increase, and $0.45 per milligram for ipratropium bromide, a 50 percent increase. We also note that in its recent study, ''Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs'' (GAO–05–72), the GAO found that acquisition costs of inhalation drugs varied widely. The GAO found that acquisition costs of albuterol sulfate ranged from $0.04 to $0.08 and ipratropium bromide ranged from $0.23 to $0.64. Based on the submission of manufacturer's average sales price data for the second quarter of 2004, Medicare's payment rates for ipratropium bromide and albuterol sulfate are within the acquisition cost range found by the GAO. The GAO also found that acquisition cost was not necessarily related to the size of the supplier.

Comment: One commenter suggested that we should consider delaying the implementation of cuts in Medicare reimbursement for inhalation drugs until 2006. The commenter suggested that a delay would ensure that physicians and beneficiaries have a range of options available for managing respiratory diseases.

Response: We do not believe that we can delay the implementation of the ASP payment system until 2006 because the MMA provides for the implementation of the ASP payment system in 2005.

Comment: Commenters strongly supported our proposal to pay a separate dispensing fee for inhalation drugs, but we received varied comments on the scope of services appropriately included in a dispensing fee. Commenters indicated that an appropriate dispensing fee is necessary because the costs associated with dispensing these drugs typically exceed ASP plus six percent. Without adequate compensation, commenters argued that Medicare beneficiary access to inhalation drugs would be harmed. Commenters referenced an August 2004 report prepared for the American Association of Homecare (AAH) by a consultant that surveyed 109 homecare pharmacies between the end of May and the middle of July 2004. Commenters cited survey results from the report suggesting that 89 percent of suppliers would discontinue providing inhalation drugs to Medicare beneficiaries in the absence of adequate compensation. One commenter believes it is reasonable to expect that reducing Medicare payment for inhalation drugs will trigger an increase in emergency room visits, doctor visits, and hospital admissions. Other commenters suggested a dispensing fee that is too low would result in a concentrated market, thereby adversely affecting beneficiary choice and access.

The AAH study indicated that in order to maintain 2004 levels of service to Medicare beneficiaries and provide an operating margin of 7 percent, Medicare would have to pay an additional payment of $68.10 per service encounter. This figure includes an average of the costs reported as being incurred during the first quarter of 2004 for the pharmacies that responded to the AAH survey. The study defined a service encounter as each instance one or more billing codes were submitted to Medicare for payment. The study reported that the typical Medicare beneficiary has 8.8 service encounters each year, or one service encounter every 42 days. Most commenters who cited the AAH study supported a fee of $68.10 per service encounter.

Commenters also cited another AAH report, dated September 2001 (and updated to 2003) from a different consultant, who surveyed a sample of 19 homecare pharmacies and found that drug acquisition costs accounted for 26 percent of costs incurred by homecare pharmacies. Facility, labor, delivery, patient care and education, billing and collection costs and other direct costs were found to account for 46 percent; indirect costs such as management information systems, regulatory compliance programs, professional liability insurance and field and corporate administration was 25 percent; and bad debt was 3 percent. The study concluded that homecare pharmacies generated after-tax returns of 9.2 percent.

A retail pharmacy commented that a dispensing fee five to six times the current dispensing fee of $5 is necessary to cover its costs. Another retail pharmacy indicated that a dispensing fee of $25 would be an adequate dispensing fee, including the additional costs of processing Medicare claims and instructing the patient on using the drugs, and would be profitable for it.

A manufacturer urged CMS to conduct a study of the appropriate pharmacy activities and their costs in calculating a dispensing fee. The commenter believes such a study would yield a more accurate amount than data and information provided as part of comments to proposed rules does. One inhalation company indicated that the costs of rent, delivery and salary had recently increased by specific percentages. Several commenters opposed the inclusion in the dispensing fee of a transitional payment. Another commenter strongly urged establishing a dispensing fee that include an appropriate transitional payment, given the significant payment reductions scheduled to begin in 2005.

On the scope of services, commenters indicated that various services involved with dispensing inhalation drugs to Medicare beneficiaries such as: (i) Training beneficiaries and caregivers on proper use of drugs with nebulizers; (ii) establishing and revising a plan of care and coordinating care; (iii) providing in-home visits; (iv) providing 24-hours/7-days a week on-call personnel; (v) contacting physicians and beneficiaries regarding dispensing of inhalation drugs; (vi) providing follow-up contact with beneficiaries, including compliance monitoring and refill calls. Commenters indicated that they felt CMS has the authority to pay for costs associated with delivering inhalation drugs under the durable medical equipment (DME) benefit.

An association representing pharmacists recommended an expansion of Part B to include compensation for therapy management services furnished by pharmacists. An association representing respiratory therapists recommended a separate payment for beneficiary training by practitioners with documented evidence of education, clinical training and competency testing, such as respiratory therapists. A company suggested that we establish a basic dispensing fee and separately reimbursable codes for those who provide additional services, reflecting the range of management services involved with inhalation drugs. Another association acknowledged that although limited peer reviewed studies exist on the role of homecare providers and the respiratory practitioners in furnishing care to COPD patients, significant anecdotal data and a consensus within the pulmonary medicine and respiratory therapy professional communities support the role and contribution of home respiratory care providers. Several commenters indicated that training a beneficiary on using a nebulizer should also be reimbursed. However, they pointed out that training cannot be done by the physician or physician's staff because many physicians do not have a nebulizer on which to train the beneficiary and the Medicare payment is not sufficient to cover the physician's staff time.

Response: We appreciate the support for our proposal to establish a dispensing fee as well as the information about the levels and components of such a fee.

The October 12, 2004 GAO report is based on a survey of 12 companies representing 42 percent of the inhalation therapy market. The GAO found wide variation in suppliers' monthly costs associated with dispensing inhalation drugs. In addition, the GAO found that large suppliers do not necessarily have lower costs and do not necessarily realize economies in costs associated with dispensing inhalation therapy drugs. The GAO indicated that the wide range is due in part to the range of services offered by suppliers and that some costs incurred by suppliers may not be necessary to dispense inhalation drugs, for example marketing, overnight shipping, and 24-hour hotlines for beneficiary questions. The GAO report indicates that the range of costs suppliers are incurring is a good starting point for a dispensing fee amount, but that the appropriate dispensing fee Medicare pays must take into account how excess payments affect the costs.

We note the extreme variation that the GAO found in the costs of dispensing nebulized drugs to Medicare beneficiaries: GAO found that per patient monthly costs of dispensing these medications ranged from a low of $7 to a high of $204 in 2003. Because it appears that the GAO survey and the 2004 AAH survey may have included different costs and services, further research is needed to understand these differences. In addition to the GAO and AAH studies, we note the wide range of comments indicating what services a dispensing fee should cover. We believe that before a determination can be made as to an appropriate dispensing fee for inhalation drugs after 2005, we need to more fully understand the components of and the reasons behind the current variability in the costs of furnishing of these drugs and the services being provided. We intend to work with the AAH, others concerned with inhalation therapy and our partners in the Department of Health and Human Services to explore these issues more fully.

In the interim, for 2005, we are establishing a $57 monthly fee and an $80 90-day fee for furnishing inhalation drugs using data in the AAH study and the GAO report. We established the monthly fee based on the weighted average of the costs for new and established patients from the 2004 AAH study after excluding sales and marketing, bad debt, and an explicit profit margin. Because the AAH study did not establish a fee for the 90-day period, we applied the methodology used in the GAO report to the data in the AAH study to calculate the 2005 90-day fee. Accordingly, we assumed that direct costs associated with a monthly fee are similar to the direct costs associated with the 90-day fee and then we tripled the indirect costs. We intend to further examine the conversion of per

encounter costs as reported in the AAH study to comparable monthly and 90-day cost figures.

We note that although the AAH study contained costs related to services that may be of potential benefit to our beneficiaries, and many commenters indicated that we should provide payment for these and the other services described above, we are concerned that these services may be outside the scope of a dispensing fee. We are continuing to study these services and associated cost categories as the new payment systems are implemented and we gain experience with them. We intend to revisit this issue and proceed through notice and comment rulemaking in order to establish an appropriate dispensing fee for 2006.

Comment: A commenter suggested that the dispensing fee be established on a per dose basis. It was argued that this would provide Medicare with protection against pharmacies dispensing partial shipments or shipments more frequently than 30 or 90 days in order to increase the number of dispensing fees. We received comments in support of a need-based dispensing fee to accommodate additional drugs when beneficiaries suffer from disease flare-ups. We also received comments indicating that beneficiary's prescriptions change, often during the first month. Other commenters cited the AAH study, which calculated different costs associated with dispensing inhalation drugs for new patients and established patient.

Response: The dispensing fee we are establishing covers all drugs shipped to a beneficiary during a month (or 90-day period) regardless of the number of times a supplier ships inhalation drugs to a beneficiary. If a supplier does not supply the prescription in full, it is the supplier's responsibility to fill and deliver the remainder of the prescription, but Medicare will not pay additional monthly dispensing fees. We will monitor the issue about partial shipments and potentially erroneous billing for multiple monthly dispensing fees. We also are concerned that a per-dose dispensing fee could provide an incentive to supply more drugs.

The 2005 fee is an average across all beneficiaries, new and established, and covers additional drugs shipped during a month if a beneficiary's prescription changes. We will study the issue further of different dispensing fees for new and established beneficiaries and the frequency that additional drugs are shipped for prescription changes.

Comment: A manufacturer recognized that compounded products can be covered under certain circumstances and that compounding could be included appropriately in a dispensing fee. Another manufacturer expressed concern about including compounding in the activities that a dispensing fee covers. A suggestion was made that a HCPCS modifier be used for inhalation drugs that are compounded.

Response: The costs of compounding are included in the AAH study but are not separately identified in the direct cost line items. Because the 2005 fee is based on the AAH study, we need to avoid duplicate payment. With compounding bundled into the fee for 2005, we have concerns about paying separately for compounding in 2005.

Comment: A commenter recommended that we address compounding circumstances that might be inconsistent with FDA's policy prohibiting pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available and compounding that might be done without the necessary controls to ensure drug product sterility and potency.

Response: The fact that we consider compounding to be included in the 2005 fee to furnish inhalation drugs does not in any way support practices that are inconsistent with FDA guidelines.

Comment: The commenter also suggested that we consider creating a HCPCS modifier for drugs that a prescribing physician intends to be compounded but which a pharmacy dispenses separately in non-compounded form. The commenter believes that such a modifier would help discourage pharmacies from leaving the responsibility for compounding to the beneficiary who would be combining the drugs in non-sterile, uncontrolled conditions.

Response: We understand the commenter's concerns and will study this issue.

Comment: We received comments suggesting that the actual savings attributable to MMA section 305 may be both higher and lower than the November 20, 2003 Congressional Budget Office (CBO) estimate for MMA section 305. One company suggested that the actual savings could be less than estimated by CBO because the ASP model potentially motivates drug manufacturers to increase drug costs, which will be directly passed on to the government. Other commenters cited two different estimates from the AAH report. Using one calculation, the commenters argued that a dispensing fee of $68.10 per encounter would still enable Medicare to achieve savings of $350 million per year or more than $4 billion over 10 years. Using another calculation, the commenters argued that the savings would be $7 billion over the 10-year budget-scoring window. The commenters indicated that the $4 billion savings figure was comparable to the initial projections made by the Congressional Budget Office (CBO) in 2003 and the $7 billion figure was in excess of the CBO estimated savings. Commenters cited these figures to argue that establishment of a per service encounter fee of $68.10 would set the payment at the level originally envisioned by Congress. Another commenter suggested that a dispensing fee of $0.85 per 2.5 mg dose for albuterol sulfate and $0.97 per dose for a blended mix of other inhalation drugs including ipratropium bromide would be consistent with what they believe are the 17.7 percent savings assumed by CBO. One commenter indicated that CBO underestimated the savings from section 305.

Response: MMA specifically requires the use of the ASP methodology to establish more appropriate payment rates for drugs. MMA explicitly requires the establishment of a supplying fee for Part B covered oral drugs as determined to be appropriate by the Secretary. MMA also explicitly requires establishment of a furnishing fee for blood clotting factors. However, MMA does not specify a particular dispensing fee amount for inhalation drugs, nor does MMA specify a method to determine a dispensing fee for inhalation drugs. Accordingly, CMS used existing authority to propose in the NPRM that an appropriate dispensing fee be established. Because MMA did not require a specific method or amount for a dispensing fee for inhalation drugs, we find the arguments unpersuasive that a dispensing fee of a particular amount was envisioned by Congress or consistent with Congressional intent as reflected in a CBO estimate.

Comment: We received comments that supported and opposed the use of 90-day prescriptions. One commenter supporting the proposed change indicated that most beneficiaries who receive nebulized medications suffer from chronic lung diseases and will require medication to manage their disease for prolonged periods. The commenter indicated that allowing a prescription for 90-days would reduce paperwork and redundant effort for beneficiaries, physicians and DME suppliers. A commenter indicated that there would be modest savings in dispensing, billing and shipping costs with allowance of a 90-day supply of

refills. One company suggested savings of 12.5 percent, most notably in shipping. Commenters opposing 90-day prescriptions gave various reasons, including that beneficiaries may experience side effects and change prescriptions within the first month and a certain percent of beneficiaries die each month resulting in non-returnable product. In addition, some argued that pharmacy savings for a 90-day shipment would not be significant because shipping costs account for only an estimated 16 percent of supplier's non-acquisition costs associated with providing inhalation drugs. Another company argued that a 90-day shipment would substantially increase provider's expenses for boxes and shipping. Some commenters agreed that certain chronic use medications should be provided in larger quantities, but urged caution due to the practices of some suppliers who automatically ship additional product without knowing whether the patient's current supply is exhausted. Some comments suggested that a 60-day supply might be more cost-effective in the long-term because there would be a reduced risk that large quantities of medications might be wasted. Another commenter suggested that the policy be defined to cover only drugs that are proven to be stable for at least 90 days following dispensing.

Response: As we indicated in the proposed rule, we believe that reasonableness should govern filling a monthly vs. 90-day prescription depending on the circumstances of the beneficiary. We agree with the commenter that the initial prescription for a new patient should be written for a 30-day period because of the potential for adverse reactions or changes in the treatment regimen. We would expect prescriptions for new patients to be for 30-day periods. In addition, we believe that it is reasonable for physicians to write a 30-day prescription for those beneficiaries who they believe are less stable. Similarly, we believe that refill prescriptions for 90-day periods are reasonable, particularly for stable beneficiaries. Although the Medicare program would achieve savings from the appropriate use of 30-day and 90-day prescriptions, we believe that given the comments it would be prudent for us to monitor the 90-day supply issue. Section 4.26.1, the Proof of Delivery Methods section of the Program Integrity Manual, instructs that suppliers of DMEPOS product refills contact the beneficiary prior to dispensing the refill to ensure that the refilled item is necessary and confirm any changes or modifications to the order. Suppliers who ship either a 30-day or 90-day supply of inhalation drugs without knowing the beneficiary's current supply is exhausted would be in violation of this policy. The 90-day period should not be of concern for inhalation drugs because most of these drugs are stable for at least 90-days and thus can be dispensed for such period. We would revisit this issue if additional inhalation drugs that are unstable after 90-days become available.

Because we received limited data on costs of furnishing a 90-day supply, it is more difficult to determine a 2005 fee for furnishing a 90-day supply of inhalation drugs. However, given that this is an optional payment arrangement for beneficiaries whose course of treatment has stabilized to the point that the required dosage can be predicted with a reasonable degree of certainty over a 90-day period, we believe that it is important to establish a 90-day fee. As described earlier, we are establishing a 90-day fee for furnishing inhalation drugs by applying the methodology from the GAO report to the data in the AAH study. We assumed all of the direct costs associated with a monthly fee are similar to the direct costs associated with a 90-day fee and we tripled the indirect costs. We plan to study this issue further.

Comment: Many commenters acknowledged that most DMEPOS items, including drugs, can be dispensed based on verbal orders. Several commenters objected to the requirement that a written order from the physician still must be obtained before billing. They suggested that we revise policy so that a prescription could be both filled and billed based solely on a verbal order from a physician. They pointed out that the requirement that a pharmacy still obtain a written order for a prescription in order to be able to bill Medicare creates a significant administrative burden for a pharmacy because it often requires persistent follow-up with a physician. Another commenter suggested that we consider accepting electronic transmissions of prescriptions, for example, e-scripts. Another commenter requested clarification of the rule for dispensing based on a verbal order for inhalation drugs and the proposed requirement that an order for an item of DMEPOS be signed and dated within 30 days of a face-to-face examination of a beneficiary.

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. Written orders from the physician can be faxed, photocopied, or provided via electronic or pen and ink forms. In accordance with current policy, pharmacies may accept electronic prescriptions from physicians.

Beneficiaries receiving inhalation drugs are having face-to-face exams routinely and generally do not need additional visits to re-order their drugs. A single face-to-face exam is generally sufficient for items ordered, that is, we would not require a separate face-to-face exam for the nebulizer and for the inhalation drugs. We assume that physicians would order them at the same time because they are used together.

Comment: One commenter supported the revision made earlier this year that provides flexibility regarding the timeframe for refilling Medicare prescriptions. The commenter noted that most third party plans allow pharmacies to refill prescriptions within five days of the end of usage for the previous prescription quantity dispensed. Another commenter recommended that the time frame for subsequent deliveries be expanded beyond five days. The commenter indicated that they believe a five-day time frame is too short a period for ground service and would not eliminate the need for overnight shipping. This is based on the commenter's experience that beneficiaries do not respond to calls to confirm that they need additional supply until the beneficiary has only a few days' supply left.

Response: As we indicated in the proposed rule, the revised time frame for delivery of refills of DMEPOS products provides for refills to occur no sooner than ''approximately five days prior to the end of the usage for the current product.'' In the proposed rule we emphasized the word ''approximately.'' While we believe that normal ground service would allow delivery in five days, if there were circumstances where ground service could not occur in five days, the guideline would still be met if the shipment occurs in six or seven days. As another commenter noted, the five-day standard is consistent with the time frame for shipping used by most third party plans. Given the consistency with private sector plans, because the requirement applies to all DMEPOS product refills, and because the standard is not a firm five-day limit, we do not believe that it is necessary to lengthen the standard. We will study further the ability of a supplier to contact beneficiaries for refills compared with its ability to provide

beneficiary and caregiver training on a monthly basis.

Comment: One commenter indicated that the DMERCs have not consistently implemented the revised proof of delivery provisions but that they are engaged in dialogue with CMS and the DMERCs to clarify the requirements and standardize their interpretation across the four DMERCs. Other commenters suggested that the proof of delivery requirement be eliminated.

Response: We encourage dialogue to ensure consistent understanding and application of the proof of delivery requirements. The proof of delivery requirements have recently undergone an extensive review and revision and, based on the need to prevent fraud and abuse, we see a need to continue them.

Comment: Those commenters who addressed our proposed elimination of the Assignment of Benefits (AOB) form for items and services, including drugs, where assignment is required by statute, supported our proposed change. Commenters agreed that obtaining an AOB in each instance is redundant because the supplier is required by statute to accept the assignment. Some commenters suggested that a onetime AOB be obtained from the beneficiary that will be valid for every DMEPOS item he or she receives during the period of his or her medical necessity.

Response: We appreciate the support for our proposal. As discussed in section IV of this final rule, we are adopting our proposal to eliminate the requirement for AOB form for items and services, including drugs, where assignment is required by statute. We do not agree with the suggestion to allow for a one-time AOB form to cover items and services provided in the future because there could be fraud and abuse issues.

Comment: We received conflicting comments about the impact of the changes and clarifications relating to billing requirements on the costs of dispensing inhalation drugs.

Commenters differed on the impact of the revisions to the proof of delivery requirements that we pointed out in the proposed rule that went into effect in early 2004. One company that currently uses automated systems indicated that the revision to the proof of delivery requirements would not generate savings for them. Commenters indicated that the DMERCs have not consistently implemented the changes, and that consequently there has not been significant administrative relief and subsequent savings.

We received conflicting comments about the impact of the revised time frame for shipping guidelines. While one commenter indicated that savings had already been achieved because the provision had already been implemented, another commenter indicated that the revision would have negligible effect because the commenter would not change its existing business practice of using overnight shipping.

One commenter said it had already adopted the provision of prescriptions being filled by verbal order, followed up by a written order for the claim submission and that these changes did not generate any additional savings for the commenter. Some suggested that the elimination of the AOB form for drugs would have limited savings because some suppliers currently obtain the AOB form at the same time that they obtain other forms that would be continued. Retail pharmacies agreed that elimination of the AOB form and verbal prescription order would reduce their paperwork. However, inhalation companies did not agree.

Response: We understand the commenters concerns and will study the impact of these billing changes on the different suppliers' costs as the new payment system is implemented.

Comment: Several commenters suggested that we review and consider changing several aspects of billing that might have cost-savings potential for suppliers of drugs. Several commenters indicated that Medicare's lack of on-line adjudication represented a significant cost and burden to them. One retail pharmacy commented that pharmacies face higher than normal rejection rate on claims because Medicare claims are not processed on-line, resulting in higher administrative costs. Others commented that pharmacies that dispense Medicare prescriptions must obtain documentation that is typically provided by the physician. For example, one company indicated that suppliers are held responsible for the appropriate medical necessity documentation in the patient's medical record but that the supplier has no control over physician records. Some suggested that we consider eliminating the requirement that a diagnosis code be required on the prescription. One pharmacy commented that pharmacies should not be expected to verify that the physician has in fact performed a face-to-face exam for the purpose of treating and evaluating the patient's medical condition or whether the physician has created appropriate documents in his records. Rather, the pharmacy believes that this responsibility should be left to the physician, and the creation of a prescription should be all that is needed to verify that the physician has complied with all Medicare requirements. A commenter noted that Medicare requires that suppliers submit claims with the physician's Unique Physician Identification Number (UPIN) while most third party plans require the physician's DEA number and suggested that we consider adopting usage of the physician's DEA number instead of UPIN. A pharmacy commented that dispensing units are different than current National Council for Prescription Drug Programs (NCPDP) standards; Medicare reimburses products based on a per mg price while the NCPDP standard suggests reimbursement on a per ml price. The pharmacy indicated that this makes it more difficult for the pharmacy to calculate proper reimbursement for these Medicare claims. Other commenters suggested that the Medicare enrollment and reenrollment process for suppliers be significantly streamlined. A retail pharmacy indicated that Medicare requires pharmacy suppliers to submit extensive and often duplicative pharmacy-specific paperwork that is more voluminous than any other third party plan in which retail pharmacies participate. One inhalation company suggested certain aspects of billing such as the requirement that the supplier query the physician and beneficiary to find out if the beneficiary had already received a same or similar item from another supplier. The company also identified what it claimed are several other labor-intensive, costly aspects of Medicare billing including electronic claims filing requirements; information system programming and testing; paperwork and new business procedures required to be compliant with HIPAA; Medicare and secondary insurance benefits verification and qualification; responding to significantly increased pre-payment audit activities; administering the Patient Financial Hardship Waiver prior to billing deductible and coinsurance amounts; billing and writing off beneficiary cost-sharing as bad debts; and differing DMERC policies concerning documentation needed to support home inhalation therapies.

Response: We thank the commenters for identifying these items. We plan to examine these aspects of billing. To the extent that there are different interpretations or applications of national policy by DMERCs, our goal is increased standardization.

Comment: A comment from a group focused on respiratory care indicated that there may be over utilization of albuterol sulfate. The comment indicated that a large amount of scientific evidence concludes that high albuterol sulfate use is indicative of

poor overall disease management. The commenter further indicated that Medicare's costs related to the use of albuterol sulfate may result from the fact that alternative drug treatment regimes are not adequately considered in the management of the patient's disease. The commenter urged us to examine the underlying causes of high utilization rates of albuterol sulfate.

Response: Our goal is to ensure that Medicare beneficiaries have access to the appropriate drugs to treat their diseases. We believe that the availability of discounts through the Medicare drug card and the implementation of the Part D drug benefit beginning in 2006 promote treatment decisions being made based on the best clinical evidence, rather than being influenced by differential coverage.

Comment: We received many comments addressing the issue of nebulizers versus metered dose inhalers (MDIs). Most commenters questioned whether a significant shift of Medicare beneficiaries to MDIs would occur when MDIs are covered in the Part D drug benefit beginning in 2006. We received many comments, studies and literature reviews on nebulizers and MDIs. Some commenters identified the specific disadvantages of MDIs and holding chambers or spacers. Some commenters questioned the conclusion of the literature review mentioned in the proposed rule that nebulizers are not clinically superior in delivering inhalation drugs than MDIs and the commenters asserted that the two are not fully substitutes. Some commenters quantified the costs to beneficiaries of nebulizers and MDIs. One commenter pointed out that MDIs would increase in 2006 based on the ban of the propellent chlorofluorocarbon. Another commenter questioned the point in the proposed rule that MDIs are more portable than nebulizers since advances in nebulizer technology have included additional portability. The commenter noted that since Medicare covers only one standard nebulizer, many of their patients have purchased portable nebulizers on an out-of-pocket basis to use as a second device while outside of their home.

Response: A number of drugs are available to treat the persons with asthma or who develop COPD. These include drugs, often inhaled, that expand the bronchial tubes and allow the patient to breathe more freely. Depending on the needs of the individual patient, these medications can be delivered using nebulizers or MDIs. Although nebulizers have long been covered under Medicare Part B, the MMA expanded access to MDIs beginning in 2006 through the new Medicare Part D drug benefit. While two meta-analyses cited by one commenter are consistent with the literature review mentioned in the proposed rule that found a lack of overall clinical superiority of MDIs over nebulizers, we recognize that even after coverage of MDIs begins in the Part D drug benefit in 2006, due to their particular circumstances, many beneficiaries will require the use of nebulizers and that nebulizers will continue to play an important role in inhalation therapy. Part B does not currently cover MDIs and we will gain experience with the costs of MDIs as the Part D drug benefit is implemented.

Comment: Comments were received from respiratory drug distributors and homecare providers addressing drugs that are supplied from the manufacturer in more than one form. One company suggested that since inhalation drugs are provided by the manufacturer in two forms, a premixed solution or as a powder (or other concentrate) that is diluted by the pharmacist, the ASP should be calculated separately for each of these two forms in order to reflect the different acquisition costs to the pharmacy for the different forms. The company suggested use of a modifier for the J-code to distinguish between these two forms for reimbursement purposes.

Response: We disagree. Consistent with the statute, the ASP is calculated by the HCPCS codes rather than the NDC code. This allows flexibility in appropriate drug delivery.

Comment: We received letters from individual beneficiaries and their family members indicating that the beneficiary has tried MDIs unsuccessfully and that inhalation drugs administered through a nebulizer were a successful treatment. They asked us not to assume that everyone on a nebulizer could be switched to inhalers and asked that we allow inhalation medications administered through nebulizers to remain funded by Medicare.

Response: We recognize that nebulizers are required by many beneficiaries due to their particular health circumstances. We did not propose to eliminate Medicare funding for inhalation medications administered through nebulizers.

Comment: Several commenters questioned why there should be public funding for COPD treatments for persons who chose to smoke cigarettes. The commenters indicate that it may be too harsh a policy to cease all reimbursement for COPD treatments, but they suggested two alternatives: (1) No individual who currently smokes should receive any Medicare benefit for the treatment of any respiratory condition, and (2) Any individual who historically smoked heavily and receives treatment for respiratory disorders should face an annual deductible equal to the cost of smoking a pack of cigarettes a day.

Response: As we indicated in the proposed rule, smoking has been linked to a large number of health problems and is the leading cause of cancer and pulmonary disease. The Department of Health and Human Services (HHS) has been actively encouraging Americans to quit smoking through its smoking cessation initiatives. Americans who quit smoking will enjoy longer, healthier lives and avoid diseases such as COPD. However, the Medicare law does not limit benefits to persons who do not currently smoke, nor does the Medicare law impose a deductible that is different for smokers and non-smokers. This regulation implements the law as it is currently written.

Result of Evaluation of Comments

In the proposed rule, we requested comments on the appropriate separate dispensing fee for inhalation drugs used in a nebulizer. In this final rule we are establishing 2005 fees of $57.00 for furnishing a 30-day prescription and $80.00 for furnishing a 90-day prescription for inhalation drugs. This fee would be paid in addition to the Medicare payment amount for the drug.

As discussed in section IV, we are finalizing our proposal to eliminate the Assignment of Benefits (AOB) form for items and services, including drugs, where assignment is required by statute. We reiterate language in the recently updated guidelines for DMEPOS refills, emphasizing the word ''approximately''. This allows for refill prescriptions to be shipped by ground service on ''approximately'' the 25th or 85th day of the respective prescription period. In addition, we clarified the ordering requirements for DMEPOS items, including drugs, which can be dispensed with just a verbal physician order.

P. Section 706—Coverage of Religious Nonmedical Health Care Institution Services Furnished in the Home

1. Background

Section 706(a) of the MMA amended section 1821(a) of the Act by adding home health services to the list of services furnished to an individual by a religious nonmedical health care institution (RNHCI). Section 706(b) added section 1861(aaa) to the Act to expand the term ''home health agency'' (HHA) to include a RNHCI. However,

this expansion is limited to RNHCI items (specified durable medical equipment) and services furnished in the beneficiary's home when the items and services are comparable to those provided by a HHA that is not a RNHCI. Moreover, payment may not be in excess of $700,000 per calendar year, and may not be made after December 31, 2006. Accordingly, we are implementing changes to the RNHCI regulation to include services furnished in the home that result from the enactment of the MMA and that are becoming effective January 1, 2005.

The new time-limited home health services benefit will be referred to as ''home benefit'' or ''home services'' throughout this rule. The RNHCI home benefit may only be provided to an eligible beneficiary who is confined to the home for health reasons and who has a condition that makes the beneficiary eligible to receive services under Medicare home health. Additionally, the beneficiary must have an effective RNHCI election and receive his or her home services from the RNHCI. The home benefit is not a substitute for hospice care. As in the original RNHCI benefit, Medicare will pay only for nonmedical services in the home, but not for those religious items or services provided by the RNHCI. Additionally, RNHCI home service patients who have a documented need for a specified DME item can obtain that item with the applicable deductible and coinsurance.

2. Legislative History

In 1965, payments to Christian Science sanatoria (inpatient nonmedical care facilities for bedfast patients) were included in the initial provisions of Medicare under title XVIII of the Act. In 1996, in *Children's Healthcare Is a Legal Duty, Inc.* v. *Vladeck,* 938 F. Supp. 1466 (D. Minn. 1996) (''*CHILD I*''), a Federal district court held that some of the provisions pertaining to Christian Science sanatoria were unconstitutional on the grounds that they were sect specific, in violation of the Establishment Clause of the U.S. Constitution.

Section 4454 of the BBA amended section 1861(a)(1) of the Act, deleting Christian Science sanatoria from the Act and creating instead the RNHCI benefit to provide Medicare Part A and Medicaid access for all religious groups whose belief structure does not include medical intervention. We note that, in the Conference Report to the BBA (H.R. Conference Report, No. 105–217, at 768 (1997)), the Congress specified that the RNHCI provisions were a sect-neutral accommodation available to any person who is relying on a religious method of healing and for whom the acceptance of medical health services would be inconsistent with his or her religious beliefs. Further, the Congressional conferees were convinced that the RNHCI provisions fully responded to and satisfied the constitutional concerns that had been addressed by the district court in CHILD I.

Besides adding the new RNHCI benefit, section 4454 of the BBA also added sections 1861(ss) and 1821 to the Act. Section 1861(ss) sets forth:

- The ten requirements that a provider must meet in order to be considered a RNHCI;
- Parameters for oversight and monitoring;
- Authority for Federal review of items and services provided for excessive or fraudulent claims; and
- Parameters for ownership/affiliations.

As in the past, the new provisions do not mention the use of a religious counselor or practitioner; we consider that to be the responsibility of the patient.

Section 1821 of the Act provides for conditions for coverage of RNHCI services including:

- The election, revocation, and limitations of the RNHCI benefit (section 1821(b));
- The monitoring and safeguarding against expenditures (section 1821(c)); and
- The sunset provisions for the RHNCI benefit (section 1821(d)).

Section 1821(a) of the Act, as amended by the MMA, provides for Part A payment for inpatient hospital services, post-hospital extended care services, or home health services furnished to a beneficiary in, or by, a RNHCI only when the beneficiary has:

- A valid election for the RNHCI benefit in effect; and
- A condition that would qualify for inpatient hospital, extended care services, or home health if the beneficiary were an inpatient or resident in a hospital or skilled nursing facility, or was a patient residing at home under the care of a HHA that was not a RNHCI.

The election of the RNHCI benefit becomes effective immediately after execution and remains in effect for a lifetime or until revoked. As described in section 1821(b) of the Act, the election is a written statement signed by the beneficiary or the beneficiary's legal representative which states that:

- The individual is conscientiously opposed to the acceptance of nonexcepted medical treatment;
- The individual's acceptance of that nonexcepted treatment would be inconsistent with the individual's sincere religious beliefs; and
- The individual's receipt of nonexcepted medical care constitutes a revocation of the election.

The RNHCI election may be revoked by voluntarily notifying the Secretary in writing of the revocation or the election may be revoked by simply receiving nonexcepted medical care for which payment is sought under Medicare. Once a RNHCI election is revoked twice, the next election may not take place until a date that is at least one year from the date of the most recent revocation. Any election thereafter does not become effective before a date that is at least five years after the date of the previous revocation. The receipt of excepted medical care does not result in a revocation of the election. As stated in § 403.702 of the regulations, the following definitions apply—

- *Excepted medical care or treatment* for purposes of the RNHCI benefit is defined as medical care or treatment (including medical or other health care services) received involuntarily (for example, following an accident), or required by any level of government (for example, immunizations).
- *Nonexcepted medical care or treatment* refers to all medical care or treatment that is not defined as excepted medical care or treatment. The beneficiary always retains the right to receive medical care under Medicare based on his or her level of coverage (for example, Part A, Parts A and B). However, using nonexcepted care will result in the revocation of the RNHCI election.

On November 30, 1999, we published the RNHCI interim final rule with comment period in the **Federal Register** (64 FR 67028), effective on January 31, 2000. The final RNHCI regulations were published on November 28, 2003 (68 FR 66710). There are currently 16 RNHCIs in the United States: Three in California; two each in Florida and Ohio; and one each in: Colorado, Illinois, Indiana, Massachusetts, New York, Texas, Virginia, Washington, and Wisconsin.

3. Summary of Section 706 of the MMA

Section 706 of the MMA amended the Act to extend Medicare coverage of RNHCI items and services to the RNHCI beneficiary's home when the items and services are comparable to those provided by a HHA that is not a RNHCI.

Specifically, section 706(a) of the MMA amended section 1821(a) of the Act by adding home health services to the list of services furnished to an individual by a RNHCI. Section 706(b) of the MMA added section 1861(aaa) to the Act to expand the term ''home

health agency'' to include a RNHCI as defined in section 1861(ss)(1) of the Act, but only for items and services that are ordinarily furnished by a RNHCI to individuals in their homes, and that are comparable to items and services furnished to individuals by a HHA that is not a RNHCI. Section 1861(aaa)(2)(A) of the Act states that, subject to section 1861(aaa)(2)(B), payment may be made for services provided by a RNHCI only to the extent and under the conditions, limitations, and requirements that are in regulations consistent with section 1821 of the Act. Section 1861(aaa)(2)(B) states that payment may not be made for RNHCI home services under section 1861(aaa)(2)(A) of the Act in excess of $700,000 per calendar year, or after December 31, 2006.

This interim final rule amends the existing RNHCI regulations in Subpart G to implement section 706 of the MMA.

4. Discussion

a. Implementation of Section 706 of the MMA

As stated above, section 706 of the MMA added section 1861(aaa)(1) to the Act to expand the term ''home health agency'' to include a RNHCI, as defined in section 1861(ss)(1) of the Act, but only for items and services that are ordinarily furnished by that institution to individuals in their homes, and that are comparable to items and services furnished by a HHA that is not a RNHCI. This posed a number of implementation challenges as a RNHCI does not conform to the statutory definition or requirements of a HHA in section 1861(m) of the Act, which is based on a medical model. Some of these challenges result from the fact that—

- RNHCIs were established to accommodate those religious groups that do not believe in the use of physicians to direct or supervise health care; and
- RNHCI nursing does not correspond to the statutory or regulatory parameters established by Medicare for ''skilled care'' in the home setting.

In addition, the RNHCI payment methodology does not readily lend itself to payment to the RNHCI for items and services under the RNHCI home benefit. Therefore, in an effort to implement the intent of the amendment, we will generally use the definition and requirements for a RNHCI, rather than a HHA (with some exceptions), in order to extend RNHCI services into the home environment. However, in order to aid in determining comparability, we are also utilizing, when appropriate, some of the home health requirements set forth in section 1861(m) of the Act.

The presence of physician orders and oversight is a keystone in the operational viability of a HHA and nonexistent in the RNHCI, where the religious practitioner (noncovered by Medicare) is the primary focal person in establishing the course for the religious method of healing. In addition, the RNHCI nurse further assists the patient in navigating the course established for the religious method of healing. To address the need for oversight for the RNHCI home benefit as with the current inpatient RNHCI benefit, we are implementing section 706 of the MMA by continuing to require that the RNHCI utilization review committee review the need for care (expanded now to include both admission to the home benefit and continued care in the home setting), and to oversee the utilization of items and services in the time-limited home benefit. The utilization review committee, however, cannot act in place of a physician in ordering items and services other than those designated specifically for the purpose of this time-limited RNHCI home benefit. A claim from any other individual or provider attempting to seek Medicare payment for non-designated RHNCI home benefit items and services without a physician order will be disallowed.

We also recognize that implementing section 706 is particularly challenging in light of the fact that no sophisticated physical treatments or procedures are provided in RNHCIs, while conventional medical care becomes more technical every year, making the care delivered by HHA personnel increasingly complex. The major challenge was determining comparability between home health services for HHAs defined in part 409 subpart E, and RNHCI services which are nonmedical in nature.

Medicare pays for supportive care or dependent services under the home health benefit only when under the orders and direction of a licensed physician if there is a medical need for skilled health care by a registered nurse, physical therapist, speech-language therapist, occupational therapist, or medical social worker. Under the Medicare home health benefit, when there is no longer a need for the ''skilled'' health care services, the supportive dependent services no longer qualify for payment. Based on section 1861(m) of the Act, we believe that Medicare home health care benefits are skilled-care oriented. These benefits were not designed to provide coverage for care related to help with activities of daily living unless the patient requires skilled nursing care or physical or speech therapy. The RNHCI nurse may be skilled in ministering to a beneficiary's religious needs (not covered by Medicare), but does not have the training or nursing skill sets required of credentialed/licensed health care professionals (for example, a registered nurse). While the RNHCI nurse may provide supportive care, that care is focused primarily on religious healing and meeting basic beneficiary needs for assistance with activities of daily living (for example, bathing, toileting, dressing, ambulation), as part of creating an environment for religious healing. The care provided by a RNHCI nurse is not at the level of either a registered nurse or a licensed practical nurse. The physical care provided by a RNHCI nurse is at a level that could be considered as supportive, but is decidedly not skilled nursing care as that term is understood under the Medicare home health program.

In the search for comparability of services, we considered the requirements and functions of the home health aide contained in sections 1861(m) and 1891(a)(3)(A) of the Act and in the regulations at 42 CFR 484.36. We performed a parallel review of the activities and skills utilized by home health aides and RNHCI nurses to determine comparability at an operational level. We determined that both the RNHCI nurse and the home health aide perform the following basic tasks—

- Assisting with activities of daily living (ADLs) that include: ambulation, bed-to-chair transfer, and assisting with range of motion exercises; bathing, shampoo, nail care, and dressing; feeding and nutrition; and toileting;
- Performing light housekeeping, incident to visit; and
- Documenting the visit.

However, the home health aide is also responsible for—

- Care of catheters and drainage equipment;
- Checking oxygen and other respiratory equipment;
- Communicating with nurse or other skilled team members;*
- Assisting with exercises as ordered by PT, OT or speech language therapist;
- Observation and reporting of existing medical conditions;*
- Recognizing and responding to emergency situations (including CPR);
- Routine care of prosthetics and orthotics;
- Taking and reporting vital signs;*
- Using basic infection control procedures;* and
- Care of wound/stoma dressings.

The home health aide during a home visit will usually perform at least three of the four skills marked with an

asterisk (*) from the ten skills listed. The remaining areas of responsibility are carried out as indicated by the patient's needs and the patient's care plan.

In analyzing the outcomes of the home health aide/RNHCI nurse review, we found that both groups engaged in the comparable tasks of assisting with activities of daily living, performing light housekeeping (incident to visit), and documenting the visit. Therefore, we will pay for the performance of these tasks by a RNHCI nurse in the home under the home benefit established by section 706 of the MMA. However, in reviewing for comparability of these services, we also found that the Medicare requirements for a home health aide exceed the preparation and skills of the RNHCI nurse for furnishing physical care. The home health aide performs activities that support the patient's prescribed medical therapeutic regimen and contribute to the Outcome and Assessment Information Set (OASIS) data collection effort. Moreover, we assumed that a significant portion of each RNHCI nurse visit is focused on religious activity (noncovered by Medicare). However, in spite of the difference in skill levels and the incorporation of non-covered religious activity into a visit, Medicare payment for the RNHCI home benefit is based on a fixed payment per visit, rather than on a total number of hours or number of caregivers involved. Unlike the home health benefit, the RNHCI benefit does not involve multiple levels of covered caregivers. Under the home health PPS only the *low utilization payment adjustment* (LUPA) rate provides for payment for individual home health visits. Due to the uniqueness of the RNHCI and RNHCI nurses in the Medicare program, we have developed a payment rate that is a percentage of the PPS LUPA rate for home health aide visits provided under the home health PPS, which we believe adequately represents the percentage of comparable tasks performed by the RNHCI nurse. Only a visit by a RNHCI nurse to a home is payable by Medicare. The cost for the religious portion of the visit continues to be the responsibility of the individual patient or the specific RNHCI.

Another challenge was posed by the provision of DME items for RNHCI patients in the home, since all DME is covered for Medicare payment only when ordered by a physician. That physician order may provide the RNHCI patient with the desired DME item, but will also revoke the patient's election for RNHCI care. We addressed the issue of DME by reviewing those items that are routinely found in a RNHCI that are comparable to those used by a HHA that is not a RNHCI. This resulted in a list of DME items that one could normally buy or rent off the shelf from a community pharmacy or health care supply store. For purposes of this time-limited benefit, we are permitting the RNHCI nurse to order from this list of designated items under the oversight of the RNHCI utilization review committee. A listing of these items is provided in Table 15 below.

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TABLE 15:

DME with HCPCS Codes Available for the Home Benefit	
CANES	
E0100	Cane, includes canes of all materials, adjustable or fixed, with tip
E0105	Cane, quad or three prong, includes canes of
	all materials, adjustable or fixed, with tip
CRUTCHES	
E0112	Crutches, underarm, wood, adjustable or fixed, pair, with pads, tips, and handgrips
E0113	Crutch, underarm, wood, adjustable or fixed, pair, with pad, tip, and handgrip
E0114	Crutches, underarm, other than wood,adjustable or fixed, pair, with pads, tips, and handgrips
E0116	Crutch, underarm, other than wood, adjustable or fixed, with pad, tip and handgrip
WALKERS	
E0130	Walker, rigid (pickup), adjustable or fixed height
E0135	Walker, folding (pickup), adjustable or fixed height
E0141	Walker, rigid, wheeled, adjustable or fixed height
E0143	Walker, folding, wheeled, adjustable or fixed height
COMMODES	
E0163	Commode chair, stationary, with fixed arms
E0167	Pail or pan for use with commode chair
WHEELCHAIRS	
K0001	Standard wheelchair
HOSPITAL BEDS and ACCESSORIES	
E0250	Hospital bed, fixed height, with any type side rails, with mattress
E0255	Hospital bed, variable height, hi-lo, with any type side rails, with mattress
E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress
E0275	Bed pan, standard, metal or plastic
E0276	Bed pan, fracture, metal or plastic
E0290	Hospital bed, fixed height, without side rails, with mattress

E0292	Hospital bed, variable height, hi-lo, without side rails, with mattress
E0325	Urinal; male, jug-type, any material
E0326	Urinal; female, jug-type, any material

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We will provide the specifics for implementing the DME items and payment under this time-limited benefit in later Medicare program instructions.

Under section 1861(aaa)(2)(B) of the Act, payments for the RNHCI home benefit may not be made that exceed $700,000 per calendar year, and not after December 31, 2006. Under the RNHCI home benefit, Medicare will pay only for nonmedical health services in the home, as well as for those DME items included in Table 15 of this preamble. Medicare will not pay for religious items or services provided by the RNHCI. We have developed a special billing system for those RNHCI providers offering the home benefit to monitor expenditures on home services and items for purposes of staying within the statutory calendar year expenditure limit.

5. RNHCI Regulatory Provisions—RNHCI Medicare Benefits, Conditions of Participation, and Payment

As noted previously, to implement section 706 of the MMA, we reviewed the requirements for both HHAs and RNHCIs to identify the most feasible approach. Accordingly, we have made the following changes to the RNHCI regulations:

a. Basis and Purpose of Religious Non-Medical Health Care Institutions Providing Home Services—§ 403.764

We added § 403.764 to set forth the basis and purpose of the RNHCI home benefit. Specifically, we added subsection (a) to include a reference to section 1861(aaa) of the Act to the general RNHCI authority noted in § 403.700 and a description of the provisions of section 1861(aaa). We also added subsection (b) to describe the home benefit, the statutory annual fiscal limitation, and the sunset provision.

b. Definitions and Terms—§ 403.702

We made no changes to the regulation.

c. Conditions for Coverage—§ 403.720

We made no changes to the regulation.

We wish to emphasize that the RNHCI home benefit is an option available to each RNHCI, and the facility is not required to offer this service to either gain or maintain RNHCI status.

The RNHCI home benefit is not to be confused with hospice care that may involve more frequent visits and can involve institutional services. If, for some reason, the RNHCI home-serviced patient requires more than what is provided under the RNHCI home benefit, RNHCI or other institutional services may be required.

d. Valid Election Requirements—§ 403.724

We made no changes to the regulation because no modification or clarification to this requirement is needed to implement the RNHCI home benefit. Section 1821(b) of the Act addresses the issues involved in beneficiary election of RNHCI services.

e. Conditions of Participation—§ 403.730 through § 403.746

We have not changed the following conditions of participation, as they do not require any modification or clarification for implementing the RNHCI home benefit:

- Patient Rights (§ 403.730)
- Quality Assessment and Performance Improvement (§ 403.732)
- Administration (§ 403.738)
- Staffing (§ 403.740)

We have not changed the following conditions of participation, as they are specific to institutions and are not applicable to the implementation of the RNHCI home benefit:

- Food Services (§ 403.734)
- Discharge Planning (§ 403.736)
- Physical Environment (§ 403.742)
- Life Safety From Fire (§ 403.744)

The following condition of participation requires the addition of a new standard to reflect the additional responsibility necessary for implementing the RNHCI home benefit:

- Utilization Review (§ 403.746)

As explained previously, the utilization review committee will review the need for care and oversee the utilization of items and services for the RNHCI home benefit. Accordingly, § 403.746 will be revised to reflect the additional responsibility necessary for implementing the RNHCI home benefit. Specifically, § 403.746 will be modified to add a new subsection (c) to read as follows:

(c) *Standard: Utilization review committee role in RNHCI home services.* In addition to the requirements in (b), the utilization review committee is responsible for the admission and continued care review (at least every 30 days) of each patient in the RNHCI home services program. The utilization review committee is responsible for oversight and monitoring of the home services program, including the purchase and utilization of designated durable medical equipment (DME) items for beneficiaries in the program.

We again note that under the RNHCI home benefit, one of the tasks of the RNHCI nurse is to order from a selected group of DME items that meet the documented needs presented by a patient, if that need is presented by the patient. The utilization review committee will provide oversight for the DME orders and utilization of the items. The utilization review committee cannot act as a physician in ordering DME items other than those items designated specifically for the purpose of this time limited RNHCI benefit. A claim from any other individual or provider attempting to seek Medicare payment for non-designated RNHCI home benefit DME items without a physician order will be disallowed.

In implementing section 706 of the MMA, we have also revised the regulations to add the following provisions:

a. Requirements for Coverage and Payment of RNHCI Home Services (§ 403.766)

The RNHCI home benefit is an option available to each RNHCI, but it is not a service that the facility must offer to gain or maintain RNHCI status. With the exception of limited DME items, we have determined that services that RNHCI nurses provide are generally covered for Medicare payment under the time limited RNHCI home benefit as these services (for example, assistance with ADLs, light housekeeping incident to the visit, and documentation of the visit), are comparable to the services of home health aides in HHAs that are not RNHCIs.

To reflect the requirements of this limited benefit, we are adding a new section 403.766. Specifically, in § 403.766(a), we are requiring the RNHCI provider to submit a notice of intent if it is interested in providing RNHCI home services. This will help us facilitate the implementation of the RNHCI home benefit by letting us focus our efforts on those providers interested in providing this new benefit. The RNHCI provider is also responsible for providing RNHCI home services to eligible beneficiaries. We are imposing this requirement because we believe the RNHCI provider itself is responsible for providing the RNHCI home services, directly or under arrangement, to the eligible beneficiary. This means that the beneficiary cannot contract directly with a supplier or RNHCI nurse, but that the RNHCI provider itself is responsible for provision of the RNHCI home benefit services. This requirement conforms to the ''under arrangement'' requirement that home health agencies generally have to comply with to receive payment under the home health prospective payment system (*see* § 409.100(a)(2)). Furthermore, because the RNHCI is not a supplier, we are explicitly requiring the RNHCI provider to make arrangements for suppliers to furnish the designated RNHCI home benefit DME items. Likewise, the RNHCI provider will have to arrange for the RNHCI nursing services. While the RNHCI regulations currently require the RNHCI provider to have a utilization review plan and committee in place, we believe it would be prudent in the RNHCI home benefit regulation to explicitly require the RNHCI home benefit provider to have a utilization review committee that assumes the additional responsibility for the oversight and monitoring of the items and RNHCI nursing services provided under the home benefit. Lastly, because the RNHCI home benefit does not supersede or otherwise replace the existing RNHCI benefit, the provider will continue to have to meet all the existing applicable RNHCI regulatory requirements in subpart G of part 403.

We will also define an ''eligible beneficiary'' for the RNHCI home benefit in § 403.766(b). First, the beneficiary must elect to receive RNHCI services. Clearly, the RNHCI home benefit can only be provided to a beneficiary who has elected RNHCI services. Second, we believe that the purpose of providing a home benefit by a RNHCI provider was not to expand the basic eligibility criteria for receiving home health services. In fact, section 1821(a) of the Act, as amended by the MMA, now states that payment for RNHCI home services be made only if the individual has an election in effect and has a condition such that the individual would otherwise qualify for Medicare home health services. Specifically, this means that the individual must be confined to the home, as defined in section 1814(a) of the Aft and have a condition that would make him or her eligible to receive Medicare home health services. Third, much like the requirement that the RNHCI provider is responsible for providing RNHCI home services directly or under arrangement to the beneficiary, the beneficiary can only receive RNHCI home services through the RNHCI. The purpose of this requirement is to provide Medicare payment for the RNHCI home benefit only to beneficiaries who receive these services through the RNHCI. This requirement is consistent with section 1821(a) of the Act, as amended, which provides Medicare payment for home services furnished an individual by a RNHCI. We note that under the home health benefit beneficiaries are responsible for the deductible and coinsurance for DME furnished as a home health services. We see no reason to modify that requirement for beneficiaries receiving RNHCI home services. As this is a new benefit for RNHCI beneficiaries, we wish to make it clear that they are responsible for deductible and coinsurance for the designated RNHCI home benefit DME items in the same manner as Medicare beneficiaries receiving DME under the home health benefit.

b. Excluded Services (§ 403.768)

Under the home health benefit, certain items and services are excluded under the benefit. The RNHCI home benefit will exclude the same items and services, which are:

- Drugs and biologicals;
- Transportation;
- Services that would not be covered as inpatient services;
- Housekeeping services;
- Services covered under the ESRD program;
- Prosthetic devices; and
- Medical social services provided to family members.

Accordingly, we are adding a new § 403.768 to reflect the services excluded under the RNHCI home benefit.

In addition, we note that the statute does not provide for the provision of the RNHCI home benefit in a home health agency that is not a RNHCI, and we will provide for this exclusion in the regulation. We wish to reiterate that items and services not provided by a RNHCI but instead provided by a supplier or RNHCI nurse not under arrangement with the RNHCI are not included under the RNHCI home benefit. The regulation will also note this exclusion.

c. Payment for RNHCI Home Services (§ 403.770)

As discussed above, providing home services in the RNHCI environment incorporates many of the same components of the provision of home health aide services under the Medicare home health benefit. Because this is a new benefit not contemplated under the original RNHCI legislation, an appropriate payment methodology needed to be developed. As explained previously, we believe that an appropriate proxy for the cost of providing RNHCI home services can be found in the low utilization payment amount for home health aide visits under the Medicare home health PPS. Generally, Medicare home health services are reimbursed a prospectively set payment amount for a 60-day episode of care, adjusted for case mix. This 60-day episode payment includes costs for non-routine medical supplies, as well as costs for the six major home health disciplines, including home health aide services. The home health episode payment rate does not include reimbursement for durable medical equipment, which is paid through a separate DME fee schedule. The home health PPS rates were required to be budget neutral to what would have been expended under the reasonable cost system. The 60-day episode rate is updated annually by some percentage of the home health market basket, as dictated by law, and is adjusted by the hospital wage index to account for geographic variations in labor costs.

Medicare home health services may also be paid on a visit basis if the home health episode has four or fewer visits. Medicare pays on the basis of a national per-visit amount by discipline, referred to as low utilization payment adjustment (LUPA), adjusted for case mix. As mentioned previously, the LUPA rate for home health aide services is a very close approximation of the cost of providing home services in the RNHCI environment. However, due to the difference in skill levels and the incorporation of RNHCI religious activities that are not covered by Medicare, payment for the RNHCI home benefit is set at 80 percent of the per visit rate for a home health aide visit under the Medicare home health benefit.

The policies and rationale governing LUPA payments under the Medicare home health benefit are described in the July 3, 2000 HH PPS final rule (65 FR 41127). Generally, low utilization episodes are paid at a standardized average per visit amount, adjusted for geographic differences in wages, which will be the basis of calculating payment under the RNHCI home benefit program. These amounts are updated annually by the home health market basket percentage as dictated by statute and are being used for the RNHCI home benefit. For CY 2005, the Medicare HHA PPS rates were updated by the home health market basket minus 0.8 percent. The HHA PPS LUPA amount for CY 2005 is $44.76 for a home health aide visit, as published in the **Federal Register** October 23, 2004 (69 FR 62124). Because we believe the intent is to provide comparable home health services to a beneficiary at home provided by a RNHCI, we believe it is similarly necessary to develop a payment methodology to reflect the provision of these comparable services. As previously mentioned, we have determined that the LUPA payment, as calculated under the home health PPS and adjusted for geographic differences in wages is an appropriate payment methodology for the RNHCI home benefit. We further note that as the LUPA will be updated by the applicable market basket percentage under the home health PPS, we will also adopt the updated LUPA payment for CY 2006 as the basis of payment for the RNHCI home benefit in CY 2006. An update of the HHA payment rates is published annually in the **Federal Register**, with CY 2006 updated figures available in Fall 2005. As mentioned above, the beneficiary receiving the RNHCI home benefit will be responsible for deductible and coinsurance for the designated RNHCI home benefit DME items. The regulation will indicate that payment for DME as a RNHCI home item is made less the deductible and coinsurance amount.

In view of the small size and low volume of most RNHCIs, we will use a 30-day cycle for the submission of RNHCI home benefit claims. Unlike standard HHAs that use a 60-day cycle, the RNHCI will use a 30-day cycle for both payment request and as a minimum for continued care home benefit review by the utilization review committee. Specific instructions on the processing of RNHCI home benefit payments will be issued in separate Medicare instructions.

Example of LUPA Payment Adapted for RNHCI Home Benefit Payment:

A RNHCI in Baltimore, Maryland is providing the RNHCI home benefit to a patient with a RNHCI election. The RNHCI has provided 12 visits within a 30-day cycle. The RNHCI would determine the payment for the home benefit visits as follows:

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TABLE 16:

Computation of Wage Index Adjusted Low Utilization Payment for the RNHCI Home Benefit

		Final wage standardized and budget neutral per-visit payment amount per 30 days for 2005
1. Home Health Aide Visit (2005)		$ 44.76
2. RNHCI Nurse Visit	(0.80 * $ 44.76)	35.81
3. Calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit	(0.76775 * $.35.81)	27.49
4. Apply wage index factor for Baltimore, MD	(0.9907 * $ 27.49)	27.23
5. Calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit	(0.23225 * $ 35.81)	8.32
6. Subtotal—Low Utilization Payment Adjustment (LUPA) wage for 1 RNHCI nurse visit	($ 27.49 +$ 8.32)	$ 35.55
7. Total - Calculate total Low Utilization Payment Adjustment (LUPA) for 12 RNHCI nurse visits provided during the 30-day episode	(12 * $ 35.55)	$ 426.60

Note: The same "labor"/"non-labor" portions applied in the home health PPS will be used
calculating the RNHCI LUPA payments.

Step 1. Take the home health aide visit base rate for the involved year from the home health PPS update published.

Step 2. To calculate the RNHCI nurse visit base rate, multiply the home health aide visit base rate ($ 44.76) by the allowed percentage for a RNHCI nurse visit (0.80 percent) =($ 35.81).

Step 3. To calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit, multiply the labor portion of 0 .76775 by the RNHCI nurse visit rate from Step 2 ($ 35.81) =($ 27.49).

Step 4. Apply the wage index for the involved Metropolitan Statistical Area (MSA)

from the home health PPS payment update published annually each November in the **Federal Register** (Baltimore, MD =0.9907) multiplied by the labor portion of the RNHCI nurse visit from Step 3 ($ 27.49) =($27.23).

Step 5. To calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit, multiply the non-labor portion of 0.23225 by the RNHCI nurse visit rate from Step 2 ($ 35.81) =($ 8.32).

Step 6. To calculate the LUPA rate for 1 RNHCI nurse visit, add the products from Step 4 ($27.49) and Step 5 ($ 8.32) =($ 35.55).

Step 7. To calculate the LUPA payment for RNHCI nurse visits to one beneficiary in a 30-day period, multiple the product of Step 6 ($ 35.55) by the number of visits (12) =($ 426.60).

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IV. Other Issues

A. Provisions Related to Therapy Services

1. Outpatient Therapy Services Performed ''Incident To'' Physicians' Services

Section 1862(a)(20) of the Act permits payment for therapy services furnished incident to a physician's professional services only if the practitioner meets the standards and conditions that would apply to the therapy services if they were furnished by a therapist, with the exception of any licensing requirement. We proposed to amend the regulations at § 410.26, § 410.59, § 410.60, and § 410.62 to reflect the statutory prohibition on payment for ''therapy'' services of individuals who do not meet the existing qualification and training standards for therapists (with the exception of licensure) as these standards are set out in § 484.4.

As discussed in the August 5, 2004 proposed rule, section 1862(a)(20) of the Act refers only to PT, OT, and SLP services and not to any other type of therapy or service. This section applies to covered services of the type described in sections 1861(p), 1861(g) and 1861(ll) of the Act; it does not, for example, apply to therapy provided by qualified clinical psychologists. This section also does not apply to services that are not covered either as therapy or as E/M services provided incident to a physician or NPP, such as recreational therapy, relaxation therapy, athletic training, exercise physiology, kinesiology, or massage therapy services.

In the following discussion, the phrase ''therapy services'' means only PT, OT, and SLP. Also, ''therapist'' means only a physical therapist, occupational therapist, and speech-language pathologist.

Section 1861(s)(2)(K) of the Act permits certain NPPs, specifically PAs, NPs, and CNSs, to function as physicians for the purposes of furnishing therapy services which they are legally authorized to perform by the State in which the services are performed. Therefore, in our responses to comments in the following discussion, the statements concerning therapy services that apply to physicians also apply to PAs, NPs, and CNSs.

We received many comments on this proposal from professionals and associations for audiologists, speech-language pathologists, physical therapists, occupational therapists, long term care facilities, kinesiotherapists, massage therapists, athletic trainers, nurses, and physicians such as physiatrists, neurologists, podiatrists, chiropractors, osteopaths, medical groups, and family practitioners.

The proposal describes covered Medicare services and is not intended to affect the policies of other insurers who may cover services that Medicare does not, for example, therapy services performed by massage therapists or athletic trainers.

Comment: Several associations believe that this proposal is based on an incorrect interpretation of the intent of section 1862(a)(20) of the Act. Some claim that the proposed clarification is prohibited by the statute. They note the lack of any elaboration upon the Congress' intent in the Conference Report accompanying section 4541(b) of the BBA, but suggest the provision was based on a 1994 OIG report, ''Physical Therapy in Physicians' Offices'' (OEI–02–90–00590, March 1994). In the view of some commenters, the intended effect of section 1862(a)(20) of the Act was to apply to incident to therapy services the standards and conditions related to treatment plans, the need for goals, and the requirement that therapy is to be restorative. This position is based on the fact that these standards were the focus of the 1994 OIG report. The commenters point out that the report did not compare therapist services to services furnished by nontherapists in a physician's office, but it only compared the services billed by therapists to those billed by physicians.

Commenters argued that the plain meaning of section 1862(a)(20) of the Act indicates that incident to services are not necessarily furnished by therapists. They point to the parenthetical exclusion of licensure requirements in the statutory language as evidence that the Congress did not intend to apply the personnel requirements applicable to therapists in private practice to incident to therapy services. Some commenters believe this exclusion was intended to preserve the right of physicians to supervise auxiliary personnel that were not licensed as therapists. They suggest that we are creating a de facto licensure requirement.

Comments from the two members of the Congress who introduced the act that resulted in section 1862(a)(20) of the Act support the proposed rule, stating that the proposed clarification meets the intent of the law when it was passed by the Congress in 1997. These commenters confirm that the legislation was based in part on the 1994 OIG report and the intent was to establish ''a consistent standard for the delivery for PT services to ensure quality patient care.'' Two additional comments were received from the Congress in support of the proposal.

Response: Our interpretation is based on the plain language of the law: no payment may be made for incident to therapy services ''that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) * * * ''

The second sentence of section 1861(p) of the Act reads as follows:

''The term 'outpatient physical therapy services' also includes PT services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary.''

It is evident then, that the standards and conditions referenced in section 1862(a)(20) of the Act encompass qualifications of the individual providing the therapy. Consequently, we disagree with those commenters who suggest that it was not the intent of section 1862(a)(20) of the Act to apply the personnel qualifications of the second sentence of section 1861(p) of the Act to therapy provided incident to a physician's service. We believe our interpretation of the law is further supported by the comment received from the Congress members who sponsored the original bill that became section 1862(a)(20) of the Act.

According to the proposed requirements, a person who is trained in therapy, but has not completed the further requirements of therapy licensure, may provide services incident to a physician's services. These individuals are not therapists, since they are not licensed, but they are qualified personnel who may, under direct supervision, provide therapy services incident to a physician.

A physician may utilize supervised unlicensed staff and may bill for a covered therapy service incident to the physician's service if it is provided according to Medicare policies, including coverage and incident to policies.

Comment: Commenters also note that qualifications at § 484.4 are in the home health agency section of the regulations, while the second sentence of section 1861(p) of the Act (referenced by section 1862(a)(20) of the Act) does not apply to therapy provided in home health agencies.

Response: The statute specifies therapy services provided incident to a physician must meet the standards and conditions that would apply to a therapist, except licensure. For the history of the qualifications for the private practice setting, please see the discussion in this rule as described below in section IV.A.2, ''Qualification Standards and Supervision Requirements in Therapy Private Practice Settings.'' We proposed to apply to all settings the qualifications in § 484.4 because they are standards that currently apply to therapists in provider settings. It is our intent to make therapist qualifications consistent in all settings (unless otherwise required by statute). Therefore, unless a person meets the standards in § 484.4, except licensure, their services may not be billed as therapy services incident to a physician's service, regardless of any other training, other licensure or certification or other experience they may have. For example, the services of chiropractors or athletic trainers who do not meet the requirements in § 484.4 except licensure, cannot be billed as therapy services incident to a physician's service.

Comment: Several associations indicated that we are changing our interpretation of the statute. They assumed any instruction relevant to the law was made in 1998 through Transmittal 1606. That transmittal provided guidance for therapy services, but did not address the qualification of the people who furnish therapy incident to physician services. It was also suggested that we delay implementation to allow further study and comment from interested parties. The AMA urged us to withdraw proposed changes and reissue a later proposal after consulting with all affected physician and other health professional organizations.

Also, the commenters note that the Administrative Procedure Act (APA) requires that we characterize this as a change rather than a clarification.

Response: In the past, we did not discuss the plain language of the law ecause we did not believe it needed extensive clarification. However, it has become clear to us that contractors have varied in their policies.

Some contractors created local policies that paid only for services provided by licensed therapists in all settings including incident to a physician's service. Others had no policies that assured the qualifications of personnel furnishing services billed as therapy services incident to a physician.

Study of the utilization of therapy services, internal discussions with contractors and medical review of claims for the purpose of error rate analysis all suggested that the services being performed in the offices of physicians did not consistently meet the standards and conditions we applied to therapy services in private practice or in provider settings. Problems associated with an imprecise definition of therapy services were discussed at length in Section 4.1 of the ''Study and Report on Outpatient Therapy Utilization'' (the DynCorp utilization study) found at *http://www.cms.hhs.gov/medlearn/therapy.* Review of medical records following this report reinforced the personnel qualification problem.

In Pub. 100–04, the Medicare Claims Processing Manual at chapter 5, section 20, there is a list of codes that represent services that are always therapy services (available online at *http://www.cms.hhs.gov/manuals/104_claims/clm104c05.pdf).* Whenever these codes are billed, they must have a modifier that identifies the type of therapy (PT, OT, or SLP) and the services provided must meet the standards and conditions that apply to outpatient therapy services. In the medical review of therapy claims, there were frequent observations of ''always therapy'' services performed by persons other than therapists, which were billed inappropriately as therapy.

Since the qualifications of therapists and therapy services continued to be problematic, we chose to raise the subject of therapist qualifications last year. Last year's comments made it clear that there is widespread use of nontherapists, particularly athletic trainers, in the offices of physicians and those services are being billed as therapy services. The volume of similar comments this year made it evident to us that the clarification was needed.

We characterize this statement as a clarification because it merely restates the law. Moreover, we announced our clarification in the proposed rule, and it has been subject to comment in last year's proposed rule and again this year. So, assuming that it did change policy, its promulgation meets the requirements of the APA.

In addition, we note that we continue to pay only for covered services whether they are therapy or other services. Coverage rules in the Program Integrity Manual, chapter 13.5.1, require, for example, that the service be safe, effective, in accordance with accepted standards of medical practice, and furnished by qualified personnel.

We recognize there has been inconsistent application of this statutory requirement. Therefore, in order to allow sufficient time for physicians to adjust their practices, and to avoid disrupting ongoing therapy in affected practices, we will delay implementation

until manual instructions are published. We anticipate publication of manual instructions on or after March 1, 2005.

Comment: Many commenters offered the opinion that restricting payment for therapy services to those performed by therapists would reduce access and quality of care and increase costs. They noted that it is more convenient for therapy to be available in a physician's office than at another site. Also, there was concern that therapists may not work in rural areas, especially because there is a shortage of qualified therapists.

Response: The statute requires that those who provide therapy services meet therapy standards. It provides an exception for licensure in an incident to setting, but it does not provide an exception for rural areas. Since recent changes allow physical and occupational therapists that are enrolled in Medicare to work for physicians, there is no legal impediment to physicians being able to provide therapy services in their offices without the use of nontherapists. The Department of Labor Bulletin 2572, titled ''Occupational Projections and Training Data 2004–05 Edition'', suggests no shortage of therapists.

Nor do we find evidence to suggest the quality of care will be decreased by the use of personnel trained in therapy services as opposed to those trained in other disciplines. The cost of therapy services to Medicare will not be changed by the use of appropriately trained personnel.

Comment: Many comments from physical therapists and PT associations agreed in principle with consistently defining the qualifications for therapists in all settings. They point out that, although the statute allows unlicensed people to provide therapy services incident to the services of a physician, the purpose of licensure is to assure that services are safely and effectively furnished by professionals who have demonstrated the necessary knowledge and skills. The statute permits the use of therapists who have not met licensing requirements and those whose licenses were revoked due to malpractice or fraud. The supervision requirement that the physician be present somewhere in the suite, but not in line of sight, is insufficient to assure the safety and quality of service provided by unlicensed staff.

Response: Although the law permits unlicensed individuals to provide services incident to the services of a physician, we believe physicians will be motivated to screen employees to weed out sanctioned or incompetent people who have training in therapy since physicians would be liable for the actions of an incompetent employee. We require direct supervision of the employee by the physician as a minimum standard, but a physician will provide whatever guidance and supervision is required to assure the safety, effectiveness and quality of the service.

Comment: Many comments were received from individuals such as athletic trainers, kinesiotherapists, massage therapists and chiropractors describing their training as equal or superior to therapists' and suggesting that they provide care similar to therapists.

Response: The statute allows Medicare to pay only for PT, OT and SLP services. Comments from therapists and nontherapists agreed that their training and licensure is unique to their professions, and they are separately trained and licensed for those unique professions. It is clear that many nontherapist health care practitioners are well-trained professionals dedicated to the provision of quality treatment for their patients. However, their training is not in PT, OT, or SLP, but in the other disciplines for which they are licensed or accredited.

Comment: A number of physicians and associations for physicians wrote to tell us that they believe it is their right and within their authority to decide who can provide effective therapy services in their offices.

Response: The statute requires Medicare to pay only for services that meet the standards and conditions, except licensure, that apply to therapists. It is the right and responsibility of a physician to recommend services for patients that in the physician's judgment are needed and effective. Medicare, however, need not pay for all services that a physician recommends. We are required to pay for services that are covered in the statute and to deny payment for services that are not covered, even if the physician considers those services necessary and effective.

Comment: Some physicians wrote to tell us they are currently billing Medicare for therapy services when athletic trainers perform services in their offices. Several commenters asked what services may be billed to Medicare when provided by auxiliary staff who are qualified as athletic trainers, or who have certification in fields other than therapy.

Response: While some carriers may have paid claims for incident to therapy services furnished by individuals without therapy training, we have never had a policy that permits athletic trainers or any other staff who do not have training in PT to provide services that are billed as PT services. Carrier payment for a service is not conclusive evidence that the service was appropriately rendered. Billing with a code that does not accurately represent the service provided is inappropriate. If identified by carrier medical review, these claims must be denied, and further development of the claim may be indicated to determine if there was intent to bill improperly.

Medicare defines PT, OT and SLP as services that require the skills of a physical therapist, occupational therapist or speech-language pathologist. Therapy codes are priced based on the salaries and expenses of therapists and we expect that therapy claims are made for services of therapists (or, for incident to services by someone with their training, except for licensure).

When a service is not a covered service, it is inappropriate to bill Medicare for that service as a service incident to a physician, or as an E/M service. For example, if a service is appropriately described as acupuncture or athletic training or massage therapy, Medicare will not pay for that service because it is not covered.

A physician may not bill Medicare for a service that is on the list of ''always therapy'' services (see Pub. 100–04, the Medicare Benefit Policy Manual, chapter 5, section 20) if the service was done by staff that is not qualified to provide a skilled therapy service, because that is not a covered therapy service. The ''always therapy'' codes always require a modifier to describe whether the service was PT, OT or SLP.

There are covered services that other staff, such as athletic trainers, may perform with other training, however, these are not therapy services. Other codes on the therapy list are ''sometimes therapy'' services and require modifiers only when they are therapy services rather than physician services. For example, a physician may apply a surface neurostimulator (CPT 64550) as an isolated service, outside of a therapy plan of care and appropriately bill the code without a therapy modifier. That service is not a therapy service. If that physician supervises auxiliary personnel in the provision of that same nontherapy service, the auxiliary personnel does not have to be qualified as a therapist because the service rendered is not therapy. In any case, when Medicare is billed for a service, the person providing the service must be qualified to provide the service, as determined by the contractor in accordance with coverage requirements

in Pub. 100–08, the Medicare Program Integrity Manual, chapter 13.5.1. However, if a therapist provides the service under any circumstance, or if either the physician or qualified personnel provides the service as part of a therapy plan of care, it is a therapy service and it requires a modifier. In cases where there is doubt, the contractor will determine whether the service is therapy or is not therapy.

Further information about services that may be completed by non-therapists will be available in implementing instructions.

Comment: The American Chiropractic Association commented that doctors of chiropractory are authorized to perform PT services in all but two States, Michigan and Washington. They request that we note that fact in our commentary and in the regulation. They note that Doctors of Chiropractic are included in the definition of ''physician'' and they propose language in addition to that in § 484.4 to define the qualifications of chiropractors, in order to recognize the State-authorized practice privileges of Doctors of Chiropractic.

Response: Chiropractors may bill services to Medicare as physicians, but only for the purposes of providing manipulation of the spine for the correction of a subluxation, which is a chiropractor service, and not a therapy service. For these manipulation services, chiropractors may directly *supervise* employees who provide incident to services. However, as Medicare physicians, chiropractors are not authorized to *order* therapy services or to perform any other services. To qualify to provide therapy services incident to a physician, chiropractors must meet all of the criteria set forth at § 484.4 except licensure.

Comment: Several associations and some individuals commented that we are creating a monopoly for therapists to provide therapy services and unnecessarily restricting other professions from providing therapy services.

Response: We are bound by the statutory authority given to us in section 1832 of the Act to pay only for services for which there are benefits enumerated in the statute. PT, OT and SLP have benefits in section 1861 of the Act. Therefore, Medicare pays only for those services.

Comment: Several commenters noted that some NPPs, specifically PAs, NPs, and CNSs, may perform therapy services billable under Medicare as therapy services if their State scope of practice allows. The commenters question whether those NPPs may also perform therapy services incident to a physician or NPP.

Response: Medicare does not impose therapy training requirements on physicians whose State scope of practice allows them to perform therapy services. Section 1861(s)(2)(K) of the Act permits PAs, NPs, and CNSs, to furnish services which would be physicians' services, that is, to function as physicians for purposes of furnishing services, including therapy services, which they are legally authorized to perform by the State in which the services are performed. Therefore, this final rule has been modified to reflect that in States that authorize physicians, PAs, NPs, and CNSs to provide one or more of the therapy services (PT, OT, or SLP services), those NPPs may provide the services incident to the services of a physician or NPP under the same conditions as physicians, that is, without meeting the training requirements applicable to therapists.

Results of Evaluation of Comments

To the extent that this policy is different from current manual text, we proposed this rule and received comments. We are finalizing the proposal in this final rule with the changes noted above in accordance with the APA. We will implement this regulation through manual guidance on or after March 1, 2005.

2. Qualification Standards and Supervision Requirements in Therapy Private Practice Settings

Sections 1861(g) and (p) of the Act include services furnished to individuals by physical and occupational therapists meeting licensing and other standards prescribed by the Secretary if the services meet the necessary conditions for health and safety. These services include those furnished in the therapist's office or the individual's home. By regulation, we have defined therapists under this provision as physical or occupational therapists in private practice (PTPPs and OTPPs).

Under Medicare Part B, outpatient therapy services, including physical and occupational therapy services, are generally covered when reasonable and necessary and when provided by physical and occupational therapists meeting the qualifications set forth at § 484.4. Services provided by qualified therapy assistants, including physical therapist assistants (PTAs) and occupational therapy assistants (OTAs), may also be covered by Medicare when furnished under the level of supervision by the therapist that is required for the setting in which the services are provided (institutions and private practice therapist offices). For PTPPs and OTPPs, the regulations now specify only that the PT or OT meet State licensure or certification standards; the regulations and do not currently refer to the professional qualification requirements at § 484.4.

Since 1999, when therapy services are provided by PTAs and OTAs in the private practice of a PT or OT, the services must be personally supervised by the PTPP or OTPP. In response to a requirement to report to the Congress on State standards for supervision of PTAs, we contracted with the Urban Institute. The Urban Institute found that no State has the strict, full-time personal supervision requirement, for any setting, that Medicare places on PTAs in PTPPs. (The report examined only PTAs, who are more heavily regulated by the States than OTAs).

To provide a consistent therapy assistant supervision policy, we proposed to revise the regulations at § 410.59 and § 410.60 to require direct supervision of PTAs and OTAs when PTs or OTs provide therapy services in private practice. We also specifically solicited comments regarding the proposed PTA supervision policy, and whether or not it would have implications for the quality of services provided, or for Medicare spending, either through increased capacity to provide these services, or, in the event that the Congress again extends the moratorium on the implementation of the limits on Medicare reimbursement for therapy services imposed by the BBA of 1997.

In addition, as discussed in the August 5, 2004 proposed rule, the current OTPP or PTPP regulations at § 410.59(c) and § 410.60(c) do not reference qualification requirements for therapy assistants or other staff working for PTs and OTs in private practices. In order to create consistent requirements for therapists and for therapy assistants, we proposed to restore the qualifications by adding the cross-reference to the qualifications at § 484.4 for privately practicing therapists and their therapy assistants at § 410.59 and § 410.60.

Comment: Commenters representing therapy organizations, as well as individual providers, were supportive of our proposal to revise the regulations at § 410.59 and § 410.60 to require direct, rather than personal, supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice.

(We use the 3 supervision levels defined at § 410.32, personal, direct, and

general, to describe the supervision requirements for various Medicare services and settings.)

Many commenters also stated that this is consistent with the Medicare requirements in other provider settings, such as hospitals, HHAs and rehabilitation agencies and is also consistent with the Medicare requirements for therapists in private practice that were in place prior to 1999. Commenters also believe that this will assist in ensuring access to therapy services and in protecting patient privacy.

Response: Requiring direct supervision of therapy assistants in PT and OT private practice settings is consistent with the supervision requirements that PTs and OTs in independent practice were required to meet, prior to 1999, at § 410.59(c) and § 410.60(c). This direct supervision requirement in PT and OT private practices requiring the therapist to be on site or ''in the office suite'' differs from our therapy assistant supervision requirements in institutional settings (for example, outpatient hospital departments, HHAs, and rehabilitation agencies). In those settings, PTs and OTs may provide general supervision of therapy assistants without being on-site.

We agree that changing the level of supervision of therapy assistants from personal to direct will help to improve access to medically necessary services.

Comment: A few commenters stated they believe permitting general supervision, rather than direct, is more consistent with State therapy supervision requirements. While State requirements vary, this variation may be due to the fact that PTAs are not licensed in some States. Other commenters stated that therapy assistants are qualified to provide services without having therapists in-the-room to provide personal supervision.

Response: A review of State practice acts revealed that Medicare's personal in-the-room supervision requirement for therapy assistants in PT and OT private practices was more stringent than any State supervision requirement for any setting. The Urban Institute report also found that most States permit a supervision level similar to our general supervision requirement for institutional settings. However, we believe that services delivered by therapy assistants in private practices require a higher level of therapist supervision than those provided in institutional settings where stringent standards for Medicare participation are enforced through State survey and certification programs, rather than the simplified carrier enrollment process for the PT or OT private practice offices.

Comment: One commenter stated that only licensed therapists should be allowed to provide and bill for therapy and another commenter demanded that therapy services only be reimbursed when provided by a therapist, not any other professional, including nurses, PAs, or chiropractors, and not by therapy assistants. They suggested that without this requirement there would be program abuses.

Response: We concur with the therapy associations and the overwhelming majority of commenters that therapy assistants are qualified by their training and education to provide services without the personal in-the-room supervision in the private practice setting. This does not mean, however, that therapy assistants may bill for the services they provide. Under the law, only PTs and OTs in private practice may bill Medicare for the therapy services provided by PTAs and OTAs. These therapists enroll in the Medicare program and receive a provider identification number (PIN) in order to file claims for the therapy services provided as a PTPP or OTPP. Institutional therapy providers bill Medicare on behalf of the PTs, OTs, and speech language pathologists who provide therapy services in these settings.

Other professionals, including nurses, athletic trainers, and chiropractors do not meet the statutory requirements for therapists in section 1861(p) of the Act and as implemented at § 484.4. We proposed to amend the regulations at § 410.59 and § 410.60 to specify that only individuals meeting the qualification standards and training consistent with § 484.4 may bill and receive Medicare payment for therapy services. In addition, a State license or certification in PT or OT will continue to be required for therapist providing services as PTPPs or OTPPs.

When PAs, NPs, or CNSs are authorized by their State practice acts to provide physical or occupational therapy services, and these NPPs are acting within their capacity to provide physician services under section 1861(s)(2)(K) of the Act, their services are considered therapy services.

Comment: One commenter stated that allowing lesser trained individuals such as therapist assistants to provide services if a therapist supervises, but prohibiting physicians from delegating performance of these services to doctors of chiropractic inappropriately gives therapists more authority than physicians.

Response: Medicare law recognizes chiropractors as physicians, but only for the limited purpose of providing manipulation of the spine for the correction of a subluxation. In order to qualify as a PT or OT for Medicare purposes, chiropractors would need to meet all of the criteria set forth at § 484.4.

Comment: In response to our request for information on the impact of this proposed change on the quality of services and Medicare spending, several individuals stated that the proposed change would not affect the way therapists practice, since they are fully accountable for services provided under their direction and, therefore, the change would not diminish the quality of services. Furthermore, commenters believe the change would also allow the appropriate and efficient utilization of therapist assistants because the in-the-room supervision unnecessarily drives up the cost of health care without providing additional consumer protection.

The American Physical Therapy Association (APTA) anticipates there will be little, if any, increase in spending as a result of this policy and believes that any increases would be due to improving access to medically necessary outpatient therapy services provided by qualified practitioners. For spending implications, the APTA believes it is highly unlikely that physical therapists would significantly alter their staffing patterns and thereby increase spending as a result of this change in policy. The majority of States have laws that establish limits on the number of PTAs that a PT can supervise (referred to as ''supervision ratios''). For example, a large number of States have a supervision ratio of one PT to two PTAs. There are also a limited number of PTAs whom PTs could supervise, and APTA does not anticipate substantial growth in the number of PTAs in the foreseeable future. To the contrary, the number of PTA education programs is declining.

Furthermore, services of PTs in private practice comprise a relatively small percentage of services billed under the Medicare program. Therefore, the overall financial impact of any change in the supervision requirement in this setting would be minimal.

Response: We appreciate the information provided by the commenters. Other opportunities already exist for therapists to provide services under Medicare in rehabilitation agencies and CORFs where the therapy assistant supervision level is general. Therapists opting to utilize therapy assistants might be more

likely to own a rehabilitation facility where the physical or occupational therapy assistant supervision level is general, rather than a private practice office where the therapist is required to be on-site to supervise services of the therapy assistant. The Urban Institute Report confirmed the limited number of therapy assistants available to be hired and found that workforce and distribution percentages of PTs and PTAs parallel each other, with nearly 25 percent of PTAs employed by PTPPs. We believe that the State supervision requirements and the limited number of PTAs are likely to limit the financial implications of this change. We plan to monitor this area to determine whether volume changes occur and, if so, in what settings they occur.

Comment: Commenters supported our proposal to revise § 410.59 and § 410.60 to cross-reference the qualifications at § 484.4 for privately practicing therapists and their therapy assistants.

Response: We appreciate the numerous letters of support for this proposal, including the national and State-level therapy organizations, other professional organizations, and many therapists and therapy assistants.

Result of Evaluation of Comments

We will finalize the proposed revisions to § 410.59 and § 410.60 to require direct supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice and also to cross-reference the qualifications at § 484.4 for privately practicing therapists and their therapy assistants.

3. Other Technical Revisions

We proposed technical corrections to § 410.62 to refer consistently to SLP (currently the terms ''speech pathology'' and ''speech-language pathology'' are used interchangeably) and proposed revisions to § 410.62(a)(2)(iii) to appropriately reference § 410.61 (the current reference is to § 410.63).

We also proposed removing subpart D, Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists, from part 486. Our November 1998 rule (63 FR 58868) discussed replacing this subpart with a simplified carrier enrollment process for physical or occupational therapists in private practice; however, the conforming regulatory change to remove subpart D was never made.

In addition, we proposed a technical change at § 484.4 to correct the title ''physical therapy assistant'' to ''physical therapist assistant'' and proposed amending § 410.59(e) and § 410.60(e) to include a reference to the 2-year moratorium on the therapy caps established by section 624 of the MMA.

Comment: Commenters representing therapy specialty organizations supported these changes.

Response: We will finalize these changes as proposed.

Result of Evaluation of Comments

We are finalizing the changes as proposed.

B. Low Osmolar Contrast Media

High osmolar and low osmolar contrast media (LOCM) are used to enhance the images produced by various types of diagnostic radiological procedures. When the Medicare physician fee schedule was established, findings of studies of patients receiving both types of contrast media had been published, and the ACR had adopted criteria for the use of LOCM. At that time, we determined that the older, less expensive high osmolar contrast media (HOCM) could be used safely in a large percentage of the Medicare population. However, we also decided that separate payment for LOCM may be made for patients with certain medical characteristics. We adopted the ACR criteria, with some modification, as the basis for a policy that separate payments are made for the use of LOCM in radiological procedures for patients meeting certain criteria. These criteria were established at § 414.38. Under these conditions, we pay for LOCM, utilizing HCPCS codes A4644 through A4646.

In the August 5, 2004 rule, we proposed to revise the regulations at § 414.38 to eliminate the restrictive criteria for the payment of LOCM. This proposal would make Medicare payment for LOCM consistent across settings since, under the OPPS, there is no longer a payment difference between LOCM and other contrast materials.

We also proposed that, effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent in accordance with the standard methodology for drug pricing established by the MMA. However, because the technical portions of radiology services are currently valued in the nonphysician work pool and the CPEP inputs for these services are not used in calculating payment, we also indicated we would continue to reduce payment for LOCM by eight percent to avoid any duplicate payment for contrast media.

Comment: Commenters representing radiology, interventional radiology, and imaging contrast manufacturers were supportive of this proposed change; however, our payment methodology of ASP plus six percent minus eight percent was questioned. Two commenters also believe that the implementation date for the application of ASP methodology should be changed from January 1, 2005. One requested an effective date of April 1, 2005 and the other requested an effective date of January 1, 2006.

Response: We appreciate the commenters' support for this change. We stated in the proposed rule that effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent. However, there is an October 30, 2004 deadline for submission of the ASP data used for the January 1, 2005 payment, and this date occurred prior to our finalizing the proposed payment methodology for LOCM. Therefore, the ASP payment methodology for LOCM will be made effective April 1, 2005. Manufacturers of LOCM will be required to submit their fourth quarter 2004 (4Q04) ASP information to us on or before January 30, 2005. Subsequent data must be submitted within 30 days after the end of each calendar quarter. The 4Q04 data will be used to determine the April 1, 2005 ASP plus six percent payment limits. Further information on the specific format of the data submission and the address to which the information can be sent is found on the CMS ASP Web site, specifically at *http://www.cms.hhs.gov/providers/drugs/asp.asp.*

Our policy to reduce payment for LOCM by 8 percent stems from the fact that the technical component RVUs for these procedures took into account the use of (and expenses for) HOCM in the (see the November 25, 1991 final rule (56 FR 59502)). However, since that time, the price differential between HOCM and LOCM has declined. In addition, upon further review, we are not able to determine accurately the degree of duplicate payment that might occur when both the imaging procedure and LOCM are billed. Therefore, we are not applying the eight percent reduction to the LOCM payment as proposed. The payment for LOCM will be consistent with the payment rate for the majority of drugs administered by physicians.

Comment: One contrast agent industry association suggested that we issue additional codes for the reporting of contrast media.

Response: For 2005, we are continuing to use the current three HCPCS codes in the reporting of low osmolar contrast agents. However, we are exploring the possibility of additional codes to accurately capture the cost differences among all contrast agents as well as the differing clinical

uses, concentration, and dose administrations. We welcome input from the medical community and the manufacturers of contrast media on this issue.

Comment: A commenter suggested that we use a model to capture volume and concentration variances of LOCM. In this model, ASP would be calculated as ASP = Total Sales/Total Volume.

Response: This suggested methodology does not take into account the weighted average for each national drug code (NDC) within a HCPCS code that must be used to derive an appropriate ASP code price.

Result of Evaluation of Comments

We are revising the regulations at § 414.38 to eliminate the criteria for the payment of LOCM. In addition, effective April 1, 2005, payment for LOCM will be made on the basis of the ASP plus six percent.

C. Payments for Physicians and Practitioners Managing Patients on Dialysis

1. ESRD-Related Services Provided to Patients in Observation Settings

In response to comments received on billing procedures for physicians and practitioners managing patients on dialysis when the dialysis patient is hospitalized during the month, we stated in the November 7, 2003 **Federal Register** (68 FR 63220) that ESRD-related visits furnished to patients in observation status would not be counted as visits under the MCP but would be paid separately. Prior to this, long-standing Medicare policy had included ESRD-related visits furnished in the observation setting within the MCP. However, upon further review of this issue, in the proposed rule published August 5, 2004, we proposed a revision to this policy and stated that ESRD-related visits provided to patients by the MCP physician in an observation setting would be counted as visits for purposes of billing the MCP codes.

Comment: Several commenters expressed support for allowing ESRD-related visits provided to patients by the MCP physician in the observation setting to be counted for purposes of billing the MCP codes. However, Kidney Care Partners (KCP) and the Renal Physicians Association (RPA) requested clarification as to how a physician or practitioner who is not part of the MCP practice team should bill for visits furnished in the hospital observation setting. The RPA suggested that a hemodialysis procedure with single physician evaluation as described by CPT code 90935 be used.

Response: Physicians or practitioners who are not part of the MCP practice team but who furnish a visit to an ESRD beneficiary in the observation setting can bill the appropriate observation codes that accurately describe the service (CPT codes 99217 through 99220). A hemodialysis procedure with single physician visit as described by CPT code 90935 will only be used when the beneficiary is an inpatient or for outpatient dialysis services for a non-ESRD patient.

2. Payment for Outpatient ESRD-Related Services for Partial Month Scenarios

Since changing our payments for physicians and practitioners managing patients on dialysis, we have received a number of comments from the nephrology community requesting guidance on billing for outpatient ESRD-related services provided to transient patients and in partial month scenarios (for example, when the patient is hospitalized during the month or receives a kidney transplant). To address this issue, we proposed to change the description of the G codes for ESRD-related home dialysis services, less than full month, as identified by G0324 through G0327. The new descriptor would include other partial month scenarios, in addition to patients dialyzing at home. The proposed descriptors for G0324 through G0327 are as follows:

- G0324, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients under two years of age;
- G0325, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between two and eleven years of age;
- G0326, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day, for patients between twelve and nineteen years of age.
- G0327, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day, for patients twenty years of age and over.

In the August 5, 2004 proposed rule, we stated that these G codes would provide a consistent way to bill for outpatient ESRD-related services provided under the following circumstances:

- Transient patients—Patients traveling away from home (less than full month);
- Home Dialysis Patients (less than full month);
- Partial month where there were one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had received a kidney transplant.

However, we noted that this proposed change to the descriptions of G0324 through G0327 was intended to accommodate unusual circumstances when the outpatient ESRD-related services would not be paid for under the MCP and that use of the codes would be limited to the circumstances listed above. Physicians who have an on-going formal agreement with the MCP physician to provide cursory visits during the month (for example ''rounding physicians'') could not use the per diem codes.

Clarification on Billing for Transient Patients

In the August 5, 2004 proposed rule, we stated that, for transient patients who are away from their home dialysis site and at another site for fewer than 30 consecutive days, the revised per diem G codes (G0324 through G0327) would be billed by the physician or practitioner responsible for the transient patient's ESRD-related care. Only the physician or practitioner responsible for the traveling ESRD patient's care would be permitted to bill for ESRD-related services using the per diem G codes (G0324 through G0327).

If the transient patient is under the care of a physician or practitioner other than his or her regular MCP physician for a complete month, the physician or practitioner responsible for the transient patient's ESRD-related care would not be able to bill using the per diem codes. We also solicited comments on when a patient will be considered transient.

Comment: Several commenters, including the ASN, KCP, and the RPA, supported our proposed change to the description of HCPCS codes G0324–G0327 (per diem codes). The KCP believed that this change would provide a consistent billing method when the patient is transient, furnished home dialysis (less than full month), and for other partial month scenarios when the patient is hospitalized, has a transplant or when the patient expires. Additionally, several commenters praised us for our willingness to work with the renal community to address the multitude of issues surrounding the way physicians and practitioners are paid for managing patients on dialysis.

However, the RPA and KCP suggested that, in addition to the situations described in the proposed rule, the per diem codes as described by G0324 through G0327 should be used to bill whenever one or more visits occurred

during the month regardless of whether the complete monthly assessment was furnished.

Response: As explained in the proposed rule, we believe the per diem codes will only be used for unusual circumstances where the ongoing management of an ESRD patient would not be paid through the MCP. As discussed earlier, we proposed to allow the per diem codes only in specific circumstances. However, after further review of this issue, we believe that it would also be appropriate to use the per diem codes when the beneficiary's MCP practitioner changes permanently during the month. For example, the ESRD beneficiary moves from one State to another and a new MCP physician or practitioner has the ongoing responsibility for the E/M of the patient's ESRD-related care who is not part of the same group practice as an employee of the previous MCP physician. We addressed this issue in a recent instruction published on September 17, 2004 (CR 3414 ''Payment for Outpatient ESRD-Related Services'', Transmittal 300). For more information on this instruction please visit our Web site at *http://www.cms.hhs.gov/manuals/* and select 2004 transmittals under the program transmittals link.

However, we will not permit the use of per diem codes (HCPCS codes G0324 through G0327) for all instances when the MCP physician or practitioner furnishes at least one visit during the month without regard to the status of a complete monthly assessment of the patient. We are concerned that permitting the per diem codes to be used in this manner may undermine the MCP. For example, the ESRD MCP includes various physician and practitioner services such as the establishment of a dialyzing cycle, outpatient E/M of the dialysis visit(s), telephone calls, patient management as well as clinically appropriate physician or practitioner visit(s) during the month. At least one of the visits must include a clinical examination of the vascular access site furnished face-to-face by a physician, CNS, NP or PA. When a practitioner bills for the MCP, the medical record must document that all of these services are furnished. By using the per diem codes in the manner suggested by the commenter, it would not be necessary for the practitioner to provide a complete monthly assessment of the ESRD beneficiary to receive payment for the ongoing management of patients on dialysis.

Comment: With regard to the ESRD-related services for home dialysis patients, less than full month, one healthcare corporation believes that the proposed coding changes continue to penalize nephrologists for prescribing home therapy because a per diem (pro-rated) payment is made when a hospitalization occurs. The commenter believes that this policy results in an inequity as compared to a physician providing 2–3 visits per month for center-based dialysis patients. Additionally, the commenter argues that the pro-rated methodology used for home dialysis patients (partial month) is inconsistent with how we pay the MCP physician for patients undergoing dialysis treatments in a dialysis facility.

The commenter believes that we should increase the payment for ESRD-related services for home dialysis patients to a level that is at least as high as the ESRD-related services (for full month) with 4 or more visits per month. The commenter contends that raising the payment amount for home-based dialysis patients would result in revenue opportunities similar to those available in the center-based scenario and would provide a greater incentive for home dialysis treatment.

Response: We do not agree with the commenter's statement that an inconsistency exists in the way we pay the MCP physician for managing a home dialysis patient (less than full month) and center dialysis patient (less than full month).

Our proposed change to the description of HCPCS codes G0324 through G0327 would apply to dialysis patients who receive dialysis in a dialysis center or other facility during the month as well as to home dialysis patients. For example, if a center dialysis patient is hospitalized during the month, has a transplant, or expires before a complete assessment is furnished (including a face-to-face examination of the vascular access site), the MCP physician would use the per diem rate to bill for ESRD-related care. When either a home dialysis patient or a patient who receives dialysis in a dialysis facility is hospitalized, the MCP physician or practitioner may bill for inpatient hemodialysis visits as appropriate (for example CPT codes 90935 and 90937).

Additionally, we believe the current payment level for physicians managing patients on home dialysis for a full month already provides an incentive for an increased use of home dialysis. For instance, payment for the monthly management of home dialysis patients is made at the same rate as the MCP with 2 to 3 visits. However, a monthly visit is not required as a condition of payment for physicians and practitioners managing home dialysis patients. Essentially, a physician or practitioner managing ESRD patients who receive dialysis in a dialysis facility would be required to furnish 2 to 3 face-to-face visits in order to receive the same level of payment as he or she would have received for managing a home dialysis patient. We do not believe it would be appropriate to pay physicians managing home dialysis patients at the highest MCP amount when no visits are required as a condition of payment.

Definition of a ''Transient Patient''

Comment: The RPA and KCP believe that it would be more appropriate to refer to these patients as ''visiting patients''. The RPA suggested that a ''visiting patient'' be defined as a ''patient receiving dialysis or renal-related care whose care is temporarily supervised (for less than one month's time) by a physician who is not a member of the practice that usually charges under the MCP or G codes''.

Response: We believe the term ''transient patients'' better describes a beneficiary who is away from his or her home dialysis site for less than a full month.

General Comments on Our Changes in Payments for Physicians and Practitioners Managing Patients on Dialysis

Comment: One commenter requested clarification as to how ESRD-related visits furnished to beneficiaries residing in a skilled nursing facility (SNF) adjacent to a hospital should be handled. The commenter explained that his SNF patients with ESRD usually receive dialysis treatments in an independent dialysis facility connected to a hospital's SNF. However, in cases when the patient is ''too ill'' to be transported to the independent dialysis facility, the dialysis treatment occurs in the inpatient dialysis treatment area (but the patient is not admitted to the hospital as an inpatient). The commenter noted that ESRD-related visits may be furnished while the patient is dialyzing or at the SNF when the patient is not dialyzing.

Response: Although we have not issued specific instructions on this issue, we believe that ESRD-related visits furnished to SNF residents are similar to other ongoing management services under the MCP. As such, ESRD-related visits furnished to patients residing in a SNF will be counted for purposes of billing the MCP codes. However, if the beneficiary is admitted to the hospital as an inpatient, the appropriate inpatient visit code will be used, for example, CPT code 90935.

Comment: With regard to our revisions to the MCP (as published in the CY 2004 final rule), the American Association of Kidney Patients (AAKP) questioned if we have any current data on or future plans to study whether access to nephrologists or the quality of medical care for ESRD patients has been improved or impaired. Additionally, AAKP questioned whether we have any plans to develop additional proposals (beyond the telehealth proposal) to address access needs in rural and other underserved areas.

Response: In evaluating the MCP, we will be looking for trends in hospitalization rates and resource utilization for ESRD patients. Moreover, we understand the challenges nephrologists face in visiting all patients on dialysis. To that end, we believe that our policy to allow clinical nurse specialists, nurse practitioners and physician assistants to furnish visits under the MCP, along with our addition of specific ESRD-related services to the list of Medicare telehealth services, will help ameliorate access issues.

Comment: The RPA and the ASN continued to express concerns with the changes made in the CY 2004 final rule to the way physicians are paid for managing patients on dialysis. The RPA strongly believes that many of the underlying principles of the new HCPCS codes for managing ESRD patients need to be changed. The RPA cited the impact on rural providers, the lack of gradation in payment amounts between furnishing 2 and furnishing 3 visits per month, and the premise that more visits will equate to better quality of care as major shortcomings of the new ESRD MCP.

The RPA and ASN emphasized their belief that more physician and practitioner visits per month does not correlate to efforts to improve the quality of care for ESRD patients. RPA contends that a stratified MCP system based on the number of monthly physician and practitioner visits is unnecessarily complicated and believes that the vast majority of nephrologists provided appropriate ESRD-related care under the previous MCP. To that end, the RPA urged us to implement a simpler system based on a minimum number of patient visits and a new documentation requirement for the services provided under the MCP.

Response: We appreciate the commenters' suggestions and will consider these comments as we continue to refine how we pay for physicians and practitioners managing patients on dialysis.

Results of Evaluation of Comments

ESRD-related visits provided to patients by the MCP physician or practitioner in an observation setting will be counted as visits for purposes of billing the MCP codes.

Moreover, we will change the description of the G codes for ESRD-related home dialysis services, less than full month, as identified by G0324 through G0327. The new descriptor will include other partial month scenarios, in addition to patients dialyzing at home. The descriptors for G0324 through G0327 will be as follows:

- G0324: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients under two years of age.
- G0325: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between two and eleven years of age.
- G0326: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between twelve and nineteen years of age.
- G0327: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients twenty years of age and over.

The revised per diem ESRD-related services G codes will be used for outpatient ESRD-related services provided in the following scenarios:

- Transient patients—Patients traveling away from home (less than full month);
- Home dialysis patients (less than full month);
- Partial month where one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had a transplant.
- Patients who have a permanent change in their MCP physician during the month.

D. Technical Revision—§ 411.404

In § 411.404, Medicare noncoverage of all obesity-related services is used as an example. Since we are currently revising this coverage policy, we proposed to omit this example.

Commenters were supportive of this proposed change and we are finalizing it as proposed.

E. Diagnostic Psychological Tests

All diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b)(2)(iii) states an exception to these physician supervision requirements for clinical psychologists and independently practicing psychologists (who are not clinical psychologists) which allows them to personally perform diagnostic psychological testing services without physician supervision. However, diagnostic psychological tests performed by anyone other than a clinical psychologist or an independently practicing psychologist must be provided under the general supervision of a physician as defined in section 1861(r) of the Act. Accordingly, clinical psychologists and independently practicing psychologists have not been permitted to supervise others in the administration of diagnostic psychological tests.

As discussed in the August 5, 2004 proposed rule, we were asked to re-evaluate our regulations regarding clinical psychologists' supervision of diagnostic psychological tests, and additional information concerning provision of these services was also supplied. Based upon our review of this issue, we determined that clinical psychologists possess knowledge sufficient to direct test selection and interpret test data. Therefore, we proposed to change the requirements at § 410.32(b)(2)(iii) to permit clinical psychologists to supervise the performance of diagnostic psychological and neuropsychological testing services.

Comment: Two specialty societies representing psychologists and many individual commenters were in support of the change. One major association representing psychiatrists and a few individual commenters opposed the proposal. According to the association, expanding the supervision requirements will not lessen the burden on physicians and healthcare facilities within rural areas. In addition, this association asked that we provide data showing that the change to the supervision requirements will reduce the burden on physicians and health care facilities, and that access will be improved in rural areas.

Response: We appreciate the positive comments in support of this proposal.

In response to the request for evidence that this change will reduce burden and improve access, we would first note that our primary reason for proposing this change was that we believe clinical psychologists possess the core knowledge to sufficiently supervise the administration of these tests. By enabling them to do so, this change will allow greater flexibility in their practices.

With regard to improved access in rural areas, we noted previously in this rule that we recognize mental health HPSAs for incentive payments for psychiatrists. Accordingly, we believe that the expansion of the supervision requirements will help improve access in these areas.

Result of Evaluation of Comments

As proposed, we are revising § 410.32(b)(2)(iii) to permit clinical psychologists to supervise the performance of diagnostic psychological and neuropsychological testing services.

F. Care Plan Oversight

Care Plan Oversight (CPO) refers to the supervision of patients receiving Medicare-covered home health or hospice services requiring complex multidisciplinary care modalities, including regular development and review of plans of care. In the August 5, 2004 rule, we proposed to revise § 414.39 to clarify that NPPs can perform home health CPO; however, they cannot certify a patient for home health services and sign the plan of care. We also proposed the conditions under which NPP services may be billed for CPO and explained that the proposed conditions are meant to ensure that the NPP has seen and examined the patient and that the appropriate and established relationship exists between the physician who certifies the patient for home health services and the NPP who will provide the home health CPO.

Comment: Several commenters support the proposed revision and conditions of coverage. They support the integrated practice arrangements required by proposed § 414.39(c)(2)(iii). They believe the proposed conditions ensure appropriate, ongoing supervision of both the patient's condition and the NPP.

Response: We appreciate the commenters' support for this proposal.

Comment: We received a comment from an association representing home care physicians requesting that we include PAs in the clarification because PAs increasingly play the same role as NPs in home health care and bill under the same house call codes.

Response: We agree with the commenter that we include PAs in the clarification. The definition of NPPs in proposed § 414.39(a) includes NPs, CNSs, and PAs. However, we also note that PAs cannot bill directly for their own services.

Comment: We received a comment requesting that we clearly state the definition of the appropriate relationship between the physician and the NPP. The commenter requested that we cross-reference applicable State standards because the meaning of collaboration varies across States and some States require employment relationships. Also, the commenter recommended that we require a written agreement regarding the responsibilities for managing care when the NP or PA is not from the same organization as the physician who has certified the skilled home care services.

Response: We agree that State laws or regulations governing collaborative relationships, where applicable, would be useful in this regard. In the absence of State laws or regulations, NPs and CNSs will be required to document their scope of practice and indicate the relationships they have with physicians to handle issues outside their scope of practice. If the NPP is a PA, the physician signing the plan of care also must be the physician who provides general supervision of PA services for the practice.

Comment: We received a comment requesting that this clarification be made retroactive to at least FY 2000 to allow denied claims to be resubmitted. The commenter stated that many claims for CPO services by NPs were denied over the past several years, despite CMS and legislative intent to have these claims reimbursed.

Response: We clarified in the November 1, 2000 final rule (65 FR 65407) that CPO services of NPPs, practicing within the scope of State law applicable to their services, could be paid under Medicare. However, our policy has also been that the physician who bills for CPO must be the same physician who signs the plan of care.

Appeal rights are available for these claims for CPO services provided by NPPs in HHAs if the appeal is requested within 120 days of the date of the claim denial. If appeal rights have expired, the physician or supplier may request a reopening for any reason within 12 months of the date of the notice of initial determination. After the 12-month period, but within 4 years from the date of the initial determination, a reopening may be requested for good cause. The decision on whether to reopen a claim at the request of the physician or supplier is at the discretion of the Medicare contractor.

Comment: We received comments noting that this clarification does not allow NPs, CNSs, or PAs to certify a patient for home health care services or to sign the plan of care. The commenters noted that certification by NPPs is not currently permitted under the statute. One of the commenters recommended that we revise the rules on certification and recertification to allow NPs, CNSs, or PAs to perform them.

Response: The commenters are correct that the statute (sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) requires a physician to certify a patient for home health care services or to sign the plan of care. Therefore, the issue of whether to allow NPs, CNSs, or PAs to certify a patient for home health care services or to sign the plan of care is not within the purview of this rule.

Result of Evaluations of Comments

We are adopting the proposed changes to § 414.39 that clarify that NPPs can provide care plan oversight for beneficiaries who receive home health services.

G. Assignment of Medicare Claims—Payment to the Supplier

The current regulation requires the beneficiary (or the person authorized to request payment on the beneficiary's behalf) to assign a claim to the supplier for an assignment to be effective. However, over time, the Act was amended in various sections to require that Medicare payment for certain services would only be made on an assigned basis regardless of whether or not the beneficiary actually assigns the claim to the supplier. In these instances, the current requirement in § 424.55(a), which specifies that the beneficiary assign the claim to the supplier, is now unnecessary. Therefore, we proposed to create an exception to the general rule in § 424.55(a). New § 424.55(c) would eliminate the requirement that beneficiaries assign claims to suppliers in situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier.

Comment: The ACLA supports the proposal and agrees that this new exception to the requirement for beneficiaries to assign benefits in situations where benefits can, by statute, only be paid on an assigned basis will reduce the paperwork burden on beneficiaries and suppliers.

Response: We agree that the proposed regulation will reduce the paperwork burden on beneficiaries and suppliers and we are finalizing the revisions as proposed.

Result of Evaluation of Comments

We are finalizing § 424.55(c) as proposed.

H. Additional Issues Raised by Commenters

Comment: Two specialty societies representing plastic surgeons and

podiatrists, as well as the RUC, recommended that the global period for CPT 15342, Application of bilaminate skin substitute/neodermis; 25 sq cm, be changed from a 10-day global period to a 0-day global period. The commenters stated that the plastic surgeons generally perform this procedure on more severely injured patients, such as burn patients, who are often seen in the inpatient setting. The podiatrists, on the other hand, typically treat patients with diabetic foot ulcers in the outpatient setting. Therefore, the commenters contend that though the work required to perform the procedure is the same for both specialties, the post-surgical work and time are not and the change in the global period would allow both scenarios to be paid appropriately.

Response: We understand that this code can represent differing scenarios. However, while podiatrists perform approximately 45 percent of the procedures and general surgeons 17 percent, plastic surgeons perform only 7 percent. In addition, only 9 percent are performed in the inpatient hospital setting. Our general approach and the one adopted by the RUC for valuing all services is to base our review on the typical patient. In this case, the podiatric scenario would clearly dominate and applying a 10-day global period to capture the post-procedure office visit appears appropriate. However, we would be willing to discuss this issue further with the specialties involved and with the RUC.

Comment: The American Society of Anesthesiologists (ASA) provided comments asking that we consider revising the current teaching regulations to place teaching anesthesiologists' reimbursements on par with the teaching of resident physicians in surgery and other high-risk specialties. Also, that we redefine the HCPCS claims service modifier ''AA'' to include both the personal administration of the anesthesia by the physician and teaching up to two resident physicians concurrently. In its comments, the ASA stated that it believes we possess the authority under the terms of section 1871 of the Medicare statute to make the requested change in its teaching reimbursement rules, effective January 1, 2005, as follows: the agency can treat the rule as a logical outgrowth of a prior proposal; it can issue a final rule with comment period as part of the 2005 physician payment final rule; or, it can promptly issue a free-standing rule proposing the change and allow for public comment and subsequent effectiveness along with the 2005 physician payment rule. The American Association of Nurse Anesthetists (AANA) asked that, if we review proposed revisions to the teaching anesthesiologist rules, that we carefully consider how these revisions might impact teaching Certified Registered Nurse Anesthetists (CRNAs). The AANA commented that our rules should not favor one type of provider over another.

Response: Surgical services are paid differently than anesthesia services. For example, surgical codes usually have global periods and payment includes the payment for the surgical procedure and postoperative visits during the global period. Anesthesia services include the preanesthesia examination and evaluation, the anesthesia service associated with the surgical service, and immediate postanesthesia care. Currently, the teaching physician's presence during the key or critical period criteria applies to both the services of the teaching surgeon and the teaching anesthesiologist. The key or critical services are different for the service of each specialty.

We plan to explore these issues further prior to deciding whether to include this change in the proposed rule for 2006.

Comment: We received comments from a manufacturer, many providers and individuals requesting that new HCPCS codes be created for a specific laser surgery treatment for benign prostatic hyperplasia. Commenters stated that current CPT codes used for billing this service under the physician fee schedule are not specific to the unique technology involved with this laser surgery treatment and result in underpayment when this technology is used. They noted that under the hospital OPPS, this treatment was assigned to a new technology code.

We also received requests from other individuals for new G codes and payment for other specific services, and for certain HCPCS codes that currently are paid only under OPPS.

Response: We do not believe that it is necessary to create new HCPCS codes for these services. Commenters that believe the existing CPT codes do not reflect their technology or services, may contact the AMA's CPT Editorial Panel to review these matters, particularly since the CPT Editorial Panel has a new coding classification specifically for new and emerging technologies.

There will be situations where codes are used under OPPS but not recognized under the physician fee schedule (PFS) because of the different payment methodologies.

Comment: A specialty society urged us to discontinue use of the HCPCS codes for positron emission tomography (PET) procedures and to instruct physicians to use the available CPT codes. They also urged us to adopt RUC recommendations for new PET codes rather than carrier price these services. The commenter stated they would like to meet to discuss these new codes and PET/computed tomography (CT) technology.

Response: We will continue to use HCPCS codes and carrier price these services at this time. We will be examining the overall issue of Medicare coding, payment, and coverage of PET services and would be happy to meet with the specialty society to discuss this issue.

General Issues

We also received comments on issues and concerns that were beyond the scope of the proposed rule. These include: The need for quality standards for diagnostic imaging; concerns about outreach and access; requests for revisions to current policy; and, concerns about the accuracy of code descriptors. While we will try to ensure these comments are provided to appropriate CMS components, commenters should also feel free to contact the appropriate CMS components about their concerns. To the extent that these comments involved valuation of services under the physician fee schedule, we are also soliciting comments on services for which the physician work may be misvalued. See section VI for additional information on this process.

V. Refinement of Relative Value Units for Calendar Year 2005 and Response to Public Comments on Interim Relative Value Units for 2004

[If you choose to comment on issues in this section, please include the caption ''Interim Work Relative Value Units'' at the beginning of your comments.]

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

Section V.B. and V.C. of this final rule describes the methodology used to review the comments received on the RVUs for physician work and the process used to establish RVUs for new and revised CPT codes. Changes to codes on the physician fee schedule reflected in Addendum B are effective for services furnished beginning January 1, 2005.

B. Process for Establishing Work Relative Value Units for the 2004 Physician Fee Schedule

Our November 7, 2003 final rule (69 FR 1084) contained the work RVUs for Medicare payment for existing

procedure codes under the physician fee schedule and interim RVUs for new and revised codes beginning January 1, 2004. We considered the RVUs for the interim codes to be subject to public comment under the annual refinement process. (Note that the November rule was subsequently revised on January 7, 2004 to reflect revisions to procedure codes required by the MMA.) In this section, we summarize the refinements to the interim work RVUs published in the November 7, 2003 rule and our establishment of the work RVUs for new and revised codes for the 2005 physician fee schedule.

C. Work Relative Value Unit Refinements of Interim Relative Value Units

1. Methodology (Includes Table Titled ''Work Relative Value Unit Refinements of the 2003 Interim and Related Relative Value Units'')

Although the RVUs in the January 2004 final rule were used to calculate 2004 payment amounts, we considered the RVUs for the new or revised codes to be interim. We accepted comments for a period of 60 days. We received substantive comments on approximately 12 CPT codes with interim work RVUs.

To evaluate these comments we used a process similar to the process used since 1997. (See the October 31, 1997 final rule (62 FR 59084) for the discussion of refinement of CPT codes with interim work RVUs.) We convened a multispecialty panel of physicians to assist us in the review of the comments. The comments that we did not submit to panel review are discussed at the end of this section, as well as those that were reviewed by the panel. We invited representatives from the organizations from which we received substantive comments to attend a panel for discussion of the code on which they had commented. The panel was moderated by our medical staff, and consisted of the following voting members:

- One or two clinicians representing the commenting organization.
- One primary care clinician nominated by the American College of Physicians and American Society of Internal Medicine.
- Four carrier medical directors.
- Four clinicians with practices in related specialties who were expected to have knowledge of the service under review.

The panel discussed the work involved in the procedure under review in comparison to the work associated with other services under the physician fee schedule. We assembled a set of 300 reference services and asked the panel members to compare the clinical aspects of the work of the service a commenter believed was incorrectly valued to one or more of the reference services. In compiling the set, we attempted to include: (1) Services that are commonly performed whose work RVUs are not controversial; (2) services that span the entire spectrum from the easiest to the most difficult; and (3) at least three services performed by each of the major specialties so that each specialty would be represented. The intent of the panel process was to capture each participant's independent judgment based on the discussion and his or her clinical experience. Following the discussion, each participant rated the work for the procedure. Ratings were individual and confidential, and there was no attempt to achieve consensus among the panel members.

We then analyzed the ratings based on a presumption that the interim RVUs were correct. To overcome this presumption, the inaccuracy of the interim RVUs had to be apparent to the broad range of physicians participating in each panel.

Ratings of work were analyzed for consistency among the groups represented on each panel. In addition, we used statistical tests to determine whether there was enough agreement among the groups of the panel and whether the agreed-upon RVUs were significantly different from the interim RVUs published in Addendum C of the final rule. We did not modify the RVUs unless there was a clear indication for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group and looked for agreement among the remaining groups as the basis for new RVUs. We used the same methodology in analyzing the ratings that we first used in the refinement process for the 1993 physician fee schedule. The statistical tests were described in detail in the November 25, 1992 final rule (57 FR 55938).

Our decision to convene multispecialty panels of physicians and to apply the statistical tests described above was based on our need to balance the interests of those who commented on the work RVUs against the redistributive effects that would occur in other specialties.

We also received comments on RVUs that were interim for 2004, but for which we did not submit the RVUs to the panel for review for a variety of reasons. These comments and our decisions on those RVUs commented upon are discussed in further detail below.

Table 17 below lists those interim codes reviewed under the refinement panel process described in this section. This table includes the following information:

- CPT Code. This is the CPT code for a service.
- Description. This is an abbreviated version of the narrative description of the code.
- 2004 Work RVU. The work RVUs that appeared in the January 2004 rule are shown for each reviewed code.
- Requested Work RVU. This column identifies the work RVUs requested by commenters.
- 2005 Work RVU. This column contains the final RVUs for physician work.

TABLE 17:

Codes Reviewed Under the Refinement Panel Process

CPT code*	Mod	Descriptor	2004 work RVU	Requested work RVU	2005 work RVU
43752		Nasal/orogastric w/stent	0.68	0.82	0.81
63103		Remove vertebral body add-on	3.90	5.00	4.82

*All CPT codes and descriptions copyright 2004 American Medical Association. All rights reserved and applicable FARS/DFARS clauses apply.

2. Interim 2004 Codes

CPT code 43752 *Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report).*

The RUC recommended a work RVU of 0.82 for this service based on a comparison of this procedure to CPT code 44500, *Introduction of long gastrointestinal tube.* While we agreed that CPT code 43752 is similar in work intensity to CPT code 44500, we believed the intra-service time is more appropriately valued at the 25th percentile (15 minutes of intra-service time vs. 20 minutes of intra-service time). This reduced the total time associated with CPT code 43752 from 30 minutes to 25 minutes. We applied the ratio of the RUC recommended value of 0.82 work RVU over 30 minutes to the revised intra-service time of 25 minutes and assigned 0.68 interim work RVUs for CPT code 43752.

Comment: Commenters disagreed with our decision not to accept the RUC recommended WRVU of 0.82 and with our rejection of the survey time, particularly since this service involves both tube placement and imaging. Based on these comments, we referred this code to the multispecialty validation panel for review.

Response: As a result of the statistical analysis of the 2004 multispecialty validation panel ratings, we have assigned 0.81 work RVUs to CPT code 43752.

CPT code 63103 *Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (for example, for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure).*

The RUC recommended a work RVU of 5.00 for this service based on a comparison of this procedure to CPT code 63088, the add-on code for the vertebral corpectomy, thoracic lumbar approach. We stated that it was unclear from the clinical vignettes supplied by the specialty society whether the additional corpectomy would more commonly involve the lumbar or the thoracic region of the spine. There is a significant difference in work intensity associated with the resection of an additional corpus in the thoracic region as opposed to the lumbar region. For this reason we applied the ratio of the reference service (CPT code 63088) to its primary service (CPT code 63087) to CPT code 63101 (primary service associated with CPT 63103) to assign 3.90 interim work RVUs for CPT code 63103.

Comment: Commenters requested that we withdraw the arbitrary reduction of the work RVU for CPT code 63103 stating that the unique aspects of the lateral extracavitary approach make the location in the lumbar and thoracic spine less relevant than the actual exposure of an additional level itself. The commenters stated that in contrast to anterior thoracic or lumbar approaches for vertebral corpectomy, the lateral extracavitary approach requires an unrelated and significantly greater muscle dissection of spinal/paraspinal tissues, as well as an additional rib, transverse process, and pedicle removal with isolation and division of another pair of segmental vessels. Based on these comments, we referred this code to the multispecialty validation panel for review.

Response: As a result of the statistical analysis of the 2004 multispecialty validation panel ratings, we have assigned 4.82 work RVUs to CPT code 63103.

CPT codes 38207 *Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage,* 38208 *Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing,* 38209 *Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing* 38210 *Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion,* 38211 *Transplant preparation of hematopoietic progenitor cells; tumor cell depletion,* 38212 *Transplant preparation of hematopoietic progenitor cells; red blood cell removal,* 38213 *Transplant preparation of hematopoietic progenitor cells; platelet depletion,* 38214 *Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion,* 38215 *Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer.*—These codes were new for CY 2003 but we did not receive the final RUC recommendations in time for inclusion in the final rule. In the December 31, 2002 rule we discussed the interim RUC recommendations and our concerns for removing these codes from the laboratory fee schedule, and paying them instead on the physician fee schedule (67 FR 80007). We received the final RUC recommendations in May 2003 and in the November 7, 2003 final rule we stated we were maintaining a status indicator ''I'' for these services making them not valid for payment under the physician fee schedule. (Note: In the December 31, 2002 rule, as part of the discussion about these CPT codes, we discussed the creation of HCPCS codes G0265, *Cryopreservation, freezing and storage of cells for therapeutic use, each cell line;* G0266 *Thawing and expansion of frozen cells for therapeutic use, each aliquot;* and G0267, *Bone marrow or peripheral stem cell harvest,*

modification or treatment to eliminate cell type(s) (for example, T-cells, metastic carcinoma). We stated that these HCPCS codes are paid under the laboratory fee schedule.)

Comment: We received comments regarding these codes in response to the 2002 and 2003 final rules. Commenters expressed concern, which was shared by the RUC about the CMS decision pertaining to these CPT codes. They stated that CMS was invited to conduct site visits to observe and have a better understanding of these services. They believe such visits would provide additional information on these services and allow for a more informed decision about their placement on the physician fee schedule.

Response: CPT codes 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214 and 38215 reflect services that are typically provided by laboratory personnel who require general oversight and supervision by a laboratory physician, analogous to a physician providing oversight in a blood banking facility. Based on site visits, we continue to believe that these services are not typically provided by a physician. We recognize that variability pertaining to the clinical and laboratory management of patients does exist and that in some bone marrow transplant centers these laboratory services are closely supervised and managed by physicians. These centers, however, do not reflect the typical practice pattern for the majority of bone marrow transplant centers. Therefore, we will continue to allow use of HCPCS codes G0265 Cryopreservation, freezing and storage of cells for therapeutic use, each cell line and G0266 Thawing and expansion of frozen cells for therapeutic use, each aliquot to report these services, and G0267 Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (for example, T-cells, metastatic carcinoma). These services are currently on the laboratory fee schedule. We welcome additional comments to help us better determine whether to place CPT codes 38207 through 38215 on either the physician or laboratory fee schedule.

Note: We identified the services provided within transplant centers as clinical services typically provided by a physician in conjunction with the following codes: CPT codes 38205—Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic, CPT 38206—Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous, CPT codes 38240—Bone Marrow or bone derived peripheral stem cell transplantation; allogenic, CPT code 38241—Bone Marrow or bone derived peripheral stem cell transplantation; autologous, and CPT code 38242—Bone Marrow or bone derived peripheral stem cell transplantation; allogeneic lymphocyte donor infusions. We believe the physician work RVUs assigned by the RUC to these codes (CPT code 38205–1.50, CPT code 38206–1.50, CPT code 38240–2.24 RVUs, CPT code 38241–2.24 RVUs, and CPT code 38242–1.71 RVUs) appropriately reflect the physician work intensity for each of these services and reaffirm our prior decision announced in 2002. CPT code 38204—Management of recipient hematopoietic progenitor cell donor search and cell acquisition was valued at 2.00 RVUs by the RUC in 2002. We believe there may be physician work when providing this service. However, information obtained during our site visits revealed that the bulk of the service was provided by the transplant coordinator, who worked closely with the physician. It is unclear at this point what the appropriate value will be for the physician who provides this service. We welcome comments on this issue.

CPT code 76514 *Ophthalmic ultrasound, echography, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness).*—We accepted the RUC recommendation of 0.17 work RVUs.

Comments: The American Academy of Ophthalmology commented that the assigned work RVU does not accurately reflect the value intended by the RUC or CPT; the value should be doubled. The Academy stated that the problem arose when the RUC recommended to CPT that the descriptor should be changed from unilateral to unilateral or bilateral. The commenter suggested that either the descriptor be changed to reflect only the unilateral, which will take a while to accomplish, or that we increase valuation to correctly reflect valuation by RUC.

Response: Because we have no data that indicates whether the unilateral or bilateral procedure is more typical, we are not changing the RVUs at this time. We would suggest that the Academy contact the CPT Editorial Panel if a change to the descriptor would be helpful to the specialty.

Establishment of Interim Work Relative Value Units for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System Codes (HCPCS) for 2005 (Includes Table Titled ''American Medical Association Specialty Relative Value Update Committee and Health Care Professionals Advisory Committee Recommendations and CMS's Decisions for New and Revised 2005 CPT Codes'')

One aspect of establishing RVUs for 2005 was to assign interim work RVUs for all new and revised CPT codes. As described in our November 25, 1992 notice on the 1993 physician fee schedule (57 FR 55983) and in section III.B. of the November 22, 1996 final rule (61 FR 59505 through 59506), we established a process, based on recommendations received from the AMA's RUC, for establishing interim work RVUs for new and revised codes.

This year we received work RVU recommendations for 149 new and revised CPT codes from the RUC. Our staff and medical officers reviewed the RUC recommendations by comparing them to our reference set or to other comparable services for which work RVUs had previously been established. We also considered the relationships among the new and revised codes for which we received RUC recommendations and agreed with the majority of the relative relationships reflected in the RUC values. In some instances, although we agreed with the relationships, we nonetheless revised the work RVUs to achieve work neutrality within families of codes. That is, the work RVUs have been adjusted so that the sum of the new or revised work RVUs (weighted by projected frequency of use) for a family will be the same as the sum of the current work RVUs (weighted by projected frequency of use) for the family of codes. We reviewed all the RUC recommendations and accepted approximately 99 percent of the RUC recommended values. For approximately 1 percent of the recommendations, we agreed with the relativity established by the RUC, but needed to adjust work RVUs to retain budget neutrality.

We received four recommendations from the HCPAC. We agreed with two of these recommendations and disagreed with two of them.

Table 18, titled ''AMA RUC and HCPAC Recommendations and CMS Decisions for New and Revised 2005 CPT Codes,'' lists the new or revised CPT codes, and their associated work RVUs, that will be interim in 2005. This

table includes the following information:

- A ''#'' identifies a new code for 2005.
- CPT code. This is the CPT code for a service.
- Modifier. A ''26'' in this column indicates that the work RVUs are for the professional component of the code.
- Description. This is an abbreviated version of the narrative description of the code.
- RUC recommendations. This column identifies the work RVUs recommended by the RUC.
- HCPAC recommendations. This column identifies the work RVUs recommended by the HCPAC.
- CMS decision. This column indicates whether we agreed or we disagreed with the RUC recommendation. Codes for which we did not accept the RUC recommendation are discussed in greater detail following this table. An ''(a)'' indicates that no RUC recommendation was provided.
- 2005 Work RVUs. This column establishes the interim 2005 work RVUs for physician work.

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TABLE 18: AMA RUC and HCPAC Recommendations and CMS Decisions for New and Revised 2005 CPT Codes

*CPT CODE	Mod	Description	RUC recommendation	HCPAC recommendation	CMS Decision	2004 work RVU
#11004		Debride genitalia & perineum	10.31	----------	Agree	10.31
#11005		Debride abdom wall	13.75	----------	Agree	13.75
#11006		Debride genit/per/abdom wall	12.61	----------	Agree	12.61
#11008		Remove mesh from abd wall	5.00	----------	Agree	5.00
#19296		Place po breast cath for rad	3.63	----------	Agree	3.63
#19297		Place breast cath for rad	1.72	----------	Agree	1.72
#19298		Place breast rad tube/caths	6.00	----------	Agree	6.00
#27412		Autochondrocyte implant knee	23.23	----------	Agree	23.23
#27415		Osteochondral knee allograft	18.49	----------	Agree	18.49
#29866		Autgrft implnt, knee w/scope	13.88	----------	Agree	13.88
#29867		Allgrft implnt, knee w/scope	17.00	----------	Agree	17.00
#29868		Meniscal trnspl, knee w/scpe	23.59	----------	Agree	23.59
#31545		Remove vc lesion w/scope	6.30	----------	Agree	6.30
#31546		Remove vc lesion scope/graft	9.73	----------	Agree	9.73
#31620		Endobronchial us add-on	1.40	----------	Agree	1.40
31630		Bronchoscopy dilate/fx repr	3.81	----------	Agree	3.81
31631		Bronchoscopy, dilate w/stent	4.36	----------	Agree	4.36
#31636		Bronchoscopy, bronch stents	4.30	----------	Agree	4.30
#31637		Bronchoscopy, stent add-on	1.58	----------	Agree	1.58
#31638		Bronchoscopy, revise stent	4.88	----------	Agree	4.88
#32019		Insert pleural catheter	4.17	----------	Agree	4.17
#32855		Prepare donor lung, single	(a)	----------	(a)	Carrier
#32856		Prepare donor lung, double	(a)	----------	(a)	Carrier
#33933		Prepare donor heart/lung	(a)	----------	(a)	Carrier
#33944		Prepare donor heart	(a)	----------	(a)	Carrier
#34803		Endovas aaa repr w/3-p part	24.00	----------	Agree	24.00
#36475		Endovenous Rf, 1st Vein	6.72	----------	Agree	6.72
#36476		Endovenous rf, vein add-on	3.38	----------	Agree	3.38
#36478		Endovenous Laser, 1st Vein	6.72	----------	Agree	6.72

#36479	Endovenous laser vein addon	3.38	----------	Agree	3.38
#36818	Av fuse, uppr arm, cephalic	11.52	----------	Agree	11.52
36819	Av fuse, uppr arm, basilic	13.98	----------	Agree	13.98
37205	Transcath iv stent, percut	8.27	----------	Agree	8.27
37206	Transcath iv stent/perc addl	4.12	----------	Agree	4.12
#37215	Transcath stent, cca w/eps	18.71	----------	Agree	18.71
#37216	Transcath stent, cca w/o eps	17.98	----------	Agree	17.98
#43257	Uppr gi scope w/thrml txmnt	5.50	----------	Agree	5.50
#43644	Lap gastric bypass/roux-en-y	27.83	----------	Agree	27.83
#43645	Lap gastr bypass incl smll i	29.96	----------	Agree	29.96
#43845	Gastroplasty duodenal switch	Carrier	----------	Agree	Carrier
#44137	Remove intestinal allograft	Carrier	----------	Agree	Carrier
#44715	Prepare donor intestine	(a)	----------	(a)	Carrier
#44720	Prep donor intestine/venous	5.00	----------	Agree	5.00
#44721	Prep donor intestine/artery	7.00	----------	Agree	7.00
#45391	Colonoscopy w/endoscope us	5.09	----------	Agree	5.09
#45392	Colonoscopy w/endoscopic fnb	6.54	----------	Agree	6.54
#46947	Hemorrhoidopexy by stapling	5.20	----------	Agree	5.20
47140	Partial removal, donor liver	54.92	----------	Agree	54.92
47141	Partial removal, donor liver	67.40	----------	Agree	67.40
47142	Partial removal, donor liver	74.89	----------	Agree	74.89
#47143	Prep donor liver, whole	(a)	----------	(a)	Carrier
#47144	Prep donor liver, 3-segment	(a)	----------	(a)	Carrier
#47145	Prep donor liver, lobe split	(a)	----------	(a)	Carrier
#47146	Prep donor liver/venous	6.00	----------	Agree	6.00
#47147	Prep donor liver/arterial	7.00	----------	Agree	7.00
#48551	Prep donor pancreas	(a)	----------	(a)	Carrier
#48552	Prep donor pancreas/venous	4.30	----------	Agree	4.30
#50323	Prep cadaver renal allograft	(a)	----------	(a)	Carrier
#50325	Prep donor renal graft	(a)	----------	(a)	Carrier
#50327	Prep renal graft/venous	4.00	----------	Agree	4.00
#50328	Prep renal graft/arterial	3.50	----------	Agree	3.50
#50329	Prep renal graft/ureteral	3.34	----------	Agree	3.34
50360	Transplantation of kidney	31.48	----------	Agree	31.48
50365	Transplantation of kidney	36.75	----------	Agree	36.75
#50391	Instll rx agnt into rnal tub	1.96	----------	Agree	1.96
50547	Laparo removal donor kidney	25.46	----------	Agree	25.46
#57267	Insert mesh/pelvic flr addon	4.88	----------	Agree	4.88
57282	Colpopexy, extraperitoneal	8.85	----------	Disagree	6.86
#57283	Colpopexy, intraperitoneal	14.00	----------	Disagree	10.84
#58356	Endometrial cryoablation	Carrier	----------	Agree	Carrier
#58565	Hysteroscopy, sterilization	7.02	----------	Agree	7.02
#58956	Bso, omentectomy w/tah	20.78	----------	Agree	20.78
#63050	Cervical laminoplasty	20.75	----------	Agree	20.75
#63051	C-laminoplasty w/graft/plate	24.25	----------	Agree	24.25
#63295	Repair of laminectomy defect	5.25	----------	Agree	5.25
66710	Ciliary transscleral therapy	4.77	----------	Agree	4.77

#66711	Ciliary endoscopic ablation	6.60	----------	Agree	6.60
75960	Transcath iv stent rs&i	0.82	----------	Agree	0.82
76075	Dxa bone density, axial	0.30	----------	Agree	0.30
76076	Dxa bone density/peripheral	0.22	----------	Agree	0.22
#76077	Dxa bone density/v-fracture	0.17	----------	Agree	0.17
#76510	Ophth us, b & quant a	1.55	----------	Agree	1.55
76511	Ophth us, quant a only	0.94	----------	Agree	0.94
76512	Ophth us, b w/non-quant a	0.94	----------	Agree	0.94
76513	Echo exam of eye, water bath	0.66	----------	Agree	0.66
76514	Echo exam of eye, thickness	0.17	----------	Agree	0.17
#76820	Umbilical artery echo	0.50	----------	Agree	0.50
#76821	Middle cerebral artery echo	0.70	----------	Agree	0.70
76827	Echo exam of fetal heart	0.58	----------	Agree	0.58
76828	Echo exam of fetal heart	0.56	----------	Agree	0.56
77750	Infuse radioactive materials	4.90	----------	Agree	4.90
#78811	Tumor imaging (pet), limited	1.54	----------	Agree	1.54
#78812	Tumor image (pet)/skul-thigh	1.93	----------	Agree	1.93
#78813	Tumor image (pet) full body	2.00	----------	Agree	2.00
#78814	Tumor image pet/ct, limited	2.20	----------	Agree	2.20
#78815	Tumorimage pet/ct skul-thigh	2.44	----------	Agree	2.44
#78816	Tumor image pet/ct full body	2.50	----------	Agree	2.50
#79005	Nuclear rx, oral admin	1.80	----------	Agree	1.80
#79101	Nuclear rx, iv admin	1.96	----------	Agree	1.96
79200	Nuclear rx, intracav admin	1.99	----------	Agree	1.99
79300	Nuclr rx, interstit colloid	1.60	----------	Agree	1.60
79440	Nuclear rx, intra-articular	1.99	----------	Agree	1.99
#79445	Nuclear rx, intra-arterial	2.40	----------	Agree	2.40
79999	Nuclear medicine therapy	Carrier	----------	Agree	Carrier
84165	Protein e-phoresis, serum	0.37	----------	Agree	0.37
#84166	Protein e-phoresis/urine/csf	0.37	----------	Agree	0.37
86334	Immunofix e-phoresis, serum	0.37	----------	Agree	0.37
#86335	Immunfix e-phorsis/urine/csf	0.37	----------	Agree	0.37
#88184	Flowcytometry/ tc, 1 marker	0.00	----------	Agree	0.00
#88185	Flowcytometry/tc, add-on	0.00	----------	Agree	0.00
#88187	Flowcytometry/read, 2-8	1.36	----------	Agree	1.36
#88188	Flowcytometry/read, 9-15	1.69	----------	Agree	1.69
#88189	Flowcytometry/read, 16 & >	2.23	----------	Agree	2.23
#88360	Tumor immunohistochem/manual	1.10	----------	Agree	1.10
88361	Tumor immunohistochem/comput	1.18	----------	Agree	1.18
88365	Insitu hybridization (fish)	1.20	----------	Agree	1.20
#88367	Insitu hybridization, auto	1.30	----------	Agree	1.30
#88368	Insitu hybridization, manual	1.40	----------	Agree	1.40
#90465	Immune admin 1 inj, < 8 yrs	0.17	----------	Agree	0.17
#90466	Immune admin addl inj, < 8 y	0.15	----------	Agree	0.15
#90467	Immune admin o or n, < 8 yrs	0.17	----------	Agree	0.17
#90468	Immune admin o/n, addl < 8 y	0.15	----------	Agree	0.15
90471	Immunization admin	0.17	----------	Agree	0.17

90472	Immunization admin, each add	0.15	----------	Agree	0.15
#91034	Gastroesophageal reflux test	0.97	----------	Agree	0.97
#91035	G-esoph reflx tst w/electrod	1.59	----------	Agree	1.59
#91037	Esoph imped function test	0.97	----------	Agree	0.97
#91038	Esoph imped Funct Test > 1h	1.10	----------	Agree	1.10
#91040	Esoph balloon distension tst	0.97	----------	Agree	0.97
#91120	Rectal sensation test	0.97	----------	Agree	0.97
93741	Analyze ht pace device sngl	0.80	----------	Agree	0.80
93742	Analyze ht pace device sngl	0.91	----------	Agree	0.91
#93745	Set-up cardiovert-defibrill	(a)	----------	(a)	Carrier
#93890	Tcd, vasoreactivity study	1.00	----------	Agree	1.00
#93892	Tcd, emboli detect w/o inj	1.15	----------	Agree	1.15
#93893	Tcd, emboli detect w/inj	1.15	----------	Agree	1.15
#94452	Hast w/report	0.31	----------	Agree	0.31
#94453	Hast w/oxygen titrate	0.40	----------	Agree	0.40
#95928	C motor evoked, uppr limbs	1.50	----------	Agree	1.50
#95929	C motor evoked, lwr limbs	1.50	----------	Agree	1.50
95971	Analyze neurostim, simple	0.78	----------	Agree	0.78
95972	Analyze neurostim, complex	1.50	----------	Agree	1.50
95973	Analyze neurostim, complex	0.92	----------	Agree	0.92
#95978	Analyze neurostim brain/1h	3.50	----------	Agree	3.50
#95979	Analyz neurostim brain addon	1.64	----------	Agree	1.64
#97597	Active wound care/20 cm or <	----------	0.58	Agree	0.58
#97598	Active wound care > 20 cm	----------	0.80	Agree	0.80
#97605	Neg press wound tx, < 50 cm	----------	0.55	Disagree	0.00
#97606	Neg press wound tx, > 50 cm	----------	0.60	Disagree	0.00

(a) No Final RUC recommendation provided

\# New CPT codes

* All CPT codes copyright 2005 American Medical Association

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Table 19, which is titled ''AMA RUC ANESTHESIA RECOMMENDATIONS AND CMS DECISIONS FOR NEW AND REVISED 2005 CPT CODES'', lists the new or revised CPT codes for anesthesia and their base units that will be interim in 2005. This table includes the following information:

- CPT code. This is the CPT code for a service.
- Description. This is an abbreviated version of the narrative description of the code.
- RUC Recommendations. This column identifies the base units recommended by the RUC.
- CMS decision. This column indicates whether we agreed or we disagreed with the RUC recommendation. Codes for which we did not accept the RUC recommendation are discussed in grreater detail following this table.
- 2005 Base Units. This column establishes the 2005 base units for these services.

TABLE 19:
AMA RUC ANESTHSIA RECOMMENDATIONS AND CMS DECISIONS FOR NEW AND REVISED CPT CODES

*CPT CODE	Description	RUC recommendation	CMS Decision	2005 Base Units
#00561	Anesth, heart surg <age 1	25.00	Agree	25.00

*All CPT codes copyright 2005 American Medical Association.

New CPT code.

Discussion of Codes for Which There Were No RUC Recommendations or for Which the RUC Recommendations Were Not Accepted

The following is a summary of our rationale for not accepting particular RUC work RVU or base unit recommendations. It is arranged by type of service in CPT order. Additionally, we discuss those CRP codes for which we received no RUC recommendations for physician work RVUs. This summary refers only to work RVUs or base units.

New and Revised Codes for 2005

CPT mode 97605 *Negative pressure wound therapy (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters* and CPT code 97606 *Negative pressure wound therapy* (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.—The RUC HCPAC review board recommended 0.55 work RVUs for CPT code 97605 and 0.60 work RVUs for CPT code 97606, which we did not accept. We disagree with their recommendation that these services contain physician work and will not assign work RVUs. Further, when the negative pressure wound therapy service does not encompass selective debridement, we consider this service to represent a dressing change and will not make separate payment. When the negative pressure wound therapy service includes the need for selective debridement, we consider the services represented by CPT codes 97605 and 97606 to be bundled into CPT codes 97597 or 97598, the new debridement codes, which will be appropriately billed. We are assigning a status indicator of ''B'' to these two new CPT codes (97605 and 97606), meaning that we will not make separate payment for these services.

CPT code 57282, *Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus) and CPT code 57283 Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy).*—The CPT Editorial Panel revised an existing code (57282) and created a new code (57283) to describe vaginal extra and intraperitoneal colpopexies. The RUC recommended maintaining the current work PVUs of 8.85 for 57282 and recommended 14.00 work PVUs for 57283. Previously, both the extra-peritoneal approach and intra-peritoneal approach were billed under CPT code 57282. Effective January 1, 2005, CPT code 57282 will be used to report colpopexy, vaginal; extra-peritoneal approach, while CPT code 57283 will be used to report colpopexy vaginal; intraperitoneal approach. Although we agree with the relativity established by the RUC, we believe that the work RVUs for CPT code 57282 should have been adjusted to reflect that the intra-peritoneal approach is now being reported using CPT code 57283. In order to retain work neutrality between these two services, we adjusted the work RVUs using the utilization crosswalks provided by the specialty survey to account for the work that was previously associated with performing these procedures when only one code existed. This results in work RVUs of 6.86 for CPT code 57282 and 10.84 work RVUs for CPT code 57283.

We have not received the final recommendations from the RUC on these services and carriers will price these services in 2005.

CPT Code 32855 *Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral;* CPT Code 32856 *Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral;* CPT Code 33933 *Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation;* CPT Code 33944 *Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation;* CPT Code 44715 *Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein;* CPT Code 47143 *Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe spilt;* CPT Code 47144 *Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into two partial liver grafts (that is, left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII));* CPT Code 47145 *Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (that is, left lobe (segments II, III, and IV) and right lobe (segments I and V through VIII));* CPT Code 48551 *Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery,* CPT Code 50323 *Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary;* CPT Code 50325 *Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary;* and CPT Code 93745 *Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problem or events.*

Establishment of Interim Practice Expense RVUs for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System (HCPCS) Codes for 2005

We have developed a process for establishing interim practice expense RVUs for new and revised codes that is similar to that used for work RVUs. Under this process, the RUC recommends the practice expense direct inputs (the staff time, supplies and equipment) associated with each new code. We then review the recommendations in a manner similar to our evaluation of the recommended work RVUs.

The RUC recommendations on the practice expense inputs for the new and revised 2005 codes were submitted to us as interim recommendations.

We have accepted, in the interim, the practice expense recommendations submitted by the RUC for the codes listed in the table titled ''AMA RUC and HCPAC RVU Recommendations and CMS Decisions for New and Revised 2005 CPT Codes.'' However, we will be reviewing the supplies, including the DNA probes, for the new and revised in situ hybridization codes (CPT 88365, 88367 and 88368) to ensure that the practice expense database accurately reflects the supplies associated with these services.

Other Issues

Comment: The RUC requested that we modify the definition of the ''preservice'' portion for the 0-, 10- and 90-day global periods to state, ''The preservice period includes the physicians' services following the visit at which the decision for surgery is finalized until the time of the operative procedure.'' The current definition of the preservice time for the 0 and 10-day global periods includes the preservice work occurring on the day of surgery, while the 90-day global period includes the preservice work occurring the day before surgery.

Response: We are reluctant to revise the definition of preservice until there is further review of the issue. Though the suggested change in preservice definition for physician work would correspond to the change made in the definition for practice expense purposes, that revision was made at the beginning of the practice expense refinement. It is not clear to us how the relativity would be maintained between existing codes valued under the current definition and new codes valued using an expanded definition of preservice work. In addition, among different procedures, there is most likely much variation in the time period between the decision to perform surgery and the time of the operative procedure. The absence of a specific timeframe could result in an inconsistent application of the definition. However, we would look forward to further discussion with the RUC concerning this issue.

Comment: Solid compensator-based intensity modulated radiation therapy (IMRT) is one of the IMRT technologies currently paid using the radiation therapy CPT code 77418, *Intensity modulated treatment delivery.* For 2005, CPT created a Category III tracking code 0073T, *Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensatory convergent beam modulated fields, per treatment session.* CPT instructions for CPT code 77418 now specifically exclude this technology.

Physicians performing compensator-based IMRT expressed concern that we generally carrier price tracking codes and that carriers often will not pay for them, considering services reported with a tracking code to be experimental. One commenter requested that, in order to allow payment for solid compensator-based IMRT under the physician fee schedule, we assign RVUs to the new CPT tracking code 0073T.

Response: As noted by the commenters, we generally do not nationally price tracking codes, which are most often used to report new or experimental services. Rather, we designate them as carrier priced until there is sufficient volume and information to develop appropriate RVUs. However, solid compensator based IMRT is an established technology that is currently paid both under the physician fee schedule and in the hospital outpatient department. We are concerned that having this service be reported using a carrier-priced tracking code could have an adverse effect on access to this technology. Therefore, we are assigning interim RVUs to this tracking code. For payment under the physician fee schedule, we will crosswalk the practice expense and malpractice RVUs assigned to CPT code 77418 to the Category III tracking code 0073T. (Note that this is a technical component only service and there are no associated physician work RVUs.)

Comment: For 2005, CPT has eliminated CPT code 79900, *Provision of Therapeutic Radiopharmaceuticals.* We received comments from several organizations and individuals concerning elimination of this CPT code. Commenters requested we either grant a grace period for the CPT code or reinstate the HCPCS code Q3001, *Radioelements for brachytherapy, any type, each,* so that payment can be made under the physician fee schedule.

Response: We are reinstating HCPCS code Q3001 under the physician fee schedule. This service will be carrier priced.

Note that there have been new HCPCS drug administration codes for physicians' services established for CY 2005. Please see section III.E.2 for specific information related to these new HCPCS codes.

VI. Five-Year Refinement of Relative Value Units

[If you choose to comment on issues in this section, please include the caption ''Five Year Refinement of Work Relative Value Units for Calendar Year 2004'' at the beginning of your comments.]

A. Background

The work RVUs were originally developed by a research team at the Harvard School of Public Health in a cooperative agreement with us. Harvard established the work RVUs for almost all fee schedule codes. The RVUs for anesthesia services were based on relative values from the American Society of Anesthesiology. The original RVUs for radiology codes were based on the American College of Radiology relative value scale. The work RVUs reflect the physician's effort in providing a service by accounting for: the physician's time; the technical difficulty of the procedure; the average severity of illness among patients receiving the procedure; and the degree of physical and mental effort required of the physician to perform the procedure.

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less than every 5 years. We initiated the first 5-year review in 1994 and refinements went into effect beginning in 1997. The second 5-year review began in 1999 and refinements went into effect beginning in 2002. It is now time to begin the third 5-year review of the physician work RVUs with the resulting changes being effective beginning in 2007.

As part of the final rule published December 8, 1994 (59 FR 63453), we solicited public comment on all work RVUs for approximately 7,000 CPT and HCPCS codes. The scope of the 5-year review was limited to work values, since at that time, the statute required practice expense and malpractice RVUs be calculated based on 1991 allowed charges and practice expense and malpractice expense shares for the specialties performing the services. Also, the December 8, 1994 final rule

outlined the proposed process for refinement of the work RVUs and provided a suggested format for submission of comments.

We indicated that we were particularly interested in receiving comments on physicians' services for which medical practice had changed since the Harvard surveys were performed, but for which there were no code changes and, therefore, no reconsideration of whether the work RVUs were still accurate. As a result of the December 8, 1994 final rule, we received more than 500 comments on approximately 1,100 codes. Subsequent to review of the comments by our medical staff, comments on approximately 700 codes were forwarded to the AMA's Specialty Society RUC for review. An additional 300 codes identified by our staff as potentially misvalued were also forwarded to the RUC. A process similar to that used for the annual physician fee schedule update was used for evaluating the proposed changes to the work RVUs and a notice discussing these proposed changes was published in the May 3, 1996 **Federal Register** (61 FR 19992). As outlined in this notice, we proposed to increase the work RVUs for 28 percent of the codes; we proposed to maintain the work RVUs for 61 percent of the codes and we proposed to decrease the work RVUs for 11 percent of the codes. (Our proposed work RVUs agreed with the RUC recommendations for 93 percent of the codes.) In response to the May 3, 1996 proposed notice, we received more than 2,900 comments on approximately 133 codes plus all anesthesia services. In order to address these comments, we convened multi-specialty panels of physicians. A detailed discussion of this process, as well as the results of the 5-year review were included in the final rule with comment period published November 22, 1996 (61 FR 59490).

We initiated the second 5-year review by soliciting comments on potentially misvalued work RVUs for all services in the CY 2000 physician fee schedule in the November 2, 1999, final rule (64 FR 59427). We indicated that the scope of the second 5-year review would be restricted to work RVUs, since resource-based malpractice RVUs had only just been implemented in CY 2000, and we were in the middle of transitioning to a fully resource-based system for practice expense RVUs.

In our July 17, 2000 proposed rule (66 FR 31028), we explained the process used to conduct the second 5-year review of work, beginning with the solicitation of comments on services that were potentially misvalued, in our November 2, 1999 final rule with comment period.

We received comments from approximately 30 specialty groups, organizations, and individuals involving over 900 procedure codes. After review by our medical staff, we shared all of the comments we received concerning potentially misvalued services with the RUC.

The RUC submitted work RVU recommendations for all of the codes we forwarded with the exception of the anesthesia codes and conscious sedation codes. We analyzed all of the RUC recommendations and evaluated both the recommended work RVUs and the rationale for the recommendations. If we had concerns about the application of a particular methodology, but thought the recommended work RVUs were reasonable, we verified that the recommended work RVUs were appropriate by using alternative methodologies. We announced our proposed decisions on the revised work RVUs in the proposed notice published June 8, 2001 (66 FR 31028).

Overall, we proposed to accept 92 percent of RUC recommended work RVUs (RVUs or 792 services). Of the RUC recommendations we disagreed with, we proposed to increase the work RVUs for 37 services and decrease the work RVUs for 22 services. We did not accept the RUC recommendations of an increase for 6 services that were previously reviewed by a multi-specialty physician panel in 2000. The Health Care Professional Advisory Committee (HCPAC), an advisory committee to the RUC representing non-physician health professionals, also reviewed a total of 12 services as part of the 5-year review. For 5 of the services reviewed, the HCPAC did not offer a recommendation. Of the remaining 7 services, we proposed to accept the HCPAC recommendations.

Comments received on the June 8, 2001 proposed notice generally supported our proposed changes. In addition, we received more than 125 comments on approximately 39 specific codes plus all the anesthesia services. The majority of these comments addressed the gastrointestinal endoscopy codes and anesthesia services. As with the first 5-year review, we convened a multi-specialty panel of physicians to assist us in the review of the comments. For additional information about this process, the comments received, and the results of the second 5-year review, see the final rule with comment period published November 2, 2001 (66 FR 55285).

B. Scope of the 5-Year Refinement

As with the second 5-year review, we are soliciting comments only on the work RVUs that may be inappropriately valued. The malpractice RVUs were implemented in CY 2000 and revisions to these RVUs are addressed as part of this final rule.

We are not including the practice expense RVUs as part of this refinement. The PEAC, an advisory committee of the RUC, has been providing us with recommendations for refining the direct practice expense inputs (clinical staff, supplies, and equipment) used in calculating the practice expense RVUs for established codes. As discussed in the August 5, 2004 proposed rule, the PEAC held its last meeting March 2004 and future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC. As we determine the process that will be used to refine the remaining codes, we will also be considering how to address future review of practice expense RVUs. We would also welcome comments on how this might be addressed. However, to the extent that there are changes in physician time or in the number or level of post procedure visits as a result of the 5-year review of work, there would be a potential impact on the practice expense inputs, and we would revise the inputs accordingly.

C. Refinement of Work Relative Value Units

During the first and second 5-year reviews, we relied on public commenters to identify services that were potentially misvalued.

For the third 5-year review, we are again requesting comments on potentially misvalued work RVUs for all services in the CY 2005 physician fee schedule. However, we recognize that this process generally elicits comments focusing on undervalued codes. Therefore, in addition to the codes submitted by commenters, we will also identify codes (especially high-volume codes across specialties) that:

- Are valued as being performed in the inpatient setting, but that are now predominantly performed on an outpatient basis; and
- Were not reviewed by the RUC, (that is, Harvard RVUs are still being used, or there is no information).

Public comments must include the appropriate CPT code (for example, CPT code 90918) and the suggested RVUs (for example, 11.00 RVUs), and evidence that the current work RVU is misvalued. Failure to provide this information may result in our inability

to evaluate the comments adequately. We will consider all comments on all work RVUs in the development of a proposed rule that we intend to publish in 2006. In that rule, we will propose the revisions to work RVUs that we believe are needed. We will then review and analyze the comments received in response to our proposed revisions and publish our decisions in the 2006 final rule.

In addition to internal review and analysis, we propose to share comments we receive on all work RVUs with the RUC, which currently makes recommendations to us on the assignment of RVUs to new and revised CPT codes. This process was used during the last 5-year review, and we believe that it was beneficial. The RUC's perspective will be helpful because of its experience in recommending RVUs for new and revised CPT codes since we implemented the physician fee schedule. Furthermore, the RUC, by virtue of its multispecialty membership and consultation with approximately 65 specialty societies, involves the medical community in the refinement process.

D. Nature and Format of Comments on Work Relative Value Units

While all written public comments are welcomed, based on our past experience we have found it particularly beneficial if the comments include certain information: the CPT code or codes recommended for review, a clinical description of the service(s), the current work RVUs and the suggested work RVUs. Because our initial assumption will be that each code is currently appropriately valued, the commenter may also include some rationale to support the need for review. For example, one approach would be to compare the physician work of each nominated code to the work involved in an analogous service that has higher or lower work RVUs. In other situations, the commenter could demonstrate that there is a rank order anomaly within a family of codes. Another reason for reviewing the physician work involved in a service could be that the physician time or intensity required by the procedure has changed since it was last reviewed, perhaps because of a change in technology or in patient characteristics.

The RUC has also developed more detailed ''Compelling Evidence Standards'' which are used by the RUC as part of their process to determine if a recommendation to change the work RVUs is warranted for a given code. We are including these standards below solely for informational purposes so that commenters are aware what kind of information will be needed to make a successful argument to the RUC for changing work RVUs.

RUC Compelling Evidence Standards

The RUC operates with the initial presumption that the current values assigned to the codes under review are correct. This presumption can be challenged by a society or other organization presenting a compelling argument that the existing values are no longer rational or appropriate for the codes in question. The argument for a change must be substantial and meet the RUC's compelling evidence standards. This argument must be provided in the comment letter to us, and then later to the RUC in writing on the Summary of Recommendation form. The following guidelines may be used to develop a ''compelling argument'' that the published relative value for a service is inappropriately valued:

- Documentation in the peer-reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following:

+ Technique
+ Knowledge and technology
+ Patient population
+ Site-of-service
+ Length of hospital stay
+ Physician time

- An anomalous relationship between the code being valued and other codes. For example, if code A describes a service that requires more work than codes B, C, and D, but is nevertheless valued lower. The specialty would need to assemble evidence on service time, technical skill, patient severity, complexity, length of stay and other factors for the code being considered and the codes to which it is compared. These reference services may be both inter- and intra-specialty.
- Evidence that technology has changed physician work that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, as documented, such as:

+ A misleading vignette, survey or flawed crosswalk assumptions in a previous evaluation;

+ A flawed mechanism or methodology used in the previous valuation, for example, evidence that no pediatricians were consulted in assigning pediatric values; and

+ A previous survey was conducted by one specialty to obtain a value, but in actuality that service is currently provided primarily by physicians from a different specialty according to utilization data.

We emphasize, however, as we reiterated for the last 5-year review, that we retain the responsibility for analyzing the comments on the suggested work RVU revisions, developing the proposed rule, evaluating the comments on the proposed rule, and deciding whether to revise RVUs. We are not delegating this responsibility to the RUC or any other organization.

VII. Update to the Codes for Physician Self-Referral Prohibition

[If you choose to comment on issues in this section, please include the caption ''Physician Self-Referral Designated Health Services'' at the beginning of your comments.]

A. Background

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to a health care entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. The following services are DHS, as specified in section 1877 of the Act and in regulations at § 411.351:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

In § 411.351, the entire scope of the first four of these DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS publications. The updated Code List appears as an addendum to the physician fee schedule final rule and is available on our Web site at *http://cms.hhs.gov/medlearn/refphys.asp.* We also include in the Code List those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.351(g)).
- Preventive screening tests, immunizations or vaccines (§ 411.351(h)).

The Code List was updated in the physician fee schedule final rule published in the **Federal Register** on November 7, 2003 (68 FR 63196). It was subsequently corrected in a notice that was published in the **Federal Register** on March 26, 2004 (69 FR 15729). We also published the Phase II physician self-referral interim final rule with comment period on March 26, 2004 in the **Federal Register** (69 FR 16054), which made several additional changes to the Code List, effective July 26, 2004.

The updated all-inclusive Code List effective January 1, 2005 is presented in Addendum L of this final rule.

B. Response to Comments

We received two public comments relating to the Code List published in the November 7, 2003 physician fee schedule final rule. One commenter supported the exclusion of interventional radiology services from the definition of radiology and certain other imaging services, as reflected on the Code List. The other commenter raised a concern over the exclusion of nuclear medicine services as a DHS.

Additionally, the proposed physician fee schedule rule that was published on August 5, 2004 in the **Federal Register** (69 FR 47488) generated one comment relating to the Code List. That comment and our response also are provided below. We note that we will address in a separate **Federal Register** document those public comments relating to the Code List that were received in response to the Phase II physician self-referral final rule published on March 26, 2004.

Comment: One commenter requested that we include nuclear medicine services as DHS. The commenter is concerned that physicians may engage in lucrative financial relationships associated with nuclear medicine studies such as PET scans.

Response: We are mindful of the issue raised by the commenter, and we continue to consider the application of section 1877 of the Act to nuclear medicine procedures. However, we note that the purpose of this update is merely to conform the Code List to the most recent publications of HCPCS and CPT codes. Substantive changes to DHS definitions, such as that advocated by the commenter, are beyond the scope of this rulemaking.

Comment: One commenter asked us to clarify that the Code List does not define all DHS and that we indicate where providers can obtain more information on the remaining categories. Additionally, the commenter suggested that we define all DHS in the Code List and that the definitions be included in the quarterly updated Microsoft Excel spreadsheet of RVU values, global periods and supervision levels for Medicare covered services posted on our Web site.

Response: We believe that most readers are aware that the Code List does not define every DHS category. Nevertheless, we will add a footnote to the Code List indicating that § 411.351 defines those DHS categories not reflected on the Code List.

The comment advocating that we define all DHS by CPT or HCPCS code on the Code List would require a substantive change to existing DHS definitions and is therefore beyond the scope of this rulemaking. We will explore the possibility of identifying certain DHS in the National Physician Fee Schedule Relative Value File (*http://www.cms.hhs.gov/providers/pufdownload/rvudown.asp*).

C. Revisions Effective for 2005

Tables 20 and 21, in this section, identify the additions and deletions, respectively, to the comprehensive Code List included in the Phase II physician self-referral interim final rule published March 26, 2004. Tables 20 and 21 also identify the additions and deletions to the lists of codes used to identify the items and services that may qualify for the exceptions in § 411.355(g) (regarding EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations and vaccines).

We will consider comments for the codes listed in Tables 20 and 21 below, if we receive them by the date specified in the **DATES** section of this final rule. We will not consider any comment that advocates a substantive change to any of the DHS defined in § 411.351.

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TABLE 20: ADDITIONS TO THE PHYSICIAN SELF-REFERRAL

HCPCS/CPT[1] CODES	
CLINICAL LABORATORY SERVICES	
0064T	Spectroscop eval expired gas
0085T	Breath test heart reject
0087T	Sperm eval hyaluronan
36415	Routine venipuncture
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY SERVICES	
97597	Active wound care/20cm or <
97598	Active wound care > 20cm
97605	Neg press wound tx, < 50 cm
97606	Neg press wound tx, > 50 cm
G0329	Electromagntic tx for ulcers
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES	
76077	Dxa bone density/v-fracture
76510	Ophth us, b & quant a
76820	Umbilical artery echo
76821	Middle cerebral artery echo

93890 Tcd, vasoreactivity study

93892 Tcd, emboli detect w/o inj

0067T Ct colonography;dx

Q0092 Set up port xray equipment

RADIATION THERAPY SERVICES AND SUPPLIES

19296 Place po breast cath for rad

19297 Place breast cath for rad

19298 Place breast rad tube/caths

57155 Insert uteri tandems/ovoids

58346 Insert Heyman uteri capsule

0073T Delivery, comp imrt

0082T Stereotactic rad delivery

0083T Stereotactic rad tx mngmt

DRUGS USED BY PATIENTS UNDERGOING DIALYSIS

[no additions]

PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES

80061 Lipid panel [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]

82465 Assay, bld/serum cholesterol [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]

82947 Assay, glucose, blood quant [only when billed with ICD-9-CM code V77.1]

82950 Glucose test [only when billed with ICD-9-CM code V77.1]

82951 Glucose tolerance test (GTT) [only when billed with ICD-9-CM code V77.1]

83718 Assay of lipoprotein [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]

84478 Assay of triglycerides [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]

90656 Flu vaccine no preserv 3 & >

[1]CPT codes and descriptions only are copyright 2004 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 21: DELETIONS TO THE PHYSICIAN SELF-REFERRAL HCPCS/CPT[1] CODES

CLINICAL LABORATORY SERVICES

G0001 Drawing blood for specimen

PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY SERVICES

97601 Wound(s) care, selective

RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES

[no deletions]

RADIATION THERAPY SERVICES AND SUPPLIES

50559 Renal endoscopy/radiotracer

DRUGS USED BY PATIENTS UNDERGOING DIALYSIS

[no deletions]

PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES

[no deletions]

[1]CPT codes and descriptions only are copyright 2004 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

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The additions specified in Table 20 generally reflect new CPT and HCPCS codes that become effective January 1, 2005 or that became effective since our last update. It also reflects the addition of codes that will be recognized by Medicare for payment purposes effective January 1, 2005.

Additionally, we are adding HCPCS code Q0092 to the category of radiology and certain other imaging services since it may be billed in conjunction with the provision of portable x-ray services and had been inadvertently omitted.

We are also adding two existing brachytherapy codes (CPT 57155 and 58346) to the category of radiation therapy services and supplies. As noted in the March 26, 2004 Phase II physician self-referral interim final rule (69 FR at 16104–16105), brachytherapy is a DHS. We inadvertently omitted these codes when compiling the Code List.

Table 20 also reflects the addition of a flu vaccine code (CPT 90656), CV screening blood tests (CPT 80061, 82465, 83718 and 84478) and diabetes screening tests (CPT 82947, 82950 and 82951) to the list that identifies preventive screening tests, immunizations and vaccines that may qualify for the exception described in § 411.355(h) for such items and services. The physician self-referral prohibition will not apply to these services if the conditions set forth in § 411.355(h) are satisfied. We note that CPT codes 80061, 82465, 83718, 84478, 82947, 82950, and 82951 are eligible for the exception at § 411.355(h) only when billed with the appropriate screening diagnosis codes specified on the Code List for each test.

Table 21 reflects the deletions necessary to conform the Code List to the most recent publications of CPT and HCPCS codes.

VIII. Physician Fee Schedule Update for Calendar Year 2005

A. Physician Fee Schedule Update

The physician fee schedule update is determined using a formula specified by statute. Under section 1848(d)(4) of the Act, the update is equal to the product of 1 plus the percentage increase in the MEI (divided by 100) and 1 plus the update adjustment factor (UAF). For CY 2005, the MEI is equal to 3.1 percent (1.031). The UAF is −7.0 percent (0.930). Section 1848(d)(4)(F) of the Act requires an additional 0.8 percent (1.008) increase to the update for 2005. The product of the MEI (1.031), the UAF (0.930), and the statutory adjustment factor (1.008) equals the CY 2005 update of −3.3 percent (0.967). However, section 601 of the MMA amended section 1848(d) of the Act to specify that the update to the single CF for 2005 cannot be less than 1.5 percent. Because the statutory formula will yield an update of −3.3 percent, consistent with section 601 of the MMA, we are establishing a 2005 physician fee schedule update of 1.5 percent.

Our calculations of all of the above figures are explained below.

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

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has 2000 base year weights, is comprised of two broad categories: physician's own time and physician's practice expense.

The physician's own time component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: wages and salaries, and fringe benefits.

The physician's practice expense category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. The physician's practice expense component also includes the following categories of nonlabor inputs: office expense, medical materials and supplies, professional liability insurance, medical equipment, professional car, and other expenses. The components are adjusted to reflect productivity growth in physicians' offices by the 10-year moving average of multifactor productivity in the private nonfarm business sector. The Table 22 below presents a listing of the MEI cost categories with associated weights and percent changes for price proxies for the 2005 update. For calendar year 2005, the increase in the MEI is 3.1 percent, which includes a 0.9 percent change in the 10-year moving average of multifactor productivity. This result is the result of a 3.0 percent increase in Physician's Own Time and a 5.2 percent increase in Physician's Practice Expense. Within the Physician's Practice Expense, the largest increase occurred in Professional Liability Insurance, which increased 23.9 percent.

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TABLE 22:

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005[1]		
Cost Categories and Price Measures	CY 2000 Weights[2]	CY 2005 Percent Changes
Medicare Economic Index Total, productivity adjusted	n/a	3.1
Productivity: 10-year moving average of multifactor productivity, private nonfarm business sector*	n/a	0.9
Medicare Economic Index Total, without productivity adjustment	100.000	4.0
1. Physician's Own Time[3]	52.466	3.0
a. Wages and Salaries: Average Hourly Earnings, private nonfarm	42.730	2.1
b. Fringe Benefits: Employment Cost Index, benefits, private nonfarm	9.735	6.8
2. Physician's Practice Expense[3]	47.534	5.2
a. Nonphysician Employee Compensation	18.653	3.8
1. Wages and Salaries: Employment Cost Index, wages and salaries, weighted by occupation	13.808	3.0

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005[1]		
2. Fringe Benefits: Employment Cost Index, fringe benefits, white collar	4.845	6.1
b. Office Expense: Consumer Price Index for Urban Areas (CPI-U), housing	12.209	2.3
c. Drugs and Medical Materials and Supplies	4.319	4.0
1. Medical Materials and Supplies: Producer Price Index (PPI), surgical appliances and supplies/CPI-U, medical equipment and supplies (equally weighted)	2.011	2.0
2. Pharmaceuticals: Producer Price Index (PPI ethical prescription drugs)	2.308	5.6
d. Professional Liability Insurance: Professional liability insurance premiums[4]	3.865	23.9
e. Medical Equipment: PPI, medical instruments and equipment	2.055	1.9
f. Other Expenses	6.433	1.4

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005[1]
* As of September 22, 2004, Bureau of Labor Statistics had not released the estimates of nonfarm multifactor productivity growth for 2002. Therefore, we used the most recently available information (thru CY 2001) to develop the productivity adjustment for the CY 2005 update. This produces a productivity adjustment that is equivalent to the one used in the CY 2004 update.
1 The rates of historical change are estimated for the 12-month period ending June 30, 2004, which is the period used for computing the CY 2005 update. The price proxy values are based upon the latest available Bureau of Labor Statistics data as of September 22, 2004.
2 The weights shown for the MEI components are the 2000 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2000. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2000 weight. The sum of these products (weights multiplied by the price index levels) over all cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.
3 The measures of productivity, average hourly earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics website- *http://stats.bls.gov*.

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005[1]	
4	Derived from data collected from several major insurers (the latest available historical percent change data are for the period ending second quarter of 2004).
n/a	Productivity is factored into the MEI categories as an adjustment to the price variables; therefore, no explicit weight exists for productivity in the MEI.

C. The Update Adjustment Factor

Section 1848(d) of the Act provides that the physician fee schedule update is equal to the product of the MEI and a UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as ''allowed expenditures'') equal. Allowed expenditures are equal to actual expenditures in a base period updated each year by the sustainable growth rate (SGR). The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act.

1. Calculation Under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with 2001 is equal to the sum of the following—

• Prior Year Adjustment Component. An amount determined by—

+ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;

+ Dividing that difference by the amount of the actual expenditures for those services for that year; and

+ Multiplying that quotient by 0.75.

• Cumulative Adjustment Component. An amount determined by—

+ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;

+ Dividing that difference by actual expenditures for those services for the prior year as increased by the sustainable growth rate for the year for which the update adjustment factor is to be determined; and

+ Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. Section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (2005 in this case), the current CY (2004) and the preceding CY (2003) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures are initially estimated and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the final revision to 2003 allowed expenditures in this final rule). Once the SGR and allowed expenditures for a year have been revised twice, they are final.

Table 23 shows annual and cumulative allowed expenditures for physicians' services from April 1, 1996 through the end of the current CY, including the transition period to a CY system that occurred in 1999. Also shown is the SGR corresponding with each period. The calculation of the SGR is discussed in detail below.

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TABLE 23:

Period	Annual Allowed Expenditures ($ in billions)	Annual Actual Expenditures ($ in billions)	Cumulative Allowed Expenditures ($ in billions)	Cumulative Actual Expenditures ($ in billions)	FY/CY SGR
4/1/96-3/31/97	$48.9	$48.9	$48.9	$48.9	N/A
4/1/97-3/31/98	50.5	49.4	99.4	98.4	FY 1998=3.2%
4/1/98-3/31/99	52.6	50.5	152.0	148.9	FY 1999=4.2%
1/1/99-3/31/99	13.3	13.1	([1])	148.9	FY 1999=4.2%
4/1/99-12/31/99	42.1	39.5	([2])	188.4	FY 2000=6.9%
1/1/99-12/31/99	55.3	52.6	194.1	188.4	FY 1999/2000[(3)]
1/1/00-12/31/00	59.4	58.1	253.4	246.5	CY 2000=7.3%
1/1/01-12/31/01	62.0	66.3	315.5	312.9	CY 2001=4.5%
1/1/02-12/31/02	67.2	71.0	382.6	383.8	CY 2002=8.3%
1/1/03-12/31/03	72.1	76.8	454.6	460.6	CY 2003=7.3%
1/1/04-12/31/04	77.1	84.9	531.8	545.5	CY 2004=7.0%

1/1/05-12/31/05	80.4	N/A	612.2	N/A	CY 2005=4.3%

(1) Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.

(2) Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

(3) Allowed expenditures in the first year (April 1, 1996--March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our website under the Medicare Office of the Actuary's (OACT) publications at the following address: http://www.cms.hhs.gov/statistics/actuary/. We expect to update the website with the most current information later this month.

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Consistent with section 1848(d)(4)(E) of the Act, Table 23 includes our final revision of allowed expenditures for 2003, a recalculation of allowed expenditures for 2004, and our initial estimate of allowed expenditures for 2005. To determine the update adjustment factor for 2005, the statute requires that we use allowed and actual expenditures from April 1, 1996 through December 31, 2004 and the 2005 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making further revisions to the 2004 and 2005 SGRs

and 2004 and 2005 allowed expenditures. Because we have incomplete actual expenditure data for 2004, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the update adjustment factor for future years.

We are using figures from Table 23 in the statutory formula illustrated below:

UAF = Update Adjustment Factor
$Target_{04}$ = Allowed Expenditures for 2004 or $77.1 billion
$Actual_{04}$ = Estimated Actual Expenditures for 2004 = $84.9 billion
$Target_{4/96–12/04}$ = Allowed Expenditures from 4/1/1996–12/31/2004 = $531.8 billion
$Actual_{4/96–12/04}$ = Estimated Actual Expenditures from 4/1/1996–12/31/2003 = $545.5 billion
SGR_{05} = 4.3 percent (1.043)

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than −0.070 or greater than 0.03. Since −0.120 is less than −0.070, the UAF for 2005 will be −0.070.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding 1 to −0.070 makes the update adjustment factor equal to 0.930.

IX. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

A. Medicare Sustainable Growth Rate

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the physician fee schedule update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with 2001) is equal to the product of the following four factors:

(1) The estimated change in fees for physicians' services.

(2) The estimated change in the average number of Medicare fee-for-service beneficiaries.

(3) The estimated projected growth in real GDP per capita.

(4) The estimated change in expenditures due to changes in law or regulations.

In general, section 1848(f)(3) of the Act requires us to publish SGRs for 3 different time periods, no later than November 1 of each year, using the best data available as of September 1 of each year. Under section 1848(f)(3)(C)(i) of the Act, the SGR is estimated and subsequently revised twice (beginning with the FY and CY 2000 SGRs) based on later data. (There were also provisions in the Act to adjust the FY 1998 and FY 1999 SGRs. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs). Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the preliminary estimate. In this final rule, we are making our preliminary estimate of the 2005 SGR, a revision to the 2004 SGR, and our final revision to the 2003 SGR.

B. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute indicates that ''the term ''physicians' services'' includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee.'' We published a definition of physicians' services for use in the SGR in the **Federal Register** (66 FR 55316) on November 1, 2001. We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. For purposes of determining allowed expenditures, actual expenditures, and SGRs through December 31, 2002, we have specified that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified):

- Physicians' services.
- Services and supplies furnished incident to physicians' services.
- Outpatient PT services and outpatient OT services.
- Antigens prepared by, or under the direct supervision of, a physician.
- Services of PAs, certified registered nurse anesthetists, CNMs, clinical psychologists, clinical social workers, NPs, and CNSs.
- Screening tests for prostate cancer, colorectal cancer, and glaucoma.
- Screening mammography, screening pap smears, and screening pelvic exams.
- Diabetes outpatient self-management training services.
- Medical nutrition therapy services.
- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).
- X-ray, radium, and radioactive isotope therapy.
- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.
- Bone mass measurements.

Sections 611 through 613 of the MMA, respectively, modified section 1861(s) of the Act to add Medicare coverage for an initial preventive exam,

CV screening blood tests, and diabetes screening tests. We believe that these services are commonly performed or furnished by a physician or in a physician's office and are including them in the definition of physicians' services for purposes of the SGR.

Comment: We received a number of comments requesting that we use our administrative authority to remove drugs from the SGR. According to one of these comments, drugs are not physicians' services and should never have been included in the SGR. One of these comments indicated that the SGR ''is a seriously flawed formula that will continue to require frequent Congressional intervention to avoid payment cuts * * *'' According to this comment, ''the Administration should reduce the price tag and help pave the way for an appropriate long-term solution by removing drugs from the SGR pool.'' We also received a number of comments suggesting that we use our administrative authority to adjust the SGR for changes in spending associated with national coverage determinations (NCDs).

Response: We remain concerned about forecasts of reductions in physician fees and will carefully consider the issues raised by the comments when we make changes to the physician fee schedule for 2006. We believe that the physician payment system should be structured to control costs and achieve predictable and stable changes to Medicare's rates while being equitable to physicians. We note that administrative changes affecting the SGR would have significant long-term cost implications but will not have an impact on the update for 2006 or the subsequent few years. Therefore, without a statutory change, there will still be a reduction in physicians' fee schedule rates for 2006 and subsequent years. Towards those goals, we have already taken several actions that will improve Medicare's physician payment system:

- Using multifactor productivity in place of labor productivity in the MEI beginning in 2003. This change increased the physician fee schedule update by 0.7 percentage points for 2003 and was estimated to increase Medicare spending by $14.5 billion over 10 years.
- Increasing the weight of malpractice costs in the MEI from 3.2 to 3.9 percent, a 21 percent increase beginning in 2004.
- Incorporating an increase in malpractice premiums of 16.9 percent into the 2004 MEI and 23.9 percent into the 2005 MEI. The increased weight for malpractice in the MEI makes the index a more accurate representation of inflation in physician office costs.

C. Preliminary Estimate of the SGR for 2005

Our preliminary estimate of the 2005 SGR is 4.3 percent. We first estimated the 2005 SGR in March and made the estimate available to the Medicare Payment Advisory Commission and on our Web site. Table 24 shows that March 2004 and our current estimates of the factors included in the 2005 SGR.

TABLE 24:

Statutory Factors	March Estimate	Current Estimate
Fees	2.6 percent (1.026)	1.3 percent (1.013)
Enrollment	-0.2 percent (0.998)	-0.3 percent (0.997)
Real Per Capita GDP	2.2 percent (1.022)	2.2 percent (1.022)
Law and Regulation	0.0 percent (1.000)	1.0 percent (1.010)
Total	4.6 percent (1.046)	4.3 percent (1.043)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.013 \times 0.997 \times 1.022 \times 1.010 = 1.37$). A more detailed explanation of each figure is provided below in section H.1.

D. Revised Sustainable Growth Rate for 2004

Our current estimate of the 2004 SGR is 7.0 percent. Table 25 shows our preliminary estimate of the 2004 SGR that was published in the **Federal Register** on November 7, 2003 (68 FR 63249) and our current estimate.

TABLE 25:

Statutory Factors	November 7, 2003 Estimate	Current Estimate
Fees	2.7 percent (1.027)	1.4 percent (1.014)
Enrollment	1.7 percent (1.017)	1.7 percent (1.017)
Real Per Capita GDP	2.8 percent (1.028)	2.2 percent (1.022)
Law and Regulation	0.0 percent (1.000)	1.5 percent (1.015)
Total	7.4 percent (1.074)	7.0 percent (1.070)

A more detailed explanation of each figure is provided below in section H.2.

E. Final Sustainable Growth Rate for 2003

The SGR for 2003 is 7.3 percent. Table 26 shows our preliminary estimate of the SGR published in the **Federal Register** on December 31, 2002 (67 FR 80027), our revised estimate published in the **Federal Register** on November 7, 2003 (67 FR 63249) and the final figures

determined using the latest available data.

TABLE 26:

Statutory Factors	12/31/02 Estimate	11/7/03 Estimate	Final
Fees	2.9 percent (1.029)	2.8 percent (1.028)	2.8 percent (1.028)
Enrollment	1.2 percent (1.012)	2.4 percent (1.024)	2.3 percent (1.023)
Real Per Capita GDP	3.3 percent (1.033)	1.4 percent (1.014)	2.0 percent (1.020)
Law and Reg	0.0 percent (1.000)	0.0 percent (1.000)	0.0 percent (1.000)
Total	7.6 percent (1.076)	6.7 percent (1.067)	7.3 percent (1.073)

A more detailed explanation of each figure is provided below in section H.2.

F. Calculation of 2005, 2004, and 2003 Sustainable Growth Rates

1. Detail on the 2005 SGR

All of the figures used to determine the 2005 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent physician fee schedule updates.

Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2005

This factor is calculated as a weighted average of the 2005 fee increases for the different types of services included in the definition of physicians' services for the SGR. Medical and other health services paid using the physician fee schedule are estimated to account for approximately 83.9 percent of total allowed charges included in the SGR in 2005 and are updated using the MEI. The MEI for 2005 is 3.1 percent. Diagnostic laboratory tests are estimated to represent approximately 7.1 percent of Medicare allowed charges included in the SGR for 2005. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI–U). However, section 629 of the MMA specifies that diagnostic laboratory services will receive an update of 0.0 percent from 2004 through 2008.

Drugs are estimated to represent 9.0 percent of Medicare allowed charges included in the SGR in 2005. As indicated earlier in this final rule, sections 303 and 304 of the MMA require Medicare to pay for most drugs at 106 percent of ASP beginning January 1, 2005. We estimated a weighted average change in fees for drugs included in the SGR using the ASP plus 6 percent pricing methodology of −14.7 percent for 2005. Table 27 shows the weighted average of the MEI, laboratory and drug price changes for 2005.

TABLE 27:

	Weight	Update
Physician	0.839	3.1
Laboratory	0.071	0.0
Drugs	0.090	-14.7
Weighted Average	1.000	1.3

We estimate that the weighted-average increase in fees for physicians' services in 2005 under the SGR (before applying any legislative adjustments) will be 1.3 percent.

Factor 2—The Percentage Change in the Average Number of Part B Enrollees From 2004 to 2005

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from 2004 to 2005. Services provided to Medicare+Choice (M+C) plan enrollees are outside the scope of the SGR and are excluded from this estimate. OACT estimates that the average number of Medicare Part B fee-for-service enrollees will decrease by 0.3 percent from 2004 to 2005. Table 28 illustrates how this figure was determined.

TABLE 28:

	2004	2005
Overall	39.041 million	39.547 million
Medicare+Choice	4.671 million	5.275 million
Net	34.370 million	34.272 million
Percent Increase		-0.3 percent

An important factor affecting fee-for-service enrollment is beneficiary enrollment in M+C plans. Because it is difficult to estimate the size of the M+C enrollee population before the start of a calendar year, at this time we do not know how actual enrollment in M+C plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for 2005 becomes known.

Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in 2005

We estimate that the growth in real per capita GDP from 2004 to 2005 will be 2.2 percent. Our past experience indicates that there have also been large changes in estimates of real per capita GDP growth made before the year begins and the actual change in GDP computed after the year is complete. Thus, it is likely that this figure will change as actual information on economic performance becomes available to us in 2005.

Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in CY 2005 Compared With CY 2004

There are a number of statutory provisions that will affect the 2005 SGR. As indicated above, sections 303 and 304 of the MMA changed Medicare payment for drugs. These provisions also changed Medicare payments for the administration of drugs. Section 303(a)(1) amended section 1848(c)(2) of the Act to require the Secretary to make a number of changes that increased Medicare payment for drug administration beginning January 1, 2004. These changes permanently increased Medicare payments for drug administration by a weighted average of 110 percent. Section 303(a)(4) of the MMA required an additional transitional adjustment (temporary increase) to Medicare's payment for drug administration of 32 percent for 2004 and 3 percent for 2005. The change in the transitional adjustment of 32 percent for 2004 to 3 percent for 2005 would reduce Medicare payments for drug administration between 2004 and 2005. However, some of this reduction will be lessened because we are also adopting changes to the codes and payment amounts for drug administration based on recommendations from the AMA's CPT Editorial Panel and Relative Value Update Committee (RUC), under the authority of section 1848(c)(2)(J) of the Act. We are further increasing physician fee schedule payments by paying separately for injections provided on the same day as another physician fee schedule service. We are further increasing physician fee schedule payments by paying separately for injections provided on the same day as another physician fee schedule service. We estimate that changes to our policy on injections and the changes to our drug administration payments taken together will increase physician spending by 0.2 percent.

We are also adjusting the SGR to account for OACT's assumptions about predicted physician behavior in response to the payment reductions. OACT assumes that reduced fees are likely to be met by a combination of an increase in volume and a shift in the mix or intensity of services furnished to Medicare beneficiaries so as to offset 30 percent of the payment reduction that would otherwise occur. Because OACT assumes that physicians will offset some of the loss in payments that will occur from changes in Medicare payments for drugs (as described earlier) and drug administration and the change in payment can be attributed to a change in law, we are increasing the SGR by 0.4 percent for this factor. (Discussion may change based on recent decisions.)

There are several other statutory provisions that are estimated to increase Medicare spending for physicians' services under the SGR. Section 413(a) of the MMA establishes a 5 percent increase in the physician fee schedule payment for services provided in physician scarcity areas. Section 413(b) improves the procedures for paying the 10 percent physician fee schedule bonus payment for services provided in health professional shortage areas. We estimate that the provisions of section 413 will increase Medicare physician fee schedule payments by 0.1 percent.

Sections 611 through 613 of the MMA, respectively, provide Medicare coverage for an initial preventive physical examination, CV and diabetes screening tests. We estimate that new Medicare coverage for these preventive services will increase spending for physicians' services under the SGR by 0.3 percent. Taken together, we estimate that all of the statutory provisions for 2005 will increase Medicare spending for physicians' services by 0.5 percent.

Comment: We received comments concerned that we will underestimate the costs associated with the initial preventive physical examination. These comments suggested that we should account for ''both spending due to use of the new or expanded benefit, as well as additional services triggered by implementation of the new benefit.'' We received other comments concerned that we will underestimate the cost of CV and diabetes screening tests because we will use the national coverage determination (NCD) process to decide if any additional tests may be eligible for coverage. The commenters have this concern because we do not adjust the SGR for NCDs.

Response: Our estimates of the costs of the initial preventive physical exam and the CV and diabetes screening tests account for utilization of other Medicare services (preventive and nonpreventive) that may result from coverage of the new preventive services. We also note that our current estimates of the initial preventive examination and CV and diabetes screening tests are based only on our projections without any data on actual use of the benefits. The statute requires us to revise our current estimate of the 2005 SGR no later than November 1, 2005 and to make a final revision to our estimate no later than November 1, 2006. At the time we make the final revision to the 2005 SGR, we will have complete data on use of the new preventive services that will enable us to more accurately reflect these costs in the SGR.

With respect to the comments about use of the NCD process to establish additional CV and diabetes screening tests that will be eligible for Medicare coverage, the regulation lists the common types of tests that are currently

used to screen patients for these conditions. Our adjustment to the SGR will cover all of the costs associated with these new Medicare covered screening tests. However, if we use the NCD process to cover additional tests, we will consider this issue further.

2. Detail on the 2004 SGR

A more detailed discussion of our revised estimates of the four elements of the 2004 SGR follows.

Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for 2004

This factor was calculated as a weighted average of the 2004 fee increases that apply for the different types of services included in the definition of physicians' services for the SGR.

We estimate that services paid using the physician fee schedule account for approximately 83.7 percent of total allowed charges included in the SGR in 2004. These services were updated using the 2004 MEI of 2.9 percent. We estimate that diagnostic laboratory tests represent approximately 7.1 percent of total allowed charges included in the SGR in 2004. Medicare payments for these tests are updated by the CPI–U. However, section 629 of the MMA specifies that diagnostic laboratory services will receive an update of 0.0 percent from 2004 through 2008. We estimate that drugs represent 9.2 percent of Medicare allowed charges included in the SGR in 2004. Historically, Medicare paid for drugs under section 1842(o) of the Act at 95 percent of average wholesale price (AWP). However, with some exceptions, sections 303 and 304 of the MMA generally require Medicare to pay for drugs at 85 percent of the AWP determined as of April 1, 2003 or a specified percentage of AWP based on studies by the Government Accountability Office and the Office of the Inspector General in 2004. (We implemented section 303 and 304 of the MMA in an interim final rule published in the **Federal Register** on January 7, 2004 (see 69 FR 1086). Taking sections 303 and 304 of the MMA into account, we estimate a weighted average change in fees for drugs included in the SGR of −11.7 percent for 2004. Table 29 shows the weighted average of the MEI, laboratory and drug price changes for 2004.

TABLE 29:

	Weight	Update
Physician	0.837	2.9
Laboratory	0.071	0.0
Drugs	0.092	-11.7
Weighted Average	1.000	1.4

After taking into account the elements described in Table 29, we estimate that the weighted-average increase in fees for physicians' services in 2004 under the SGR (before applying any legislative adjustments) will be 1.4 percent. Our November 7, 2003 estimate of this factor was 2.7 percent. The reduction from 2.7 percent to our current estimate of 1.4 percent is primarily due to application of the drug pricing changes required by sections 303 and 304 of the MMA.

Factor 2—The Percentage Change in the Average Number of Part B Enrollees From 2003 to 2004

OACT estimates that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in M+C plans) increased by 1.7 percent in 2004. Table 30 illustrates how we determined this figure.

TABLE 30:

	2003	2004
Overall	38.465 million	39.041 million
Medicare+Choice	4.655 million	4.671 million
Net	33.810 million	34.370 million
Percent Increase		1.7 percent

OACT's estimate of the 1.7 percent change in the number of fee-for-service enrollees, net of M+C enrollment for 2004 compared to 2003, is the same as our original estimate published in the November 7, 2003 final rule (68 FR 63250). While our current projection based on data from 8 months of 2004 is the same as our original estimate when we had no data, it is still possible that our final estimate of this figure will be different once we have complete information on 2004 fee-for-service enrollment.

Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in 2004

We estimate that the growth in real per capita GDP will be 2.2 percent for 2004. Our past experience indicates that there have also been large differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is likely that this figure will change further as complete actual information on 2004 economic performance becomes available to us in 2005.

Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in 2004 Compared With 2003

There are four statutory provisions that are increasing 2004 Medicare spending relative to 2003. Section 412 of the MMA established a floor of 1.0 on adjustments to the physician work relative value unit for the geographic practice cost index (GPCI) for the years 2004 through 2006. Section 602 of the MMA increases the GPCIs for work, practice expense, and malpractice in Alaska to 1.67. Because these provisions increase the work GPCIs that are below 1.0 to 1.0 and, for services in Alaska, we estimate that sections 412 and 602 of the MMA are increasing 2004 Medicare spending included in the SGR by 0.6 percent. Sections 303 and 304 of the MMA increased Medicare's payments for drug administration in 2004. It further exempted the increases in payment from the budget neutrality provisions of section 1848(c)(2) of the Act. We estimate the section 303 and 304 provisions will increase spending for physicians' services by 0.8 percent in 2004. Taken together, we estimate that statutory provisions are increasing 2004 spending for physicians' services by 1.5 percent (after accounting for rounding).

3. Detail on the 2003 SGR

A more detailed discussion of our revised estimates of the four elements of the 2003 SGR follows.

Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for 2003

This factor was calculated as a weighted average of the 2003 fee increases that apply for the different types of services included in the definition of physicians' services for the SGR.

Services paid using the physician fee schedule accounted for approximately 83.0 percent of total Medicare allowed charges included in the SGR for 2003 and are updated using the MEI. The MEI for 2003 was 3.0 percent. Diagnostic laboratory tests represent approximately 7.2 percent of total Medicare allowed charges included in the SGR and are updated by the CPI–U. The CPI–U applied to payments for laboratory services for 2003 was 1.1 percent. Drugs represented approximately 9.8 percent of total Medicare allowed charges included in the SGR for 2003. According to section 1842(o) of the Act, Medicare pays for drugs based on 95 percent of AWP. Using wholesale pricing information and Medicare utilization for drugs included in the SGR, we estimate a weighted average fee increase for drugs of 1.9 percent for 2003. Table 31 shows the weighted average of the MEI, laboratory, and drug price increases for 2003.

TABLE 31:

	Weight	Update
Physician	0.830	3.0
Laboratory	0.072	1.1
Drugs	0.098	1.9
Weighted Average	1.000	2.8

After taking into account the elements described in Table 31, we estimate that the weighted-average increase in fees for physicians' services in 2003 under the SGR (before applying any legislative adjustments) was 2.8 percent.

Factor 2—The Percentage Change in the Average Number of Part B Enrollees From 2002 to 2003

We estimate the increase in the number of fee-for-service enrollees (excluding beneficiaries enrolled in M+C plans) from 2002 to 2003 was 2.3 percent. Our calculation of this factor is based on complete data from 2003. Table 32 illustrates the calculation of this factor.

TABLE 32:

	2002	2003
Overall	38.049 million	38.465 million
Medicare+Choice	5.005 million	4.655 million
Net	33.044 million	33.810 million
Percent Increase		2.3 percent

Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in 2003

We estimate that the growth in real per capita GDP was 2.0 percent in 2003. This figure is a final one based on complete data for 2003.

Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in 2003 Compared With 2002

There are no statutory or regulatory changes that affect Medicare expenditures for services included in the SGR in 2003.

X. Anesthesia and Physician Fee Schedule Conversion Factors (CF) for Calendar Year 2005

The 2005 physician fee schedule CF will be $37.8975. The 2005 national average anesthesia conversion factor is $17.7594.

Physician Fee Schedule Conversion Factor

Under section 1848(d)(1)(A) of the Act, the physician fee schedule CF is equal to the CF for the previous year multiplied by the update determined under section 1848(d)(4) of the Act. Using this formula would result in a 3.3 percent reduction to the physician fee schedule CF for 2005. However, section 601 of the MMA amended section 1848(d) of the Act to specify that the update to the single CF for 2004 and 2005 will not be less than 1.5 percent. Because the statutory formula will yield a 3.3 percent reduction to the 2005 physician fee schedule CF and the amendments to the statute indicate that the update for 2005 cannot be less than 1.5 percent, we are increasing the physician fee schedule conversion factor by 1.5 percent.

We illustrate the calculation for the 2005 physician fee schedule CF in Table 33 below.

TABLE 33:

2004 Conversion Factor	$37.3374
2005 Update	1.5 percent (1.015)
2005 Conversion Factor	$37.8975

• *Anesthesia Fee Schedule Conversion Factor*

Anesthesia services do not have RVUs like other physician fee schedule services. Therefore, we account for any necessary RVU adjustments through an adjustment to the anesthesia fee schedule CF. The only adjustment we are applying to the anesthesia fee schedule CF for 2005 is the physician fee schedule update. We used the following figures to determine the anesthesia fee schedule CF (see Table 34).

TABLE 34:

2004 Anesthesia Conversion Factor	$17.4969
2005 Update	1.5 percent (1.0150)
2005 Anesthesia Conversion Factor	$17.7594

XI. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001 through December 31, 2002, at $20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2005 is 3.1 percent.

Therefore, for CY 2005, the payment amount for HCPCS code ''Q3014, telehealth originating site facility fee'' is 80 percent of the lesser of the actual charge or $21.86. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 35.

TABLE 35:

Facility Fee	MEI Increase	Period
$20.00	N/A	10/01/2001 - 12/31/2002
$20.60	3.0%	01/01/2003 - 12/31/2003
$21.20	2.9%	01/01/2004 - 12/31/2004
$21.86	3.1%	01/01/2005 - 12/31/2005

XII. Provisions of the Final Rule

The provisions of this final rule restate the provisions of the August 2004 proposed rule, except as noted elsewhere in the preamble.

XIII. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds

good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that providing a notice and comment procedure with regard to the RNHCI home benefit would be contrary to the public interest. The RNHCI home benefit provisions were added by the Congress to get a RNHCI benefit to those beneficiaries who are confined to the home. We believe that the Congress intended to provide the benefit to the homebound RNHCI beneficiaries as means of providing a similar home option as is offered to the general Medicare population. However, this expanded benefit is, by statute, a time limited benefit. Any delay in implementation could prevent beneficiaries from utilizing this expanded benefit at all or could seriously impinge on the amount of time they can use the benefit. Therefore, we find good cause to waive notice and comment procedures as contrary to the public interest with regard to the RNHCI home benefit. We are, however, providing a 60-day period for public comment.

XIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

Section 403.766 Requirements for Coverage/Payment of Home Services

In summary, § 403.766 states the RNHCI provider must submit a written letter of intent to us if they choose to participate in offering the home service benefit.

The burden associated with this requirement is the time and effort of the RNHCI provider to prepare and submit a letter of intention. It is estimated that this two-sentence letter should take no longer than 15 minutes to prepare and submit. There are currently 16 RNHCI providers and, if all elected to participate, it would result in a one-time burden of 4 hours.

We have submitted a copy of this final rule with comment to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

Section 410.16 Initial Preventive Physical Examination: Conditions for Limitations on Coverage

In summary, § 410.16 requires the furnishing of education, counseling and referral services as part of an initial preventive physical examination, a written plan for obtaining the appropriate screening and other preventive services which are also covered as separate Medicare B Part services.

The burden associated with this requirement is the time required of the physician or practitioner to provide beneficiaries with education, counseling, and referral services and to develop and provide a written plan for obtaining screening and other preventive services.

While these requirements are subject to the PRA; we believe the burden associated with these requirements to be usual and customary business practice; therefore, the burden for this collection requirement is exempt under 5 CFR 1320.3(b)(2)&(3).

Section 411.404 Criteria for Determining That a Beneficiary Knew That Services Were Excluded From Coverage as Custodial Care or as Not Reasonable and Necessary

In summary, § 411.404 requires that written notice must be given to a beneficiary, or someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

Although this section is subject to the PRA, the burden associated with this requirement is currently captured and accounted for in two currently approved information collections under OMB numbers 0938–0566 and 0938–0781.

Section 418.205 Special Requirements for Hospice Pre-Election Evaluations and Counseling Services

In summary, § 418.205 states that written documentation is required and must be maintained for referral requests and services furnished.

While these information collection requirements are subject to the PRA, the burden associated with them is exempt as defined in 5 CFR 1320.3(b)(2).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services Office of Strategic Operations and Regulatory Affairs, Attn: Melissa Musotto (CMS–1429–FC) Room C5–13–28, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer (CMS–1429–P), *Christopher Martin@omb.eop.gov.* FAX (202) 395–6974.

XV. Response to Comments

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

XVI. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for final rules with economically significant effects (that is, a final rule that would have an annual effect on the economy of $100 million or more in any 1 year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities).

As indicated in more detail below, we expect that the physician fee schedule provisions included in this final rule will redistribute more than $100 million in 1 year. We also anticipate that the combined effect of several provisions of the MMA implemented in this final rule will increase spending by more than $100 million. Other MMA provisions implemented in this final rule are expected to reduce spending by more than $100 million. We are considering this final rule to be economically significant because its provisions are expected to result in an increase, decrease or aggregate redistribution of Medicare spending that will exceed $100 million. Therefore, this final rule is a major rule and we have prepared a regulatory impact analysis.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this final rule would have minimal impact on small hospitals located in rural areas. Of 517 hospital-based ESRD facilities located in rural areas, only 40 are affiliated with hospitals with fewer than 100 beds.

For purposes of the RFA, physicians, nonphysician practitioners, and suppliers are considered small businesses if they generate revenues of $6 million or less. Approximately 95 percent of physicians are considered to be small entities. There are about 875,000 physicians, other practitioners and medical suppliers that receive Medicare payment under the physician fee schedule. There are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. As noted previously in this final rule and described further below, we are implementing significant changes to the payments for drugs.) The 20,000 physicians that receive payments for drugs are generally concentrated in the specialties of oncology, urology, rheumatology and infectious disease. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent in urology.

For purposes of the RFA, approximately 98 percent of suppliers of durable medical equipment (DME) and prosthetic devices are considered small businesses according to the Small Business Administration's (SBA) size standards. We estimate that 106,000 entities bill Medicare for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) each year. Total annual estimated Medicare revenues for DME suppliers exceed approximately $4.0 billion. Of this amount, approximately $1.6 billion are for DME drugs. These suppliers will be affected by the payment changes being made in this final rule for drugs.

In addition, most ESRD facilities are considered small entities, either based on nonprofit status, or by having revenues of $29 million or less in any year. We consider a substantial number of entities to be affected if the rule is estimated to impact more than 5 percent of the total number of small entities. Based on our analysis of the 785 nonprofit ESRD facilities considered small entities in accordance with the above definitions, we estimate that the combined impact of the changes to payment for renal dialysis services included in this rule would have a 1.6 percent increase in payments relative to current composite rate payments.

The analysis and discussion provided in this section, as well as elsewhere in this final rule, complies with the RFA requirements. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. Medicare beneficiaries are considered to be part of the private sector for this purpose. The net impact of the provisions of this rule, including those related to the MMA, are estimated to result in a savings to beneficiaries of nearly $485 million for FY 2005. However, we note that this savings figure compares FY 2005 beneficiary costs occurring as a result of provisions of this final rule to FY 2005 estimated beneficiary costs in the absence of final rule implementation (that is, the savings figure compare beneficiary costs with implementation of the ASP drug payment provisions to continuing the AWP drug payment methodology). The specific effects of the provisions being implemented in this final rule are explained in greater detail below.

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

We have prepared the following analysis, which, together with the information provided in the rest of this preamble, meets all assessment requirements. It explains the rationale for and purposes of the rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we use to minimize the burden on small entities. As indicated elsewhere in this final rule, we are refining resource-based practice expense RVUs and making a variety of other changes to our regulations, payments, or payment policy to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. We are also implementing several changes resulting from the MMA, including changes to Medicare payment rates for outpatient drugs, changes to the payment for renal dialysis services, creating new preventive health care benefits and creating incentive payment program improvements for physician scarcity.

We are providing information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

A. Resource-Based Practice Expense and Malpractice Relative Value Units

Under section 1848(c)(2) of the Act, adjustments to RVUs may not cause the amount of expenditures to differ by more than $20 million from the amount of expenditures that would have resulted without such adjustments. We are implementing several changes that would result in a change in expenditures that would exceed $20 million if we made no offsetting adjustments to either the conversion factor or RVUs.

With respect to practice expense RVUs, our policy has been to meet the budget-neutrality requirements in the statute by incorporating a rescaling adjustment in the practice expense methodologies. That is, we estimate the aggregate number of practice expense RVUs that will be paid under current and revised policy in CY 2005. We

apply a uniform adjustment factor to make the aggregate number of revised practice expense RVUs equal the number estimated that would be paid under current policy. While we are continuing to apply this policy for general changes in coding and RVUs, we are increasing aggregate physician fee schedule payments to account for the higher payments for drug administration. These increases in payment are being made under the authority of section 1848(c)(2)(J) of the Act that exempts the changes in payments for drug administration from the budget neutrality requirements of section 1848(c)(2)(B)(iv) of the Act.

Table 36 shows the specialty level impact on payment of the practice expense and malpractice RVU changes being implemented for CY 2005. Our estimates of changes in Medicare revenues for physician fee schedule services compare payment rates for 2005 with payment rates for 2004 using 2003 Medicare utilization for both years. We are using 2003 Medicare claims processed and paid through June 30, 2004, that we estimate are 98.5 percent complete, and have adjusted the figures to reflect a full year of data. Thus, because we are using a single year of utilization, the estimated changes in revenues reflect payment changes only between 2004 and 2005. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown here. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the physician fee schedule. For instance, independent laboratories receive approximately 80 percent of their Medicare revenues from clinical laboratory services that are not paid under the physician fee schedule. The table shows only the payment impact on physician fee schedule services.

The column labeled ''NPRM Impacts'' shows the effect of the changes in payment attributable to practice expense and malpractice RVUs from the proposed rule. (*See* 69 FR 47556 through 47559 for a complete description of the payment changes shown in this column). We have also made some additional changes to the practice expense and malpractice RVUs since the proposed rule in response to comments and additional information that became available to us during the comment period. The additional changes in payment based on further refinements of the practice expense RVUs generally have no specialty level impact. The 1 percent increase in payment for vascular surgery shown in the practice expense refinements column is attributed to substitution of a vascular ultrasound room for a general ultrasound room in the equipment resources for CPT code 93880. Similarly, the increase in practice expense RVUs for diagnostic testing facilities is also attributable to the increase in payment for 93880 and 93925 due to the substitution of a vascular ultrasound room for a general ultrasound room in the equipment resources.

The column labeled ''Additional Malpractice RVU Refinements'' show the additional impact of changes in the malpractice expense RVUs since the proposed rule on total payment for physician fee schedule services. As explained earlier, we are making several changes to malpractice RVUs that will change the impacts we illustrated in the proposed rule. We are removing assistants-at-surgery from the Medicare utilization that goes into determining the malpractice RVUs. Relative to the proposed rule, this change will increase total payments to neurosurgeons by nearly 1 percent. We also increased the ISO risk classification for the all physician crosswalk used for podiatry increasing their payments by 1 percent relative to the proposed rule. Several specialty groups, including dermatology commented that the major surgery risk factor should not be used for the dermatology codes. Relative to the proposed rule, payments to dermatologists will decrease by approximately 1 percent as a result of this change. The changes also increase payment to the specialty of allergy/immunology by nearly 1 percent relative to the proposed rule. This increase occurs because we are setting a minimum value of 0.01 malpractice RVUs. In the proposed rule, we did show malpractice RVUs in Addendum B if the rounded RVU equaled 0.0.

The column labeled ''Immunizations/Injections'' shows the impact of making separate payment for injections provided on the same day as another physician fee schedule service and the increase in payment for immunizations. These changes generally benefit those specialties that provide injections and immunizations in their offices. The provision is estimated to increase payment by 2 percent to family practice and by 1 percent to general practice, geriatrics, internal medicine and pediatrics. The column labeled ''Total'' shows the combined percentage change in payments resulting from the practice expense and malpractice RVU changes including those that were described in the proposed rule and the additional changes we are making in this final rule.

As explained in the proposed rule, the practice expense refinements will reduce payments to audiologists by approximately 4 percent. Virtually all of the reduction in payment is due to the refinement of procedure code 92547. We accepted the PEAC recommendation to reduce the clinical staff time of the audiologist involved in this service from 71 minutes to 1 minute. The refinement of clinical staff and equipment resulted in a reduction from 1.15 to 0.08 practice expense RVUs producing the 4 percent reduction in payments shown in table 37. However, this impact assumes no change in how frequently these services are performed. While we received comments suggesting that the code was valued based on only one occurrence of the service, the commenter asserted that it is typically performed more than once per day. Currently, CPT allows it only to be billed once per day. If CPT were to change its policy and the service was billed more frequently, the impact shown in table 37 would be less than shown here.

In the proposed rule, we estimated that payments to vascular surgeons would increase by 3 percent as a result of the repricing of medical equipment used in performing noninvasive vascular diagnostic tests. As indicated above, the total increase in payments including the additional refinements we made to equipment will make the total increase in payment from RVU changes equal to 4 percent. We originally estimated that payments to interventional radiology would increase by 2 percent due practice expense refinements and the establishment of nonfacility pricing for procedure codes 35470 to 35476. Due to additional practice expense RVU refinements, we are now estimating that the total increase in payments will be 3 percent. We are estimating slightly less than a 3.5 percent increase in payment to oral and maxillofacial surgeons from the refinement of medical supplies for procedure codes 21210 and 21215. The estimated impact for this specialty is slightly less than we were estimating for the proposed rule. As we indicated in the proposed rule, the 1 percent decrease in payment to nurse practitioners and geriatricians is

attributed to the refinement of the nonfacility practice expense RVUs for nursing facility visits (procedure codes 99301 through 99316). These impacts are unchanged from the proposed rule.

As we indicated in the proposed rule, the increases for pathology and independent laboratories result from use of a practice expense survey provided by the College of American Pathology (CAP). The increases in the final rule are similar to the figures we estimated for the proposed rule. We further note that independent laboratories receive approximately 20 percent of their total Medicare revenues from physician fee schedule services. The remaining 80 percent of their Medicare revenues are from clinical diagnostic laboratory services that will be unchanged by use of the CAP survey data. Thus, total Medicare revenues to independent laboratories as a result of using the CAP survey will increase by slightly more than 1 percent (or 20 percent of the 6 percent increase in physician fee schedule revenues). There will be little or no impact on all other specialties from use of the CAP survey.

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TABLE 36:
Impact of Practice Expense and Malpractice RVU Changes on Total Medicare Allowed Charges by Physician, Practitioner and Supplier Subcategory

Specialty	Medicare Allowed Charges ($ in Millions)	NPRM Impacts	Additional Practice Expense Refinements	Additional Malpractice RVU Refinements	Injections Immunizations	Total
Physicians:						
ALLERGY/IMMUNOLOGY	$ 161	-2%	0%	1%	0%	-1%
ANESTHESIOLOGY	$ 1,422	0%	0%	0%	0%	0%
CARDIAC SURGERY	$ 359	0%	0%	1%	0%	1%
CARDIOLOGY	$ 6,579	0%	0%	0%	0%	0%
COLON AND RECTAL SURGERY	$ 110	1%	0%	0%	0%	1%
CRITICAL CARE	$ 130	0%	0%	0%	0%	0%
DERMATOLOGY	$ 1,864	1%	0%	-1%	0%	0%
EMERGENCY MEDICINE	$ 1,687	0%	0%	0%	0%	0%
ENDOCRINOLOGY	$ 279	0%	0%	0%	0%	0%
FAMILY PRACTICE	$ 4,456	0%	0%	0%	2%	1%
GASTROENTEROLOGY	$ 1,634	0%	0%	0%	0%	0%
GENERAL PRACTICE	$ 1,003	0%	0%	0%	1%	1%
GENERAL SURGERY	$ 2,264	1%	0%	0%	0%	1%
GERIATRICS	$ 116	-1%	0%	0%	1%	0%
HAND SURGERY	$ 57	0%	0%	0%	0%	0%
INTERNAL MEDICINE	$ 8,784	0%	0%	0%	1%	1%
INTERVENTIONAL RADIOLOGY	$ 191	2%	1%	0%	0%	3%
NEPHROLOGY	$ 747	1%	0%	0%	0%	1%

NEUROLOGY	$	1,197	0%	0%	0%	0%	0%
NEUROSURGERY	$	492	-1%	0%	1%	0%	0%
NUCLEAR MEDICINE	$	85	0%	0%	0%	0%	0%
OPHTHALMOLOGY	$	4,566	-1%	0%	0%	0%	-1%
ORTHOPEDIC SURGERY	$	2,903	0%	0%	0%	0%	0%
OTOLARNGOLOGY	$	814	0%	0%	0%	0%	0%
PATHOLOGY	$	846	2%	0%	0%	0%	2%
PEDIATRICS	$	60	-1%	0%	0%	1%	0%
PHYSICAL MEDICINE	$	680	0%	0%	0%	0%	0%
PLASTIC SURGERY	$	283	1%	0%	0%	0%	0%
PSYCHIATRY	$	1,109	0%	0%	0%	0%	0%
PULMONARY DISEASE	$	1,446	0%	0%	0%	0%	0%
RADIATION ONCOLOGY	$	1,163	0%	0%	0%	0%	0%
RADIOLOGY	$	4,693	0%	0%	0%	0%	0%
THORACIC SURGERY	$	464	0%	0%	0%	0%	1%
VASCULAR SURGERY	$	487	3%	1%	0%	0%	4%
Practitioners:							
AUDIOLOGIST	$	28	-4%	0%	0%	0%	-4%
CHIROPRACTOR	$	658	-1%	0%	0%	0%	-1%
CLINICAL PSYCHOLOGIST	$	494	0%	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	$	317	0%	0%	0%	0%	0%
NURSE ANESTHETIST	$	485	0%	0%	0%	0%	0%
NURSE PRACTITIONER	$	556	-1%	0%	0%	0%	-1%
OPTOMETRY	$	666	0%	0%	0%	0%	0%
ORAL/MAXILLOFACIAL SURGERY	$	36	4%	0%	0%	0%	4%
PHYSICAL/OCCUPATIONAL THERAPY	$	998	-2%	0%	0%	0%	-2%
PHYSICIAN ASSISTANT	$	414	0%	0%	0%	0%	0%
PODIATRY	$	1,392	-1%	0%	1%	0%	1%
Suppliers:							
DIAGNOSTIC TESTING FACILITY	$	879	1%	1%	0%	0%	2%

INDEPENDENT LABORATORY	$	452	6%	0%	0%	0%	6%	0%	1%	0%
PORTABLE X-RAY SUPPLIER	$	92	0%	0%	0%	0%	0%	0%	0%	0%
Other:										
ALL OTHER	$	93	2%	0%	0%	0%	0%	0%	0%	0%
ALL PHYSICIAN FEE SCHEDULE	$	65,803	0%	0%	0%	0%	0%	0%	0%	0%

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As discussed in section II.C of this rule, we are making changes to the malpractice RVUs based on more current malpractice premium data. As anticipated from past revisions to the malpractice RVUs, use of more current malpractice premium data results in minimal impacts on the specialty level payments. The table below shows the impact on total physician fee schedule revenues from the changes to the malpractice RVUs, the additional changes resulting from this final rule and the total impact. See Table 37, ''Impact of Malpractice RVU Changes Proposed Rule and Final Rule'', for a breakdown of the impacts of these revisions on individual specialties. As described above, policies we are adopting in this final rule will increase payments for allergy, neurosurgery and podiatry and decrease payments for dermatology relative to the proposed rule. These changes will also slightly increase payments to cardiac surgery, orthopedic surgery, thoracic surgery and result in a smaller increase in payment for vascular surgery.

Table 37:
Impact Malpractice RVU Changes
Proposed Rule and Final Rule

Specialty	Medicare Allowed Charges ($ in Millions)	NPRM Impacts	Change due to Final Rule	% Change in Total Payment from MP RVU Changes
Physicians:				
ALLERGY/IMMUNOLOGY	$ 161	-0.9%	0.8%	-0.1%
ANESTHESIOLOGY	$ 1,422	0.0%	0.0%	0.1%
CARDIAC SURGERY	$ 359	-0.1%	0.5%	0.4%
CARDIOLOGY	$ 6,579	0.0%	-0.2%	-0.1%
COLON AND RECTAL SURGERY	$ 110	0.6%	0.1%	0.7%
CRITICAL CARE	$ 130	0.5%	-0.2%	0.3%
DERMATOLOGY	$ 1,864	0.7%	-0.9%	-0.2%
EMERGENCY MEDICINE	$ 1,687	0.0%	0.0%	0.0%
ENDOCRINOLOGY	$ 279	0.1%	-0.1%	0.0%
FAMILY PRACTICE	$ 4,456	0.0%	-0.1%	-0.1%
GASTROENTEROLOGY	$ 1,634	0.5%	0.1%	0.6%
GENERAL PRACTICE	$ 1,003	0.0%	-0.1%	-0.1%
GENERAL SURGERY	$ 2,264	0.5%	0.1%	0.6%
GERIATRICS	$ 116	0.3%	-0.2%	0.1%
HAND SURGERY	$ 57	-0.1%	0.1%	0.0%
HEMATOLOGY/ONCOLOGY	$ 1,747	0.0%	-0.1%	0.0%
INFECTIOUS DISEASE	$ 401	0.4%	-0.3%	0.1%
INTERNAL MEDICINE	$ 8,784	0.1%	-0.1%	0.0%
INTERVENTIONAL RADIOLOGY	$ 191	0.0%	0.0%	-0.1%
NEPHROLOGY	$ 747	0.1%	-0.1%	0.0%
NEUROLOGY	$ 1,197	0.2%	-0.1%	0.2%
NEUROSURGERY	$ 492	-0.6%	0.9%	0.3%
NUCLEAR MEDICINE	$ 85	-0.1%	0.0%	-0.1%
OBSTETRICS/GYNECOLOGY	$ 582	0.1%	0.0%	0.1%
OPHTHALMOLOGY	$ 4,566	0.0%	0.0%	0.0%
ORTHOPEDIC SURGERY	$ 2,903	-0.4%	0.4%	0.0%
OTOLARNGOLOGY	$ 814	-0.1%	0.0%	-0.1%
PATHOLOGY	$ 846	0.2%	0.0%	0.2%
PEDIATRICS	$ 60	-0.1%	0.0%	0.0%
PHYSICAL MEDICINE	$ 680	0.2%	-0.1%	0.1%
PLASTIC SURGERY	$ 283	0.6%	-0.5%	0.2%
PSYCHIATRY	$ 1,109	0.3%	-0.3%	0.0%
PULMONARY DISEASE	$ 1,446	0.3%	-0.2%	0.1%
RADIATION ONCOLOGY	$ 1,163	0.0%	0.0%	0.0%
RADIOLOGY	$ 4,693	-0.3%	0.0%	-0.3%
RHEUMATOLOGY	$ 412	-0.1%	0.0%	-0.1%
THORACIC SURGERY	$ 464	0.0%	0.4%	0.4%
UROLOGY	$ 1,695	0.0%	0.0%	-0.1%
VASCULAR SURGERY	$ 487	0.1%	0.2%	0.3%
Practitioners:				
AUDIOLOGIST	$ 28	-0.1%	0.1%	0.0%
CHIROPRACTOR	$ 658	-0.2%	0.0%	-0.2%
CLINICAL PSYCHOLOGIST	$ 494	-0.1%	0.0%	-0.1%
CLINICAL SOCIAL WORKER	$ 317	0.0%	0.0%	0.0%

NURSE ANESTHETIST	$	485	0.0%	0.0%	0.0%
NURSE PRACTITIONER	$	556	0.2%	-0.2%	0.1%
OPTOMETRY	$	666	0.2%	-0.1%	0.1%
ORAL/MAXILLOFACIAL SURGERY	$	36	0.6%	0.0%	0.6%
PHYSICAL/OCCUPATIONAL THERAPY	$	998	-1.3%	-0.1%	-1.4%
PHYSICIAN ASSISTANT	$	414	-0.1%	0.1%	0.1%
PODIATRY	$	1,392	-0.4%	1.1%	0.7%
Suppliers:					
DIAGNOSTIC TESTING FACILITY	$	879	0.0%	0.0%	0.0%
INDEPENDENT LABORATORY	$	452	0.2%	0.0%	0.2%
PORTABLE X-RAY SUPPLIER	$	92	-0.1%	0.0%	-0.1%
Other:					
ALL OTHER	$	93	0.0%	0.0%	0.0%
ALL PHYSICIAN FEE SCHEDULE	$	65,803	0.0%	0.0%	0.0%

Section 1848(d) and (f) of the Act requires the Secretary to set the physician fee schedule update under the sustainable growth rate (SGR) system. For 2004 and 2005, the statute requires the update to be no less than 1.5 percent. Using the statutory formula in section 1848(d)(4) will produce an update of less than 1.5 percent for 2005. Therefore, the physician fee schedule update for 2005 will be 1.5 percent. We have included a complete discussion of our methodology for calculating the SGR and physician fee schedule update in another section of this final rule. Table 38 below shows the estimated change in average payments by specialty resulting from changes to the practice expense and malpractice RVUs and the 2005 physician fee schedule update. (Please note that the table does not include the specialties of Hematology/Oncology, Urology, Rheumatology, Obstetrics/Gynecology and Infectious Disease. There are unique issues related to drug administration that will further affect these specialties that are presented in detail below).

Table 38:

Impact of Practice Expense and Malpractice RVU Changes
and Physician Fee Schedule Update on Total Medicare Allowed Charges
by Physician, Practitioner and Supplier Subcategory

Specialty	Medicare Allowed Charges ($ in Millions)	Practice Expense & Malpractice RVU Changes	Physician Fee Schedule Update	Total
Physicians:				
ALLERGY/IMMUNOLOGY	$ 161	-1%	1.5%	1%
ANESTHESIOLOGY	$ 1,422	0%	1.5%	2%
CARDIAC SURGERY	$ 359	1%	1.5%	2%
CARDIOLOGY	$ 6,579	0%	1.5%	2%
COLON AND RECTAL SURGERY	$ 110	1%	1.5%	2%
CRITICAL CARE	$ 130	0%	1.5%	2%
DERMATOLOGY	$ 1,864	0%	1.5%	2%
EMERGENCY MEDICINE	$ 1,687	0%	1.5%	2%
ENDOCRINOLOGY	$ 279	0%	1.5%	2%
FAMILY PRACTICE	$ 4,456	1%	1.5%	3%
GASTROENTEROLOGY	$ 1,634	0%	1.5%	2%
GENERAL PRACTICE	$ 1,003	1%	1.5%	2%
GENERAL SURGERY	$ 2,264	1%	1.5%	2%
GERIATRICS	$ 116	0%	1.5%	1%
HAND SURGERY	$ 57	0%	1.5%	2%
INTERNAL MEDICINE	$ 8,784	1%	1.5%	2%
INTERVENTIONAL RADIOLOGY	$ 191	3%	1.5%	4%
NEPHROLOGY	$ 747	1%	1.5%	2%
NEUROLOGY	$ 1,197	0%	1.5%	2%
NEUROSURGERY	$ 492	0%	1.5%	2%
NUCLEAR MEDICINE	$ 85	0%	1.5%	2%
OPHTHALMOLOGY	$ 4,566	-1%	1.5%	0%
ORTHOPEDIC SURGERY	$ 2,903	0%	1.5%	1%
OTOLARNGOLOGY	$ 814	0%	1.5%	2%
PATHOLOGY	$ 846	2%	1.5%	4%

PEDIATRICS	$	60	0%	1.5%	2%
PHYSICAL MEDICINE	$	680	0%	1.5%	1%
PLASTIC SURGERY	$	283	0%	1.5%	2%
PSYCHIATRY	$	1,109	0%	1.5%	1%
PULMONARY DISEASE	$	1,446	0%	1.5%	2%
RADIATION ONCOLOGY	$	1,163	0%	1.5%	1%
RADIOLOGY	$	4,693	0%	1.5%	2%
THORACIC SURGERY	$	464	1%	1.5%	2%
VASCULAR SURGERY	$	487	4%	1.5%	6%
Practitioners:					
AUDIOLOGIST	$	28	-4%	1.5%	-2%
CHIROPRACTOR	$	658	-1%	1.5%	1%
CLINICAL PSYCHOLOGIST	$	494	0%	1.5%	1%
CLINICAL SOCIAL WORKER	$	317	0%	1.5%	1%
NURSE ANESTHETIST	$	485	0%	1.5%	2%
NURSE PRACTITIONER	$	556	-1%	1.5%	0%
OPTOMETRY	$	666	0%	1.5%	1%
ORAL/MAXILLOFACIAL SURGERY	$	36	4%	1.5%	5%
PHYSICAL/OCCUPATIONAL THERAPY	$	998	-2%	1.5%	-1%
PHYSICIAN ASSISTANT	$	414	0%	1.5%	1%
PODIATRY	$	1,392	1%	1.5%	2%
Suppliers:					
DIAGNOSTIC TESTING FACILITY	$	879	2%	1.5%	3%
INDEPENDENT LABORATORY	$	452	6%	1.5%	8%
PORTABLE X-RAY SUPPLIER	$	92	0%	1.5%	1%
Other:					
ALL OTHER	$	93	1%	1.5%	3%
ALL PHYSICIAN FEE SCHEDULE	$	65,803	0%	1.5%	2%

Table 39 shows the impact on payments for selected high-volume procedures of all of the changes previously discussed. We selected these procedures because they are the most commonly provided procedures by a broad spectrum of physician specialties, or they are of particular interest to the physician community (for example, the initial preventive physical exam and EKG, codes G0344, G0366, G0367 and G0368). We note that the table below shows Medicare payment for the administration of an influenza vaccine, G0008, increasing from $8.21 to $18.57, or 126 percent. As explained earlier, we are establishing the same RVUs for the administration of a vaccine and an injection. For 2005 only, we will pay 3 percent more for the injection ($19.13) because of the transitional adjustment required by section 303. After 2005, the payment for the administration of a vaccine and an injection will be the same. This table shows the combined impact of the change in the practice expense and malpractice RVUs and the estimated physician fee schedule update on total payment for the procedure. There are separate columns that show the change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility practice expense RVUs refer to § 414.22(b)(5)(i). The table shows the estimated change in payment rates based on provisions of this final rule and the estimated physician fee schedule update.

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Table 39:

Impact of Final Rule and Physician Fee Schedule Update
on Medicare Payment for Selected Procedures

			Non-Facility			Facility		
CODE	MOD	DESCRIPTION	Old	New	% Change	Old	New	% Change
11721		Debride nail, 6 or more	$ 38.08	$ 38.66	2%	$ 29.87	$ 29.94	0%
17000		Destroy benign/premlg lesion	$ 60.49	$ 61.39	1%	$ 35.84	$ 45.10	26%
27130		Total hip arthroplasty	N/A	N/A	N/A	$1,370.28	$1,383.26	1%
27244		Treat thigh fracture	N/A	N/A	N/A	$1,115.27	$1,128.97	1%
27447		Total knee arthroplasty	N/A	N/A	N/A	$1,475.95	$1,493.16	1%
33533		CABG, arterial, single	N/A	N/A	N/A	$1,882.18	$1,905.49	1%
35301		Rechanneling of artery	N/A	N/A	N/A	$1,114.89	$1,122.52	1%
43239		Upper GI endoscopy, biopsy	$321.85	$333.88	4%	$ 159.43	$ 162.58	2%
66821		After cataract laser surgery	$240.83	$248.23	3%	$ 237.09	$ 230.42	-3%
66984		Cataract surg w/iol, 1 stage	N/A	N/A	N/A	$ 684.39	$ 684.05	0%
67210		Treatment of retinal lesion	$577.98	$599.54	4%	$ 560.81	$ 573.39	2%
71010	26	Chest x-ray	$ 9.33	$ 9.47	2%	$ 9.33	$ 9.47	2%
76091	26	Mammogram, both breasts	$ 44.80	$ 45.10	1%	$ 44.80	$ 45.10	1%
76091		Mammogram, both breasts	$ 96.33	$ 97.40	1%	N/A	N/A	N/A
76092	26	Mammogram, screening	$ 36.22	$ 36.38	0%	$ 36.22	$ 36.38	0%
76092		Mammogram, screening	$ 84.76	$ 85.65	1%	N/A	N/A	N/A
77427		Radiation tx management, x5	$169.14	$172.05	2%	$ 169.14	$ 172.05	2%
78465	26	Heart image (3d), multiple	$ 76.17	$ 77.31	1%	$ 76.17	$ 77.31	1%
88305	26	Tissue exam by pathologist	$ 41.44	$ 42.07	2%	$ 41.44	$ 42.07	2%
90801		Psy dx interview	$150.84	$153.48	2%	$ 142.26	$ 144.39	1%
90862		Medication management	$ 51.15	$ 52.30	2%	$ 48.17	$ 49.27	2%
90935		Hemodialysis, one evaluation	N/A	N/A	N/A	$ 72.06	$ 73.14	1%
92012		Eye exam established pat	$ 63.47	$ 65.18	3%	$ 36.22	$ 37.14	3%
92014		Eye exam & treatment	$ 93.34	$ 96.26	3%	$ 58.99	$ 60.64	3%
92980		Insert intracoronary stent	N/A	N/A	N/A	$ 812.09	$ 830.33	2%
93000		Electrocardiogram, complete	$ 26.51	$ 27.29	3%	N/A	N/A	N/A
93010		Electrocardiogram report	$ 8.96	$ 9.10	2%	$ 8.96	$ 9.10	2%
93015		Cardiovascular stress test	$106.78	$108.39	2%	N/A	N/A	N/A
93307	26	Echo exam of heart	$ 49.29	$ 49.27	0%	$ 49.29	$ 49.27	0%
93510	26	Left heart catheterization	$252.77	$257.32	2%	$ 252.77	$ 257.32	2%
98941		Chiropractic manipulation	$ 36.22	$ 36.76	1%	$ 31.74	$ 31.83	0%
99203		Office/outpatient visit, new	$ 95.96	$ 97.02	1%	$ 71.69	$ 72.38	1%
99213		Office/outpatient visit, est	$ 52.65	$ 52.68	0%	$ 35.47	$ 35.62	0%
99214		Office/outpatient visit, est	$ 82.14	$ 82.62	1%	$ 57.87	$ 59.12	2%

99222	Initial hospital care	N/A	N/A	N/A	$ 111.27	$ 112.93	1%
99223	Initial hospital care	N/A	N/A	N/A	$ 154.95	$ 157.27	1%
99232	Subsequent hospital care	N/A	N/A	N/A	$ 54.89	$ 56.09	2%
99233	Subsequent hospital care	N/A	N/A	N/A	$ 78.04	$ 79.58	2%
99236	Observ/hosp same date	N/A	N/A	N/A	$ 226.26	$ 223.60	-1%
99239	Hospital discharge day	N/A	N/A	N/A	$ 95.21	$ 96.64	2%
99243	Office consultation	$120.60	$122.79	2%	$ 92.22	$ 93.99	2%
99244	Office consultation	$170.63	$172.81	1%	$ 136.65	$ 138.70	2%
99253	Initial inpatient consult	N/A	N/A	N/A	$ 97.45	$ 98.91	1%
99254	Initial inpatient consult	N/A	N/A	N/A	$ 140.39	$ 142.12	1%
99261	Follow-up inpatient consult	N/A	N/A	N/A	$ 22.40	$ 22.36	0%
99262	Follow-up inpatient consult	N/A	N/A	N/A	$ 44.80	$ 45.48	2%
99263	Follow-up inpatient consult	N/A	N/A	N/A	$ 66.09	$ 67.46	2%
99283	Emergency dept visit	N/A	N/A	N/A	$ 61.61	$ 62.15	1%
99284	Emergency dept visit	N/A	N/A	N/A	$ 95.58	$ 97.02	2%
99291	Critical care, first hour	$242.69	$256.57	6%	$ 203.12	$ 207.68	2%
99292	Critical care, addÏl 30 min	$107.91	$114.07	6%	$ 101.56	$ 104.22	3%
99302	Nursing facility care	$ 97.82	$ 87.92	-10%	$ 82.52	$ 87.92	7%
99303	Nursing facility care	$120.97	$108.39	-10%	$ 102.68	$ 108.39	6%
99312	Nursing fac care, subseq	$ 63.10	$ 56.85	-10%	$ 51.53	$ 56.85	10%
99313	Nursing fac care, subseq	$ 86.25	$ 79.96	-7%	$ 72.43	$ 79.96	10%
99348	Home visit, est patient	$ 75.42	$ 72.01	-5%	N/A	$ 68.22	N/A
99350	Home visit, est patient	$169.89	$165.23	-3%	N/A	$ 160.31	N/A
G0008	Admin influenza virus vac	$ 8.21	$ 18.57	126%	N/A	N/A	N/A
G0317	ESRDrelsvc 4+/mo;20+yr	$303.18	$307.73	2%	$ 303.18	$ 307.73	2%
G0344	Initial preventive exam	N/A	$ 97.40	N/A	N/A	$ 72.76	N/A
G0366	EKG for initial prevent exam	N/A	$ 27.29	N/A	N/A	N/A	N/A
G0367	EKG tracing for initial prev	N/A	$ 17.81	N/A	N/A	N/A	N/A
G0368	EKG interpret & report preve	N/A	$ 9.10	N/A	N/A	$ 9.10	N/A

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Section 303(a)(1) of the MMA amended section 1848(c)(2) of the Act to require increased work and practice expense RVUs for drug administration services. Section 303(a)(4) of the MMA required an additional temporary increase in payment to specific drug administration services of 32 percent for 2004 and 3 percent for 2005. Table 41 shows the payment amounts for selected high-volume drug administration CPT codes from 2002 to 2006 including the effect of the transition adjustment of 32 percent required for 2004 and 3 percent for 2005. Because we may also pay an additional $130 per encounter under the national demonstration project in 2005, we are also including the effect of this additional payment where applicable. Table 42 that follows table 41 shows the payment amount for 2004 and 2005 without the additional transition adjustment required by the MMA and national demonstration payment amount. By showing the payment amounts without the transition and demonstration, we can isolate the permanent change in the payment amounts that is occurring as a result of the MMA, the CPT/RUC review and the physician fee schedule update. The amounts shown in the table include the effect of the 1.5 percent update for 2004 and 2005. As described above, the CPT and RUC have recommended changes to the coding and payment for drug administration services. The CPT/RUC review was undertaken at our request under the authority of section 1848(c)(2)(J) of the Act that requires the Secretary to promptly evaluate existing drug administration codes using existing processes. While this review was completed expeditiously, CPT did not have sufficient time to adopt the coding recommendations into the 2005 version of CPT. For this reason, we are establishing new G-codes for 2005 that correspond with the new CPT codes that will become active in 2006.

Tables 41 and 42 show the payment amounts for the most frequently performed drug administration services from 2002 to 2004 under the CPT codes and payment for the comparable service in 2005 using the G code. For instance, a therapeutic injection was previously billed under the CPT code 90782. This same service will now be billed using HCPCS code G0351. As a result of the RUC review, our acceptance of their recommendations for refinements to the practice expense inputs, our policy of pooling the utilization for the injection with vaccine administration, and the required reduction in the transitional adjustment, payment for this service will be reduced from $24.64 in 2004 to $19.13 in 2005. However, the 2004 transition adjustment largely accounts for the decline. If the transitional adjustment of 32 percent for 2004 and 3 percent for 2005 were not applied, payment for the injection would be virtually the same in 2005 as in 2004, a decline of $0.10 from $18.67 to $18.57. This table shows the permanent large increase in payment for this code from 2002 to 2005. The payment for a therapeutic injection increased from $3.98 in 2002 to $19.13 in 2005, a 381

percent increase (or $18.57 if the transitional adjustment were not applied, a 367 percent increase).

CPT is also recommending separate codes for the administration of hormonal anti-neoplastic subcutaneous/intramuscular (SC/IM) injections from other anti-neoplastic injections. Under the current CPT codes, all anti-neoplastics administered SC/IM are billed using CPT code 96400. HCPCS code G0356 will be used for the administration of hormonal anti-neoplastic injections. CPT code 96400 is currently paid $64.07. Its comparable code for 2005 (G0356) will be paid $36.69 or a reduction of 43 percent. Without the transition, payment for the code would have been reduced from $48.54 to $35.62 or 27 percent between 2004 and 2005. However, payment for this code increased from $5.07 to $35.62 (without the transition) between 2002 and 2005 or by 603 percent.

There is currently one CPT code for anti-neoplastic drugs administered by intravenous (IV) push (96408). In 2004, physicians are receiving $154.76 for CPT code 96408. Payment in 2005 for G0351 (the comparable code) will be $125.69. In addition, Medicare may also pay an additional $130.00 per encounter under the demonstration increasing the total payment to $255.69 or an increase of 65 percent between 2004 and 2005. Without the transitional adjustments or the demonstration, payment for this service would have increased from $117.24 in 2004 to $122.03 in 2003 or by 4 percent. From 2002 to 2005, payment will have increased from $35.11 to $122.03 (without the transition), or a 248 percent increase.

CPT will be creating new codes that distinguish between the first and subsequent administration of a drug by IV push to the same patient on the same day. The RUC is recommending fewer inputs for the subsequent administration of a drug by IV push than the initial drug. We are creating code G0358 for each subsequent drug administered by IV push for 2005. Before the enactment of the MMA, Medicare allowed CPT code 96408 to be paid only once per patient per day. However, as a result of the MMA, we changed our policy and allowed physicians to bill and be paid for more than one administration of a chemotherapy drug by IV push to the same patient on a single day (see 69 FR 1094–1095). Thus, because separate codes do not currently exist for the multiple administrations of chemotherapy drugs by IV push on a single day, physicians currently are paid at the rate for 96408 (or $154.76) for each subsequent administration. Using the CPT's and RUC recommendations, we will pay $72.99 for subsequent drugs administered by IV push using HCPCS code G0358. While the payment is less in 2005 and 2004, payment remains higher in 2005 than in 2003 and prior years when Medicare provided no payment for the subsequent administration of a drug by IV push.

We are creating HCPCS codes G0359 and G0360 for the initial and subsequent hour respectively of chemotherapy drugs administered by IV infusion. As described in the drug administration section, CPT has changed its definition of chemotherapy to include infusion of substances such as monoclonal antibody agents or other biologic response modifiers in addition to anti-neoplastic drugs. Thus, services previously billed under the CPT code 90780 (initial hour) and 90781 (each additional hour) that meet this new definition of chemotherapy will now be billed under CPT code G0359 (initial hour) and G0360 (each additional hour). Payment for the infusion of substances such as monoclonal antibody agents or other biologic response modifiers paid under CPT code 90780 will be increasing from $117.79 in 2004 to $177.61 in 2005 using HCPCS code G0359, a 51 percent increase. Without including the transition adjustment, payment for these services will have increased by 93 percent from $89.24 in 2004 to $172.43 in 2005 or by 325 percent from the 2002 rate of $40.54. Payment for the subsequent hour infusion under CPT code 90781 will increase from $33.02 in 2004 to $40.21 in 2005 under HCPCS code G0360 or by 22 percent. Without including the transition adjustment, payment for the subsequent hour infusion will have increased 56 percent from $25.02 in 2004 to $39.03 in 2005 or 93 percent from its 2002 rate of $20.27.

Anti-neoplastic agents that were previously billed under CPT code 96410 (initial hour) and 96412 (each additional hour) will also be billed under codes G0359 and G0360. We have listed codes G0359 and G0360 twice to reflect that Medicare payment for each respective code is paid under two different CPT codes for services rendered prior to January 1, 2005. Payment for the initial hour of an anti-neoplastic agent administered by infusion under CPT code 96410 will be going from $217.35 in 2004 to $177.61 in 2005. Including the $130.00 per encounter demonstration payment in this amount brings the total payment to $307.61, an increase of 65 percent. Without including the transition adjustment, payment for these services will have increased by 5 percent from $164.66 in 2004 to $172.43 in 2005 or by 209 percent from the 2002 rate of $55.75. Payment for the subsequent hour infusion under CPT code 96412 will decrease from $48.30 in 2004 to $40.21 in 2005 under HCPCS code G0360 or by 17 percent. Without including the transition adjustment, payment for the subsequent hour infusion will have increased 7 percent from $36.59 in 2004 to $39.03 in 2005. Payment for the subsequent hour infusion of an anti-neoplastic agent has been reduced by 6 percent from its 2002 rate of $41.63. The reduction in payment is occurring because resource-based pricing replaced the use of charge-based RVUs when the services were removed from the nonphysician work pool in 2004.

The CPT is also recommending a new code for the initial hour of a subsequent chemotherapy drug administered by infusion. The new code would recognize that there are higher resources associated with the first hour of infusion of a subsequent drug than there are in the subsequent hour of the initial drug. Under current CPT coding, the first hour of a subsequent drug administered by IV infusion is paid under CPT code 96412. In 2004, Medicare pays $48.30 for this service. In 2005, we will pay $86.66 or 79 percent more for HCPCS code G0362 that will be used for the initial hour of a subsequent drug administered by IV infusion. Without including the transition adjustment, payment for this service will have increased 130 percent from $36.59 in 2004 to $84.13 in 2005 or 102 percent from the 2002 rate of $41.63.

The volume-weighted average permanent increase in payment among all drug administration services is approximately 117 percent from 2003 to 2005 including the effect of the CPT/RUC recommendations but excluding the effect of the transition adjustment. Including the effect of the transition (but not the demonstration payment) makes the volume-weighted increase in payment for these codes more than 120 percent from 2003 to 2005.

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Table 40:

Impact of Final Rule and Physician Fee Schedule Update
on Medicare Payment for Selected Drug Administration Services
Including the Effect of the 32 and 3% Transition Adjustments and Demonstration Project

Old Code	New Code	Description	2002 Payment	2003 Payment	2004 Payment with Transition	2005 Payment with Transition	2005 Demo Payment*	2005 w/Transition and Demo	% Change 04 to 05
90782	G0351	Therapeutic/diagnostic injec	$ 3.98	$ 4.41	$ 24.64	$ 19.13	N/A	$ 19.13	-22%
96400	G0356	Hormonal anti-neoplastic	$ 5.07	$ 37.52	$ 64.07	$ 36.69	N/A	$ 36.69	-43%
96408	G0357	IV push single/initial subst	$ 35.11	$ 37.52	$ 154.76	$ 125.69	$130.00	$ 255.69	65%
N/A	G0358	IV push each additional drug	N/A	N/A	$ 154.76	$ 72.99	N/A	$ 72.99	-53%
96410	G0359	Chemotherapy IV one hr initi	$ 55.75	$ 59.22	$ 217.35	$ 177.61	$130.00	$ 307.61	42%
90780	G0359	Chemotherapy IV one hr initi	$ 40.54	$ 42.67	$ 117.79	$ 177.61	N/A	$ 177.61	51%
96412	G0360	Each additional hr 1-8 hrs	$ 41.63	$ 44.14	$ 48.30	$ 40.21	N/A	$ 40.21	-17%
90781	G0360	Each additional hr 1-8 hrs	$ 20.27	$ 21.70	$ 33.02	$ 40.21	N/A	$ 40.21	22%
96412	G0362	Each add sequential infusion	$ 41.63	$ 44.14	$ 48.30	$ 86.66	N/A	$ 86.66	79%

- The demonstration payments will only be made once per day per patient with a diagnosis of cancer. Thus, we are only showing them as an additional payment to an initial drug administration service when an anti-neoplastic agent is administered.

Table 41:

Impact of Proposed Rule and Physician Fee Schedule Update on Medicare Payment for Selected Drug Administration Services Excluding the Effect of the 32 and 3% Transition Adjustments and Demonstration Project

Old Code	New Code	Description	2002 Payment	2003 Payment	2004 Payment without Transition	2005 Payment without Transition
90782	G0351	Therapeutic/diagnostic injec	$ 3.98	$ 4.41	$ 18.67	$ 18.57
96400	G0356	Hormonal anti-neoplastic	$ 5.07	$ 37.52	$ 48.54	$ 35.62
96408	G0357	IV push single/initial subst	$ 35.11	$ 37.52	$ 117.24	$ 122.03
N/A	G0358	IV push each additional drug	N/A	N/A	$ 117.24	$ 70.87
96410	G0359	Chemotherapy IV one hr initi	$ 55.75	$ 59.22	$ 164.66	$ 172.43
90780	G0359	Chemotherapy IV one hr initi	$ 40.54	$ 42.67	$ 89.24	$ 172.43
96412	G0360	Each additional hr 1-8 hrs	$ 41.63	$ 44.14	$ 36.59	$ 39.03
90781	G0360	Each additional hr 1-8 hrs	$ 20.27	$ 21.70	$ 25.02	$ 39.03
96412	G0362	Each add sequential infusion	$ 41.63	$ 44.14	$ 36.59	$ 84.13

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Table 42 below shows the impact of physician fee schedule changes for selected specialties that receive a significant portion of their total Medicare revenues from drugs. Table 43 that follows table 42 shows the combined impact of the physician fee schedule and drug payment changes on total Medicare revenues. Our estimates of changes in Medicare revenues for drugs and physician fee schedule services compare payment rates for 2005 with payment rates for 2004 using 2003 Medicare utilization for both years. For physician fee schedule services, we mapped the 2003 Medicare utilization to the code set in use for 2005 based on assumptions about how the new drug administration codes will be billed. These assumptions are based on our consultations with the American Society of Clinical Oncology and other physician specialty societies that participated in the CPT's Drug Administration workgroup. We are using 2003 Medicare claims processed and paid through June 30, 2004 that we

estimate are 98.5 complete and have adjusted the figures to reflect a full year of data. Thus, because we are using a single year of utilization, the estimated changes in revenues reflect payment changes only between 2004 and 2005. To the extent that there are year-to-year changes in the volume and mix of drugs and physician fee schedule services provided by physicians, the actual impact on total Medicare revenues will be different than those shown here.

The column labeled ''NPRM Impacts'' shows the impact of the practice expense and malpractice RVU changes described earlier. The refinements of the practice expense RVUs and 5-year review of malpractice will have little or no impact on physician fee schedule payments for the 5 specialties shown. The column labeled ''Coding and RVU Changes'' shows the impact of our adoption of the CPT/RUC recommended revisions to the codes and payment amount for drug administration services. We estimate that the changes from the CPT/RUC process will increase physician fee schedule payments for oncologists by 5 percent. This impact is generally attributable to higher permanent increases in payment for the administration of drugs by IV push (G0357), infusion (G0359 and G0360) and the ability to be paid at a higher rate for the initial hour of infusion of a subsequent drug administered. We estimate that the changes from the CPT/RUC process will increase payments to rheumatologists by 4 percent. This impact is due to the change in the definition of the chemotherapy that will allow rheumatologists to bill substances such as monoclonal antibody agents or other biologic response modifiers using the chemotherapy administration codes. The CPT/RUC changes will have little or no specialty level impact on other specialties that administer drugs.

The next column shows the effect of the drug administration transition on Medicare physician fee schedule revenues for the specialties shown. As explained earlier, section 303(a)(4) requires that the transition adjustment percentage be reduced from 32 percent in 2004 to 3 percent in 2005. The change to the transition payment percentage will reduce payments for the specialties that provide drug administration services. The reduction has a larger impact on oncologists than the other physician specialties shown because drug administration services represent a larger proportion of their physician fee schedule revenues.

The column labeled ''Additional Payments for Injections'' shows the effect of paying for injections (as well as non-chemotherapy drugs administered by IV push) provided on the same day as other physician fee schedule services. We estimate that this policy change will increase payment an estimated 3 percent for oncologists and 1 percent for other specialties. This policy change will also modestly increase payment to other specialties that provide injections (primarily family practitioners and internists) and has been incorporated into the earlier impact tables.

The next column shows the impact of the 1.5 percent physician fee schedule update. The column labeled ''One-Year Demonstration Project'' shows the impact of our plan to establish a national demonstration project that will pay oncologists $130 for providing specific services to their patients and reporting patient quality data. If oncologists participate in this demonstration project and provide the required services and requested information, we estimate that their payments will increase by 15 percent. Taken together, we estimate that the coding and RVU changes, the change to the transition amount for drug administration, the additional payments for injections, the physician fee schedule update and the national demonstration project will increase physician fee schedule payments to oncologists by 10 percent. The combined impact of these factors (other than the national demonstration project) will increase physician fee schedule payments by 1 percent urologists, 5 percent for rheumatologists, 1 percent for obstetrics/gynecologists and 0 percent for infectious disease.

Table 43 shows the combined impact of changes we are making to Medicare drug and physician fee schedule payments for the same specialties shown in table 42. The payment impacts for drugs are based on the 2nd quarter ASP submissions from drug manufacturer's and reflect ¾ of an annualized increase in drug prices between the 2nd quarter of 2004 and the 1st quarter of 2005 of 3.39 percent or 2.54 percent. The drug payment impacts are based on ASP prices for drugs accounting for approximately 94 percent of Medicare's total drug payments. Of Medicare's total payments for drugs, at least 4 percent are paid under ''not otherwise classified (NOC)'' codes (*i.e.* J3490 and J0999). Thus, we based our impacts on ASP prices for drugs accounting for approximately 98 percent of Medicare revenues that are not in the NOC category.

The column labeled ''% of Total Medicare Revenues from Fee Schedule'' shows the proportion of total Medicare revenues received from physician fee schedule services. The following column shows the physician fee schedule payment impact. All of the payment impacts are the same as those shown in Table 43. The following column shows the proportion of total Medicare revenues received from drugs, while the next column shows the payment impact from adoption of the ASP drug payment methodology. The next 3 columns show combined Medicare revenues from all sources and the combined Medicare payment impact from the earlier described changes being adopted for 2005.

Our estimates of changes in Medicare revenues for both drugs and drug administration services compare payment rates for 2005 with payment rates for 2004 using the same utilization in both years. We used 2003 utilization for these comparative impacts since they are the latest data available. Thus, the estimated changes in revenues reflect *purely* price changes between 2004 and 2005. We note that these impacts and percentages represent averages for each specialty or supplier. The percentages and impacts for any individual physician are dependent on the mix of drugs and physician fee schedule services they provide to Medicare beneficiaries. For this analysis, we are also supplementing the data showing the change in revenues with volume growth based on historical trends.

As indicated in Table 43, physician fee schedule services account for approximately 28 percent of oncology's 2004 Medicare revenues. The changes we are adopting in this final rule are estimated to increase Medicare payments for physician fee schedule services by 10 percent from 2004 to 2005. We estimate that approximately 69 percent of total 2004 Medicare revenues for oncologists are attributed to drugs and the adoption of the ASP pricing methodology will reduce these revenues by 13 percent. We based our analysis on drugs accounting for approximately 92 percent of total oncology drug revenues (and 99 percent of oncology drug revenues not paid under NOC codes). The actual impact on oncologists' total Medicare revenues will be different from these estimated impacts to the extent that utilization of drugs and drug administration services does increase. In recent years, increasing utilization, for example, drug spending growth in excess of 20 percent per year, has occurred. The weighted average of the drug and physician fee schedule changes assuming no change in utilization would decrease Medicare revenues to oncology by 6 percent. However, if the volume of drugs and physician fee schedule services

increased at historical rates, total Medicare revenues for oncologists are estimated to increase by 4 percent between 2004 and 2005, excluding the demonstration project. If we include the demonstration project, Medicare revenues to oncologists are estimated to increase by 8 percent between 2004 and 2005. We note that our actuaries' estimates of section 303 with the drug prices and policy changes in this final rule match earlier estimates of the FY 2005 and 10-year savings figures.

We estimate that urology receives approximately 57 percent of their 2004 total revenues from physician fee schedule services and 35 percent from drugs. We estimate that physician fee schedule revenues for urologists will increase by approximately 1 percent from 2004 to 2005. Based on ASP prices for drugs accounting for 100 percent of urologists' drug revenues, we estimate a 40 percent reduction assuming no growth in the volume of services provided. In this scenario, combined Medicare payments to urologists would decline approximately 14 percent. However, if the volume of physician fee schedule services and drugs were to grow at historical rates, we estimate that Medicare revenues to urologists would decline by 8 percent.

We estimate that physician fee schedule revenues account for approximately 49 percent of rheumatology's total revenues. Drugs account for approximately 44 percent rheumatology's total revenues. Physician fee schedule revenues are estimated to increase 5 percent for rheumatology and revenues from drugs are estimated to decline by 8 percent. Assuming no growth in utilization, the combined reduction in rheumatologists' revenues would be 1 percent. If the volume of drugs and physician fee schedule services grew at historical rates, rheumatologists' revenues from Medicare would increase by 9 percent.

We estimate that physician fee schedule revenues account for approximately 87 percent of total revenues for obstetrics/gynecology. These revenues are anticipated to increase by 1 percent. Drug revenues represent 13 percent of total Medicare revenues for obstetrics/gynecology and are estimated to decline by 21 percent. Assuming no growth in utilization, we estimated that obstetrics/gynecology's combined Medicare revenues would decline by 2 percent. Using the historical projected rates of growth for the volume of drugs and physician fee schedule services would make the estimated change in revenues equal an increase of 4 percent.

We estimate that physician fee schedule revenues account for approximately 94 percent of total revenues for infectious disease physicians. These payments are not estimated to change. The remainder of Medicare revenues for infectious disease physicians can be attributed to drugs. These payments are expected to decline by 25 percent. The weighted average change in infectious disease revenues from the changes we are adopting in this final rule is -2 percent assuming no growth in the volume of drugs and physician fee schedule services. If future growth in the volume of drugs and physician fee schedule services were to grow at historical rates, revenues to infectious disease physicians would increase would increase 7 percent.

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Table 42:

Impact of Drug and Physician Fee Schedule Payment Changes
on Total Medicare Allowed Charges
for Selected Specialties

		Physician Fee Schedule						
Specialty	Medicare Allowed Charges ($ in Millions)	NPRM Impacts	Coding and RVU Changes	Drug Administration Transition	Additional Payments for Injections	Physician Fee Schedule Update	One-Year Demonstration Project	Total
HEMATOLOGY/ONCOLOGY	$ 1,747	0%	5%	-12%	3%	1.5%	15%	10%
UROLOGY	$ 1,695	0%	0%	-1%	0%	1.5%	N/A	1%
RHEUMATOLOGY	$ 582	0%	4%	-2%	1%	1.5%	N/A	5%
OBSTETRICS/GYNECOLOGY	$ 412	0%	0%	-1%	0%	1.5%	N/A	1%
INFECTIOUS DISEASE	$ 401	0%	0%	-1%	0%	1.5%	N/A	0%

Table 43:
Combined Payment Impact
Drug and Physician Fee Schedule Payment Changes
for Selected Specialties

	Physician Fee Schedule		Drugs			All Revenues			
Specialty	% of Total Medicare Revenues from Fee Schedule	% Change Medicare Physician Fee Schedule Revenues	% of Total Medicare Revenues from Drugs	% Change Medicare Drug Revenues	Combined Medicare Revenues All Sources ($ in Millions)	Combined % Change All Medicare Revenues Constant Utilization	Combined % Change All Medicare Revenues** w/Utilization Growth
HEMATOLOGY/ONCOLOGY	28%	10%	69%	-13%	$ 6,346	-6%	8%
UROLOGY	57%	1%	35%	-40%	$ 2,967	-14%	-8%
RHEUMATOLOGY	49%	5%	44%	-8%	$ 844	-1%	16%
OBSTETRICS/GYNECOLOGY	87%	1%	13%	-21%	$ 667	-2%	5%
INFECTIOUS DISEASE	94%	0%	6%	-25%	$ 428	-2%	7%

** Note: We estimate that Medicare payments to oncologists would increase by 8% between 2004 and 2005 if growth in the volume of drugs and physician fee schedule services were to continue growing at historical rates and the effect of the demonstration project was included. Revenue projections including price and volume changes for the other specialties are shown as well.

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B. Geographic Practice Cost Indices

As discussed in section II.B, in this rule, we are proposing changes to the work and practice expense GPCIs based on new census data. The resulting geographic redistributions would not result in an overall increase in the current geographic adjustment indices by more than 3.5 percent or a decrease by more than 1.6 percent for any given locality in 2005. These geographic redistributions would not result in an overall increase in the current geographic adjustment indices by more than 7 percent or a decrease by more than 3.5 percent for any given locality in 2006. Addenda F and G illustrate the

locality specific overall impact of this proposal. The GAF, as displayed in Addenda F and G is a weighted composite index of the individual revisions to the work, practice expense, and malpractice expense GPCIs, respectively. The malpractice GPCI was updated as part of the November 7, 2003 final rule, and the MMA provisions were addressed in the final rule published on January 7, 2004.

C. Coding Issues

1. Additions to the List of Medicare Telehealth Services

In section II.D, we are adding end stage renal disease (ESRD) services, as represented by HCPCS codes G0308, G0309, G0311, G0312, G0314, G0315, G0317, G03178 to the list of telehealth services. We believe that this change will have little effect on Medicare expenditures.

2. National Pricing of G0238/G0239 (Respiratory Therapy Service Codes)

As discussed earlier in the preamble, we are using the nonphysician workpool to value two respiratory therapy service codes (G0238 and G0239) that are currently carrier priced. We believe that this change will eliminate the uncertainty surrounding payment of these codes when performed in comprehensive outpatient rehabilitation facilities that are paid under the physician fee schedule through fiscal intermediaries. We do not anticipate that nationally pricing these services will have a significant impact on Medicare expenditures.

3. New HCPCS Code for Bone Marrow Aspiration

We are implementing a new HCPCS add-on code, GO367 for instances when a bone marrow aspiration and a bone marrow biopsy are performed on the same day through a single incision. While this coding change will allow for a small additional payment for the second procedure performed through a single incision on the same day, we anticipate that the costs will be insignificant.

4. New HCPCS Code for Venous Mapping

As stated earlier in the preamble, we are implementing a new HCPCS code G0365, for mapping of vessels for hemodialysis access. Payment for this code will be crosswalked by CPT code 93990, Doppler Flow Testing. We anticipate that the costs of this change will be minor and may result in improved care to Medicare beneficiaries and less long-term costs to Medicare.

D. MMA Provisions

1. Section 611—Preventive Physical Examination

As discussed earlier in this preamble, the MMA authorizes coverage of an initial preventive physical examination effective January 1, 2005, subject to certain eligibility and other limitations. This new benefit will result in an increase in Medicare expenditures for new payments made to physicians and other practitioners who provide these examinations and for any medically necessary follow-up tests, counseling, or treatment that may be required as a result of the coverage of these examinations. The impact of this provision is shown in the following table.

TABLE 44:
Medicare Cost Estimates for MMA Provision 611
(in millions)

MMA provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Sec. 611	$40	$40	$40	$40	$40

2. Section 613—Diabetes Screening

Section 613 of the MMA adds subsection (yy) to section 1861 of the Social Security Act and mandates coverage of diabetes screening tests, effective on or after January 1, 2005. We expect that this change in coverage for certain beneficiaries will result in an increase in Medicare payments. These payments will be made to physicians' office laboratories and other laboratory suppliers who perform these tests as a result of the increased frequency of coverage of these tests. The impact of this provision is shown in Table 45 that follows.

3. Section 612—Cardiovascular Screening

Section 612 of the MMA provides for Medicare coverage for cholesterol and other lipid or triglyceride levels of cardiovascular screening blood tests for the early detection of abnormalities associated with an elevated risk for such diseases effective on or after January 1, 2005. We estimate that this change in coverage for certain beneficiaries will result in an increase in Medicare payments. These payments will be made to physician office laboratories and other laboratory suppliers who perform these tests as a result of the increased frequency of coverage of these tests. Increased Medicare program expenditures for this provision are shown in Table 45 below.

TABLE 45:
Medicare Cost Estimates for MMA Provisions 612 and 613
(in millions)

MMA Provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Sec. 612 Cholesterol and Blood Lipid	50	80	90	90	100
Sec. 613 Diabetes Screening	20	40	50	60	80

4. Section 413—Incentive Payment for Physician Scarcity

a. Physician Scarcity Areas

Section 413(a) of the MMA provides a new 5-percent incentive payment to physicians who furnish services in physician scarcity areas. The MMA provides for paying primary care physicians furnishing services in a primary care scarcity area, and specialty physicians furnishing services in a specialist care scarcity county, an additional amount equal to 5 percent of the amount paid for their professional services under the fee schedule from January 1, 2005 to December 31, 2007. We estimate that this new incentive payment for physicians' services will result in an increase in Medicare payments that are shown in Table 46.

b. Improvement to Medicare HPSA Incentive Payment Program

Section 413(b) of the MMA amended section 1833(m) of the Act to mandate that we automate payment of the 10 percent HPSA incentive payment to eligible physicians. Since the inception of the HPSA incentive payment program, physicians have been required to determine their eligibility and correctly code their Medicare claims using modifiers. We estimate that this change to the HPSA incentive payment program to provide for automation of payment will result in an increase in Medicare payments because many eligible physicians are not applying for bonuses due to the burden of verifying eligibility. The impact of this provision is shown in Table 46.

TABLE 46:
Medicare Cost Estimates for MMA Provisions
(in millions)

MMA Provision	FY05	FY06	FY07	FY08	FY09
Sec. 413(a) Physician Scarcity Areas	30	50	50	20	-
Sec. 413(b) Improvement to HPSA	20	30	30	30	30

5. Sections 303–304—Payment for Covered Outpatient Drugs and Biologicals and Section 305—Payment for Inhalation Drugs

Sections 303 and 304 of the MMA make changes to Medicare payment for covered outpatient drugs and biologicals and changes to the administration of those drugs. Section 305 makes changes to payment for inhalation drugs. We implemented provisions of sections 303 through 305 changing payments in 2004 for drugs and their administration in the January 7, 2004 **Federal Register** (69 FR 1084). In this final rule, we are making further changes to Medicare's payment for drugs and drug administration for 2005 required by sections 303 through 305 of the MMA. As indicated earlier in this final rule, we are revising the codes and payments for drug administration based on recommendations of the CPT Editorial Board and the Relative Value Update Committee. Consistent with section 1848(c)(2)(J) of the Act (as amended by section 303(a) of the MMA), the increase in payment resulting from this review are exempt from the budget neutrality requirements that apply to changes in RVUs. We are further increasing payments to physicians that treat patients with cancer who participate in a national demonstration project. In addition, we are also paying a supplying fee of $50 per month for the first month and $24 for each subsequent month for Medicare Part B oral drug prescriptions. We are also proposing to pay a furnishing fee of $0.14 per unit of clotting factor and a dispensing fee of $57 per month for inhalation drugs. Taking all of these provisions into account, we estimate Medicare savings for section 303–305 as follows:

TABLE 47:

Medicare Cost (Savings)
Estimates for MMA Provision 303-305
(in millions)

Provision	FY05	FY06	FY07	FY08	FY09
303-305	(730)	(1,300)	(1,650)	(1,820)	(1,990)

6. Section 952—Reassignment

The reassignment provisions discussed in section III.F is currently estimated to have no significant impact on Medicare expenditures.

7. Section 623—Payment for Renal Dialysis Services

a. Effects on the Medicare Program (Budgetary Effect)

Because the basic case mix adjusted composite payment rate and the revised payment for ESRD drugs must be budget neutral in accordance with section 623(d)(1) of the MMA, except for the statutorily required 1.6 percent increase set forth in section 623(a), we estimate that there would be no budgetary impact for the Medicare program beyond this increase. The impact of this provision (net of beneficiary liability) is shown in the following table:

TABLE 48:

Medicare Cost Estimates for MMA Provision 623
(in millions)

Provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Section 623	$40	$50	$50	$60	$60

b. Impact on ESRD Providers

To understand the impact of the changes affecting payments to ESRD facilities that result from enactment of the MMA on different categories of ESRD facilities, it is necessary to compare estimated payments under the current payment system (current payments) to estimated payments under the revisions to the composite rate payment system as set forth in this final rule (MMA payments). To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and MMA payments contain similar inputs. Therefore, we simulated MMA payments only for those ESRD facilities for which we are able to calculate both current payment and MMA payment.

Due to data limitations, we are unable estimate current and MMA payments for 461 facilities that bill for ESRD drugs. ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from HCRIS. We also used the June 2004 update of CY 2003 Standard Analytical File (SAF) claims as a basis for Medicare dialysis treatments and separately billable drugs and biologicals. As we stated in the proposed rule, this final rule impact on providers uses updated OSCAR, cost report and claims data.

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Table 49:

Impact of MMA Section 623
Payments to Hospital Based and Independent ESRD Facilities
(Includes Drug and Composite Rate Payments)

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

	Number Of facilities	Number of Dialysis Treatments (in millions)	Effect of Changes In Drug Payments 1/	Effect of 1.6% Composite rate Update on Total Payments 2/	Effect of Case Mix 3/	Overall Effect 4/
All	3,907	31.0	0.0	1.0	0.0	1.0
Independent	3,390	27.5	-0.6	1.0	0.0	0.4
Hospital Based	517	3.5	5.2	1.1	0.3	6.6
Size						
Small <5000 treatment per year	1,274	3.9	0.2	1.0	0.5	1.5
Medium 5000-10000 treatments per yr	1,586	11.5	-0.3	1.0	0.1	0.7
Large > 10000 treatments per year	1,047	15.6	0.2	1.0	-0.2	1.0
Type of Ownership						
For-profit	2,782	22.6	-0.7	1.0	-0.2	0.1
Not-for-profit	785	5.8	3.0	1.1	0.4	4.3
Other	340	2.6	0.5	1.0	0.6	1.8
Urban	2,903	25.0	0.0	1.0	-0.1	0.9
Rural	1,004	6.0	-0.1	1.0	0.4	1.1
Region						
New England	128	1.1	0.8	1.0	-0.3	1.7
Middle Atlantic	498	4.3	0.5	1.0	-0.5	1.2

East North Central	570	4.6	0.3	1.0	1.0	1.9
West North Central	270	1.7	1.0	1.0	1.3	2.9
South Atlantic	920	7.2	-0.9	0.9	0.5	0.3
East South Central	317	2.3	-0.9	0.9	1.2	0.7
West South Central	530	4.3	-0.9	1.0	-0.3	-0.1
Mountain	204	1.3	2.4	1.0	-0.7	3.0
Pacific	442	3.8	0.8	1.0	-1.7	0.8
Puerto Rico	28	0.4	0.7	1.0	-4.1	-0.9

1/ This column shows the effect of the changes in drug payments to ESRD providers. These include changes in payment for separately billable drugs and the 8.7% drug add-on.

2/ This column shows the effect of the 1.6% update to the composite rate on total payments to ESRD providers. Note that ESRD providers receive an average of 39% of their total revenues from separately billable drugs which results in an average net increase of 1.0%.

3/ This column shows impact of case-mix adjustments only.

4/ This column shows the overall effect of payments to ESRD facilities with and without the application of MMA Section 623. The MMA provisions include the 1.6% increase, the 8.7% drug add-on, and the case-mix adjustments times treatments plus MMA payment for separately billable drugs. The current payment to ESRD facilities includes the current composite rate times treatments plus current drug payments for separately billable drugs.

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Table 49 shows the impact of MMA Section 623 on hospital based and independent facilities. We have included both composite rate payments as well as payments for separately billable drugs and biologicals because both are effected by section 623 of the MMA. The first column of Table 49 identifies the type of ESRD provider, the second column indicates the number of ESRD facilities for each type, and the third column indicates the number of dialysis treatments.

The fourth column shows the effect of the changes in drug payments to ESRD

providers. The overall effect of changes in drug payments is budget-neutral as required by MMA. The drug add-on adjustment is designed to result in the same aggregate amount of expenditures as would have been made without the statutory policy change.

Current payments for drugs represent 2005 Medicare reimbursement using 95 percent of AWP prices for the top ten drugs. Medicare spending for drugs other than EPO is estimated using 2004 AWP prices updated by a 3 percent inflation factor times actual drug utilization from 2003 claims. EPO is priced $10 per 1000 units (EPO units are estimated using payments because the units field on bills represents the number of EPO administrations rather than the number EPO units). Medicare spending under the MMA is 2003 average acquisition cost for the top ten drugs updated to 2005 figures (using the PPI for prescriptions drugs) times actual drug utilization from 2003 claims. These inflation factors were 4.81 percent and 3.72 percent for 2004 and 2005, respectively.

Payment for drugs under MMA also includes the 8.7 percent drug add-on to the composite rate. This amount is computed by multiplying the composite rate for each provider (with the 1.6 percent increase) times dialysis treatments from 2003 claims. Column 4 is computed by comparing spending under MMA provisions for drugs including the 8.7 percent drug add-on amount to spending under current payments for drugs. In order to make column 4 comparable with rest of Table 49, current composite rate payments to ESRD facilities were included in both current and MMA spending calculations.

Column 5 shows the effect of the 1.6 percent increase to the composite rate on total payments to ESRD providers. While all ESRD providers will get a 1.6 percent increase to their composite rate, this table shows the net effect of this increase on ESRD providers' total Medicare revenues (both drug and composite rate payments combined), and therefore does not show a 1.6 percent increase.

On average, ESRD providers receive an average of 39 percent of their total revenues from separately billable drugs and 61 percent of their total revenues from composite rate payment. Since the 1.6 percent increase is applied to the 61 percent portion of their total Medicare revenues, the 1.6 percent composite rate increase is also arithmetically equal to a 1.0 percent increase in ESRD providers' total Medicare revenues. Column 5 is computed by combining MMA payment for drugs (including the 8.7 percent drug add-on amount) with: (1) current composite rate times dialysis treatments from 2003 claims or (2) composite rate with 1.6 percent increase times dialysis treatments from 2003 claims. The difference between these two combinations is the net effect of the 1.6 percent increase on total payments to ESRD providers. In order to isolate the effect of the 1.6 percent increase, the computation in Column 5 assumes that drug payments to ESRD providers remain constant.

Column 6 shows the impact of the case-mix adjustments as described earlier in this preamble of this final rule. Because MMA requires this adjustment to be budget-neutral in the aggregate, there is no overall impact on ESRD providers as a whole. While the case-mix adjustment will have an impact within the various provider types, Column 6 shows that the effect between provider groupings is minimal. Column 6 is computed as the difference between payments to ESRD providers with the case-mix adjustments compared to payments to providers without the case-mix adjustments. As described earlier in this preamble, we developed a case-mix budget neutrality factor to meet the MMA requirement that payment be budget-neutral with respect to aggregate payments. Therefore, there is no change for ESRD providers in the aggregate. We note that when applying the case-mix adjustments, we did so at the facility level.

Column 7 shows the overall effect of all changes in drug and composite rate payments to ESRD providers. The overall effect of payments to ESRD facilities is measured as the difference between payment with and without application of MMA section 623 as described in this final rule and current payment. MMA payment is computed by multiplying the composite rate for each provider (with both 1.6 percent increase and the 8.7 percent add-on) times dialysis treatments from 2003 claims times the appropriate case-mix adjustment by provider. In addition, MMA payment includes payments for separately billable drugs under the revised pricing methodology as described in this preamble. Current payment is the current composite rate for each provider times dialysis treatments from 2003 claims plus current drug payments for separately billable drugs.

The overall impact to ESRD providers in aggregate is 1.0 percent. Among the three separately shown effects, the effect of changes in drug payments has the most variation among provider type and contributes most to the overall effect. Separately billable ESRD drugs are paid differently to hospital-based and independent ESRD providers. As discussed earlier in this preamble, we are using a single drug add-on to the composite rates for both hospital based and independent facilities. The 6.6 percent increase in payments to hospital-based providers is largely due to the single drug add-on to the composite rate.

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

The coverage of routine costs associated with certain Category A clinical trials as discussed in MMA section 731(b) will have no significant impact on Medicare expenditures.

9. Section 629—Part B Deductible

As explained earlier in the preamble, section 629 of the MMA provides for annual updates to the Medicare Part B deductible. The MMA stipulates that the Medicare Part B deductible will be $110 for calendar year 2005, and, for subsequent years, the deductible will be the previous year's deductible increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) of the Act, ending with that subsequent year (rounded to the nearest dollar). We note that while this MMA provision results in a savings to the Medicare program, it also increases beneficiary costs by an equal amount and was implemented in a **Federal Register** notice published on September 9, 2004 (69 FR 54675).

TABLE 50: ESTIMATED MEDICARE SAVINGS FOR MMA PROVISION 629

[in millions]

MMA provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Sec. 629	110	290	440	590	770

10. Section 512—Hospice Consultation Service

As explained in section III.K of this preamble, effective January 1, 2005, section 512 of the MMA provides for payment to be made to a hospice for specified services furnished by a physician who is either the medical director of, or an employee of, a hospice agency. We estimate that this MMA provision will increase Medicare expenditures by $10 million per year beginning in 2005.

11. Section 706 Coverage of Religious Nonmedical Health Care Institution (RNHCI) Services Furnished in the Home

We anticipate that the time limited RNHCI home benefit will either meet or fall short of the annual $700,000 per calendar year statutory spending limit and therefore will not have a significant financial impact on the Medicare program.

E. Other Issues

1. Outpatient Therapy Services Performed ''Incident To'' Physicians' Services

As discussed in section IV.A, we are amending the regulations to include the statutory requirement that only individuals meeting the existing qualification and training standards for therapists (with the exception of licensure) consistent with § 484.4 qualify to provide therapy services incident to physicians' services. We believe that while this will have little impact on Medicare expenditures, it will assist in ensuring the quality of services provided to beneficiaries.

2. Supervision Requirements for Therapy Assistants in Private Practice

As discussed earlier in section IV.A, we are revising the regulations at § 410.59 and § 410.60 to replace a requirement to provide personal supervision and instead require direct supervision of physical therapist assistants and occupational therapy assistants when therapy services are provided by physical therapists or occupational therapists in private practice. This policy change will provide beneficiaries access to medically necessary therapy services, under a physician-certified plan of care. We believe that this change could result in a 5 percent increase in therapy billing in therapy private practice settings with an estimated cost of $9 million for FY 2005. Projected costs for FY 2006 are $17 million while each subsequent year would only increase by $1 million each year, assuming the therapy caps are applied.

3. Low Osmolar Contrast Media

As discussed earlier in the preamble, we are revising the regulations at § 414.38 to eliminate the restrictive criteria for the payment of LOCM. This regulation will make payment for LOCM consistent across Medicare payment systems. Shown in the following table are estimates of program costs due to the removal of the restrictive criteria for administering LOCM, assuming increased utilization and removal of the 8 percent reduction. Without current ASP data, we could not include the additional impact of the change in payment for LOCM to ASP plus 6 percent, effective April 1, 2005. Contrast-enhanced procedures that most commonly use LOCM, the typical ranges of LOCM amounts used by modality, and the cost ranges for LOCM in the marketplace were considered in valuing the additional program costs.

TABLE 51:

Regulatory Provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
LOCM	20	30	30	30	30

4. Payments for Physicians and Practitioners Managing Patients on Dialysis

We believe that the proposals with respect to ESRD-related services furnished to patients in observation settings and payment for outpatient ESRD-related services for partial month scenarios discussed earlier in section xx provide clarification of current policy surrounding these issues. We do not believe these proposals will have a significant impact on Medicare expenditures.

5. Supervision of Clinical Psychological Testing

We are changing the supervision requirements regarding who can supervise diagnostic psychological testing services. As previously discussed, having ancillary staff supervised by clinical psychologists will enable these practitioners with a higher level of expertise to oversee psychological testing and potentially relieve burdens on physicians and healthcare facilities.

Additionally, in rural areas, we anticipate that permitting psychologists to supervise diagnostic psychological testing services will reduce delays in testing, diagnosis, and treatment that could result from the unavailability of physicians to supervise the tests. We believe that this revision to the supervision requirements will have little impact on Medicare expenditures.

6. Care Plan Oversight

As discussed earlier in the preamble, we are revising § 414.39 to clarify that NPPs can perform home health care plan oversight even though they cannot certify a patient for home health services and sign the plan of care. We do not expect that this change will have an impact on Medicare expenditures, since it is primarily a clarification in policy.

7. Assignment of Medicare Claims

The changes with respect to assignment of Medicare claims are currently estimated to have no significant impact on Medicare expenditures. However, as stated earlier in this preamble at section IV.G, we believe the changes will reduce the paperwork burden on beneficiaries and suppliers.

F. Alternatives Considered

This final rule contains a range of policies, including proposals related to specific MMA provisions. The preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised and presents rationale for our decisions and, when possible, alternatives that were considered.

G. Impact on Beneficiaries

There are a number of changes made in this rule that would have an effect on

beneficiaries. In general, we believe these changes will improve beneficiary access to services that are currently covered or will expand the Medicare benefit package to include new services. As explained in more detail below, the MMA or regulatory provisions may increase beneficiary liability in some cases. Any changes in aggregate beneficiary liability from a particular provision will be a function of the coinsurance (20 percent if applicable for the particular provision after the beneficiary has met the deductible) and the effect of the aggregate cost (savings) of the provision on the calculation of the Medicare Part B premium rate (generally 25 percent of the provision's cost or savings).

The MMA provisions that expand Medicare benefits include: Section 611, adding an initial preventive physical exam for newly eligible Medicare beneficiaries; section 612 providing coverage of cardiovascular screening blood tests; and section 613, providing coverage for diabetes screening tests for Medicare beneficiaries at risk for diabetes. While the initial preventive physical examination for newly eligible Medicare beneficiaries is subject to deductible and coinsurance, we believe Medicare beneficiaries will continue to benefit from expanded coverage for this service. We believe many beneficiaries have supplemental insurance coverage or Medicaid that pays the Medicare deductible on their behalf and there will be no immediate additional out-of-pocket cost. Further, even if a beneficiary pays nearly all of the costs of this new benefit, the preventive office visit will substitute for another service a beneficiary may need to meet the annual deductible and the beneficiary will receive more covered benefits at little additional cost. There are no out-of-pocket costs to the beneficiary for the cardiovascular screening blood tests and diabetes screening tests.

Other proposals in this rule related to the MMA will also impact beneficiary liability, with the most significant related to indexing of the part B deductible (section 629 of the MMA) and the drug administration payment changes (sections 303 and 305 of the MMA). MMA provisions that improve administration of the 10 percent HPSA bonus and provide an additional 5 percent bonus payment to physicians in Medicare scarcity areas will have no impact on beneficiary liability because the bonus payments are applied to the amount Medicare pays the physician net of beneficiary liability. These provisions will also improve access for Medicare beneficiaries by increasing payments to physicians in areas that traditionally have had a low ratio of physicians to population.

We are summarizing the impact of all of the changes we are adopting in this rule in table 52. We note that Medicare savings estimates are relative to projected expenditures that would occur if the provisions of the MMA and this final regulation were not implemented. Thus, the savings figures are reductions in beneficiary liability relative to the amounts they otherwise would have paid. The figures do not necessarily mean that we are estimating that beneficiaries will have lower out-of-pocket costs in 2005 than 2004.

TABLE 52:
Estimated Medicare Beneficiary
Impact of MMA Provisions Being Implemented
In this Final Rule
(in millions)

Provision	FY 05	FY06	FY07	FY08	FY09
Sections 303-305	-$570	-$930	-$1,090	-$1,200	-$1,320
Section 611	20	20	20	20	20
Section 612	13	20	23	23	25
Section 613	5	10	13	15	20
Section 413(a)	8	13	13	5	-
Section 413(b)	5	8	8	8	8
Section 623	20	25	25	30	30
Section 629	110				
Section 512	5	5	5	5	5
LOCM	10	15	15	15	15
Physical Therapy	0	10	10	10	10

The implementation of MMA provisions related to drugs and drug administration will reduce Medicare beneficiary liability for Medicare covered services even after including the additional increases in payment for drug administration and establishing a supplying fee for immunosuppressive drugs, a furnishing fee for the clotting factor and a dispensing fee for immunosuppressive drugs. We do not believe that the drug and drug administration payment changes required by the MMA are intended to lessen beneficiary access to care. As indicated earlier, the changes we are making to Medicare payments for the administration of drugs are permanently increasing them by a weighted average of more than 117 percent between 2003 and 2005 and they are being increased by an additional 3 percent for 2005 only. While payments for drugs are being reduced between 2004 and 2005, the statute requires Medicare to pay for them at 6 percent more than their average sales price or the price they are purchased at in the market after taking into account rebates and discounts. Nevertheless, we acknowledge that there is a concern among physicians and others that the large changes in Medicare's payments may affect their ability or willingness to continue making drugs and related services available. CMS' Office of Research

Demonstrations and Information is analyzing Medicare utilization for drugs and drug administration beginning in 2002 and plans to continue to analyze the data for shifts or changes in utilization patterns as the information becomes available to us. To date, we have no evidence that beneficiaries are having any problems with access to drugs. While we do not believe the payment changes for drugs and drug administration 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 related issues. Specifically, section 303(a)(5) of the MMA requires MedPAC to study items and services furnished by oncologists and drug administration services furnished by other specialists.

We are also undertaking several changes using our administrative authority that will affect Medicare beneficiaries. Our proposal to remove restrictions that limit Medicare payment for use of low osmolar contrast material to specific indications would update Medicare's payment policy to be consistent with the standard practice of medicine and will improve the quality of care for beneficiaries.

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

List of Subjects

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

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

42 CFR Part 410

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

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

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

42 CFR Part 418

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

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

42 CFR Part 486

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

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1359b–3 and secs 1102 and 1871 of the Social Security act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 403.746 is amended by adding a new paragraph (c) to read as follows:

§ 403.746 Condition of participation: Utilization review.

* * * * *

(c) *Standard: Utilization review committee role in RNHCI home services.* In addition to the requirements in paragraphs (a) and (b) of this section, the utilization review committee is responsible for:

(1) The admission, and at least every 30 days, the continued care review of each patient in the RHNCI home services program.

(2) Oversight and monitoring of the home services program, including the purchase and utilization of designated durable medical equipment items for beneficiaries in the program.

■ 3. In subpart G, § 403.764 through § 403.770 are added to read as follows:

§ 403.764 Basis and purpose of religious nonmedical health care institutions providing home service.

(a) *Basis.* This subpart implements sections 1821, 1861, 1861(e), 1861(m), 1861(y), 1861(ss) and 1861(aaa), 1869 and 1878 of the Act regarding Medicare payment for items and services provided in the home setting furnished to eligible beneficiaries by religious nonmedical health care institutions (RNHCIs).

(b) *Purpose.* The home benefit provides for limited durable medical equipment (DME) items and RNHCI services in the home setting that are fiscally limited to $700,000 per calendar year, with an expiration date of December 31, 2006, or the date on which the 2006 spending limit is reached.

§ 403.766 Requirements for coverage and payment of RNHCI home services.

(a) Medicare Part B pays for RNHCI home services if the RNHCI provider does the following:

(1) Submit a notice of intent to CMS to exercise the option of providing home service.

(2) Provide RNHCI services to eligible beneficiaries,

(3) Arrange with suppliers to furnish appropriate DME items as required to meet documented eligible beneficiary needs.

(4) Arrange for RNHCI nurse home visits to eligible beneficiaries.

(5) Have a utilization committee that assumes the additional responsibility for the oversight and monitoring of the items and RNHCI nursing services provided under the home benefit.

(6) Meet all applicable requirements set forth in subpart G of this part.

(b) To be an eligible beneficiary to RNHCI home services the beneficiary must:

(1) Have an effective election in place.

(2) Be confined to the home, as specified in § 409.42(a) of this chapter.

(3) Have a condition that makes him or her eligible to receive services covered under Medicare home health.

(4) Receive home services and DME items from a RNHCI.

(5) Be responsible for deductible and coinsurance for DME, as specified in § 409.50 of this chapter.

§ 403.768 Excluded services.

In addition to items and services excluded in § 409.49 of this chapter, items and services are also excluded if they are provided by:

(a) A HHA that is not a RNHCI.

(b) A supplier who is not providing RNHCI designated items under arrangement with a RNHCI.

(c) A nurse who is not providing RNHCI home nursing services under arrangement with a RNHCI.

§ 403.770 Payments for home services.

(a) The RNHCI nursing visits are paid at the modified low utilization payment

adjusted (LUPA) rate used under the home health prospective payment system at § 484.230 of this chapter.

(b) Appropriate DME items are paid as priced by Medicare, minus the deductible and coinsurance liability of the beneficiary.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 4. The authority citation for part 405 continues to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr, and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 5. Section 405.207 is amended by revising paragraph (b) to read as follows:

§ 405.207 Services related to a noncovered device.

* * * * *

(b) *When payment is made.* Medicare payment may be made for—

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care services related to experimental/investigational (Category A) devices as defined in § 405.201(b); and furnished in conjunction with an FDA-approved clinical trial. The trial must meet criteria established through the national coverage determination process; and if the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

(3) Routine care services related to a non-experimental/investigational (Category B) device defined in § 405.201(b) that is furnished in conjunction with an FDA-approved clinical trial.

■ 6. Section 405.517 is amended by adding a new paragraph (a)(3) to read as follows:

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

(a) *Applicability.* * * *

(3) *Payment for drugs and biologicals on or after January 1, 2005.* Effective January 1, 2005, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart K of this chapter.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

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

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

■ 8. Section 410.1 is amended by adding a new paragraph (a)(6) to read as follows:

§ 410.1 Basis and scope.

(a) * * *

(6) Section 1842(o)—Payment for drugs and biologicals not paid on a cost or prospective payment basis.

* * * * *

■ 9. Section 410.10 is amended by adding new paragraph (y) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

■ 10. Section 410.16 is added to read as follows:

§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

Eligible beneficiary means an individual who receives his or her initial preventive physical examination within 6 months after the effective date of his or her first Medicare Part B coverage period, but only if that first Part B coverage period begins on or after January 1, 2005.

Initial preventive physical examination means all of the following services furnished to an eligible beneficiary by a physician or other qualified nonphysician practitioner with the goal of health promotion and disease detection:

(1) Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in this section.

(2) Review of the beneficiary's potential (risk factors) for depression, including current or past experiences 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 nonphysician practitioner may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.

(3) Review of the beneficiary's functional ability, and level of safety as those terms are defined in this section, as described in paragraph (4) of this definition, based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified nonphysician practitioner may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(4) An examination to include measurement of the beneficiary's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.

(5) Performance and interpretation of an electrocardiogram.

(6) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(7) Education, counseling, and referral, including a brief written plan such as a checklist provided to the beneficiary for obtaining the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in section 1861(s)(10), section 1861(jj), section 1861(nn), section 1861(oo), section 1861(pp), section 1861(qq)(1), section 1861(rr), section 1861(uu), section 1861(vv), section 1861(xx)(1), and section 1861(yy) of the Act.

Medical history is defined to include, at a minimum, the following:

(1) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

(2) Current medications and supplements, including calcium and vitamins.

(3) Family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk.

A *physician* for purposes of this section means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

A qualified nonphysician practitioner for purposes of this section means a physician assistant, nurse practitioner, or clinical nurse specialist (as authorized under section 1861(s)(2)((K)(i) and section

1861(s)(2)((K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in § 410.74, § 410.75, and § 410.76).

Review of the beneficiary's functional ability and level of safety must include, at a minimum, a review of the following areas:

(1) Hearing impairment.
(2) Activities of daily living.
(3) Falls risk.
(4) Home safety

Social history is defined to include, at a minimum, the following:

(1) History of alcohol, tobacco, and illicit drug use.
(2) Diet.
(3) Physical activities.

(b) *Condition for coverage of an initial preventive physical examination.* Medicare Part B pays for an initial preventive physical examination provided to an eligible beneficiary, as described in this section, if it is furnished by a physician or other qualified nonphysician practitioner, as defined in this section.

(c) *Limitations on coverage of initial preventive physical examinations.* Payment may not be made for an initial preventive physical preventive examination that is performed for an individual who is not an eligible beneficiary as described in this section.

■ 11. A new § 410.17 is added to read as follows:

§ 410.17 Cardiovascular disease screening tests.

(a) *Definition.* For purposes of this subpart, the following definition apply:

Cardiovascular screening blood test means:

(1) A lipid panel consisting of a total cholesterol, HDL cholesterol, and triglyceride. The test is performed after a 12-hour fasting period.

(2) Other blood tests, previously recommended by the U.S. Preventive Services Task Force (USPSTF), as determined by the Secretary through a national coverage determination process.

(3) Other non-invasive tests, for indications that have a blood test recommended by the USPSTF, as determined by the Secretary through a national coverage determination process.

(b) *General conditions of coverage.* Medicare Part B covers cardiovascular disease screening tests when ordered by the physician who is treating the beneficiary (*see* § 410.32(a)) for the purpose of early detection of cardiovascular disease in individuals without apparent signs or symptoms of cardiovascular disease.

(c) *Limitation on coverage of cardiovascular screening tests.* Payment may be made for cardiovascular screening tests performed for an asymptomatic individual only if the individual has not had the screening tests paid for by Medicare during the preceding 59 months following the month in which the last cardiovascular screening tests were performed.

■ 12. A new § 410.18 is added to read as follows:

§ 410.18 Diabetes screening tests.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Pre-diabetes means a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100—125 mg/dL, or a 2-hour post-glucose challenge of 140—199 mg/dL. The term pre-diabetes includes the following conditions:

(1) Impaired fasting glucose.
(2) Impaired glucose tolerance.

(b) *General conditions of coverage.* Medicare Part B covers diabetes screening tests after a referral from a physician or qualified nonphysician practitioner to an individual at risk for diabetes for the purpose of early detection of diabetes.

(c) *Types of tests covered.* The following tests are covered if all other conditions of this subpart are met:

(1) Fasting blood glucose test.

(2) Post-glucose challenges including, but not limited to, an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, a 2-hour post glucose challenge test alone.

(3) Other tests as determined by the Secretary through a national coverage determination.

(d) *Amount of testing covered.* Medicare covers the following for individuals:

(1) Diagnosed with pre-diabetes, two screening tests per calendar year.

(2) Previously tested who were not diagnosed with pre-diabetes, or who were never tested before, one screening test per year.

(e) *Eligible risk factors.* Individuals with the following risk factors are eligible to receive the benefit:

(1) Hypertension.
(2) Dyslipidemia.
(3) Obesity, defined as a body mass index greater than or equal to 30 kg/m^2.
(4) Prior identification of impaired fasting glucose or glucose intolerance.
(5) Any two of the following characteristics:
(i) Overweight, defined as body mass index greater than 25, but less than 30 kg/m^2.
(ii) A family history of diabetes.
(iii) 65 years of age or older.
(iv) A history of gestational diabetes mellitus or delivery of a baby weighing more than 9 pounds.

■ 13. Section 410.26 is amended by revising paragraph (c) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

* * * * *

(c) *Limitations.* (1) Drugs and biologicals are also subject to the limitations specified in § 410.29.

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in § 410.59(a)(3)(iii), § 410.60(a)(3)(iii), and § 410.62(a)(3)(ii).

■ 14. Section 410.32 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *
(2) * * *

(iii) Diagnostic psychological testing services when—

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician or a clinical psychologist.

* * * * *

■ 15. Section 410.59 is amended by—
■ A. Revising paragraph (a) introductory text and paragraph (a)(3)(ii).
■ B. Adding new paragraph (a)(3)(iii).
■ C. Revising paragraph (b) heading.
■ C. Revising paragraph (c)(2).
■ D. Adding new paragraph (e)(1)(iii).

The additions and revisions read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient occupational therapy services only if they are furnished by an individual meeting the qualifications in § 484.4 of

this chapter for an occupational therapist or by an appropriately supervised occupational therapy assistant but only under the following conditions:

* * * * *

(3) * * *

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

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform occupational therapy services within the scope of State law. When an occupational therapy service is provided incident to the service of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to occupational therapy and occupational therapists, except that a license to practice occupational therapy in the State is not required.

(b) *Conditions for coverage of outpatient therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* * * *

(c) * * *

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

* * * * *

(e) * * *

(1) * * *

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

* * * * *

■ 16. Section 410.60 is amended by—

■ A. Revising paragraph (a) introductory text.

■ B. Revising paragraph (a)(3)(ii).

■ C. Adding new paragraph (a)(3)(iii).

■ D. Revising paragraph (b) heading.

■ E. Revising paragraph (c)(2).

■ F. Adding new paragraph (e)(1)(iii).

The additions and revisions read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient physical therapy services only if they are furnished by an individual meeting the qualifications in § 484.4 of this chapter for a physical therapist or by an appropriately supervised physical therapist assistant but only under the following conditions:

* * * * *

(3) * * *

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

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform physical therapy services under State law. When a physical therapy service is provided incident to the service of a physician, physician's assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to physical therapy and physical therapists, except that a license to practice physical therapy in the State is not required.

(b) *Condition for coverage of outpatient physical therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* * * *

(c) * * *

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

* * * * *

(e) * * *

(1) * * *

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

* * * * *

■ 17. Section 410.62 is amended by—

■ A. Revising paragraph (a) introductory text and (a)(2)(i), (a)(2)(iii) and (a)(3).

■ B. Revising paragraphs (b) and (c).

The revisions read as follows:

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

(a) *Basic rule.* Except as specified in paragraph (a)(3)(ii) of this section, Medicare Part B pays for outpatient speech-language pathology services only if they are furnished by an individual who meets the qualifications for a speech-language pathologist in § 484.4 of this chapter and only under the following conditions:

* * * * *

(2) * * *

(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech-language pathologist who provides the services to the particular individual;

(ii) * * *

(iii) Meets the requirements of § 410.61.

(3) They are furnished—

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

(ii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform speech-language pathology services under State law. When a speech-language pathology service is provided incident to the services of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to speech-language pathology and speech-language pathologists, except that a license to practice speech-language pathology services in the State is not required.

(b) *Condition for coverage of outpatient speech-language pathology services to certain inpatients of a hospital, CAH, or SNF.* Medicare Part B pays for outpatient speech-language pathology services furnished to an inpatient of a hospital, CAH, or SNF who requires the services but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) Excluded services. No service is included as an outpatient speech-language pathology service if it is not included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

* * * * *

■ 18. Section 410.63 is amended by—

■ A. Revising paragraph (b) heading.

■ B. Adding a new paragraph (c).

The revision and addition reads as follows:

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

* * * * *

(b) *Blood clotting factors: Conditions.* * * *

(c) *Blood clotting factors: Furnishing Fee.*

(1) Effective January 1, 2005, a furnishing fee of $0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay.

(2) The furnishing fee for blood clotting factors furnished in 2006 or a subsequent year is be equal to the furnishing fee paid the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

■ 19. Section 410.78 is amended by—
■ A. Revising paragraph (a)(4).
■ B. Revising paragraph (b) introductory text.

The revisions read as follows:

§ 410.78 Telehealth services.

* * *

(4) *Originating site* means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

(b) *General rule.* Medicare Part B pays for office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management and end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site) furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

■ 20. Section 410.160 is amended by revising paragraph (f) to read as follows:

§ 410.160 Part B annual deductible.

* * * * *

(f) *Amount of the Part B annual deductible.* (1) Beginning with expenses for services furnished during calendar year 2006, and for all succeeding years, the annual deductible is the previous year's deductible plus the annual percentage increase in the monthly actuarial rate for Medicare enrollees age 65 and over, rounded to the nearest dollar.

(2) For 2005, the deductible is $110.

(3) From 1991 through 2004, the deductible was $100.

(4) From 1982 through 1990, the deductible was $75.

(5) From 1973 through 1981, the deductible was $60.

(6) From 1966 through 1972, the deductible was $50.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 21. The authority citation for part 411 continues to read as follows:

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

■ 22. Section 411.15 is amended by—
■ A. Revising paragraph (a)(1).
■ B. Adding paragraph (k)(11).

The revision and addition read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(a) * * *

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic exams, prostate cancer screening tests, glaucoma screening exams, or initial preventive physical examinations that meet the criteria specified in paragraphs (k)(6) through (k)(11) of this section.

* * * * *

(k) * * *

(11) In the case of initial preventive physical examinations, with the goal of health promotion and disease prevention, subject to the conditions and limitations specified in § 410.16 of this chapter.

* * * * *

■ 23. Section 411.404 is amended by revising paragraph (b) to read as follows:

§ 411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

* * * * *

(b) *Written notice.* (1) Written notice is given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

(2) A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion.

(3) After a beneficiary is notified that there is no Medicare payment for a service that is not covered by Medicare, he or she is presumed to know that there is no Medicare payment for any form of subsequent treatment for the non-covered condition.

* * * * *

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

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

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

§ 414.38 [Removed]

■ 25. Section 414.38 is removed.
■ 26. Section 414.39 is amended by—
■ A. Revising paragraph (a).
■ B. Adding paragraph (c).

The revision and addition read as follows:

§ 414.39 Special rules for payment of care plan oversight.

(a) *General.* Except as specified in paragraphs (b) and (c) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule. For purposes of this section a nonphysician practitioner (NPP) is a nurse practitioner, clinical nurse specialist or physician assistant.

* * * * *

(c) *Special rules for payment of care plan oversight provided by nonphysician practitioners for beneficiaries who receive HHA services covered by Medicare.*

(1) An NPP can furnish physician care plan oversight (but may not certify a patient as needing home health services) if the physician who signs the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight and either:

(i) The physician and NPP are part of the same group practice; or

(ii) If the NPP is a nurse practitioner or clinical nurse specialist, the physician signing the plan of care also has a collaborative agreement with the NPP; or

(iii) If the NPP is a physician assistant, the physician signing the plan of care is also the physician who provides general supervision of physician assistant services for the practice.

(2) Payment may be made for care plan oversight services furnished by an NPP when:

(i) The NPP providing the care plan oversight has seen and examined the patient;

(ii) The NPP providing care plan oversight is not functioning as a

consultant whose participation is limited to a single medical condition rather than multi-disciplinary coordination of care; and

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.

■ 27. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§ 414.65 Payment for telehealth services.

(a) * * *

(1) The Medicare payment amount for office or other outpatient visits, consultation, individual psychotherapy, psychiatric diagnostic interview examination, pharmacologic management and end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site) furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

* * * * *

■ 28. Section 414.66 is added to subpart B to read as follows:

§ 414.66 Incentive payments for physician scarcity areas.

(a) *Definition.* As used in this section, the following definitions apply.

Physician scarcity area is defined as an area with a shortage of primary care physicians or specialty physicians to the Medicare population in that area.

Primary care physician is defined as a general practitioner, family practice practitioner, general internist, obstetrician or gynecologist.

(b) Physicians' services furnished to a beneficiary in a Physician Scarcity Area (PSA) for primary or specialist care are eligible for a 5 percent incentive payment.

(c) Primary care physicians furnishing services in primary care PSAs are entitled to an additional 5 percent incentive payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

(d) Physicians, as defined in section 1861(r)(1) of the Act, furnishing services in specialist care PSAs are entitled to an additional 5 percent payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

■ 29. Section 414.67 is added to subpart B to read as follows:

§ 414.67 Incentive payments for Health Professional Shortage Areas.

(a) Physicians' services furnished to a beneficiary in a geographic-based Health Professional Shortage Area (HPSA) are eligible for a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(b) Physicians furnishing services in a geographic-based primary medical care HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(c) Psychiatrists furnishing services in a mental health HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule. (The only physicians eligible to receive the 10 percent incentive payment in mental health HPSAs that do not overlap with primary care HPSAs are psychiatrists.)

■ 30. Part 414 is amended by adding a new subpart K to read as follows:

Subpart K—Payment for Drugs and Biologicals in 2005

Sec.

Subpart K—Payment for Drugs and Biologicals in 2005

§ 414.900 Basis.

(a) This subpart implements section 1842(o) of the Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

(1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.

(2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.

(3) Statutorily covered drugs, for example—

(i) Influenza.

(ii) Pneumococcal and hepatitis vaccines.

(iii) Antigens.

(iv) Hemophilia blood clotting factor.

(v) Immunosuppressive drugs.

(vi) Certain oral anti-cancer drugs.

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Drug means both drugs and biologicals.

Manufacturer's average sales price means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

Multiple source drug means a drug described by section 1847A(c)(6)(C) of the Act.

Single source drug means a drug described by section 1847A(c)(6)(D) of the Act.

Unit is defined as in part 414, subpart J of this chapter.

Wholesale acquisition cost (WAC) means the price described by section 1847A(c)(6)(B) of the Act.

§ 414.904 Basis of payment.

(a) *Method of payment.* Payment for a drug for calendar year 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(b) *Multiple source drugs.* (1) *Average sales prices.* The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price.* The average sales price is determined by—

(i) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(c) *Single source drugs.* (1) *Average sales price.* The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price.* The average sales price is determined by computing—

(i) The sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(d) *Limitations on the average sales price.* (1) *Wholesale acquisition cost for a single source drug.* The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of

the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient.* (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2005, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.

(e) *Exceptions to the average sales price.* (1) *Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, and influenza vaccine and are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003 and is not updated in 2005.

(3) *Blood and blood products.* In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment limit in a case where the average sales price during the first quarter of sales is unavailable.* In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

■ 31. Part 414 is amended by adding a new subpart L to read as follows:

Subpart L—Supplying and Dispensing Fees

Sec.
414.1000 Purpose.
414.1001 Basis of Payment.

§ 414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

§ 414.1001 Basis of payment.

(a) A supplying fee of $24 shall be paid to a pharmacy for each supplied prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) A supplying fee of $50 is paid to a pharmacy for the initial supplied prescription of drugs and biologicals described in sections 1861(s)(2)(J) of the Act provided to a patient during the first month following a transplant.

(c) During 2005, a dispensing fee of $57 is paid to a supplier for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) During 2005, a dispensing fee of $80 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

PART 418—HOSPICE CARE

■ 32. The authority citation for part 418 continues to read as follows:

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

■ 33. Section 418.205 is added to subpart F to read as follows:

§ 418.205 Special requirements for hospice pre-election evaluation and counseling services.

(a) *Definition.* As used in this section the following definition applies.

Terminal illness has the same meaning as defined in § 418.3.

(b) *General.* Effective January 1, 2005, payment for hospice pre-election evaluation and counseling services as specified in §418.304(d) may be made to a hospice on behalf of a Medicare beneficiary if the requirements of this section are met.

(1) *The beneficiary.* The beneficiary:

(i) Has been diagnosed as having a terminal illness as defined in § 418.3.

(ii) Has not made a hospice election.

(iii) Has not previously received hospice pre-election evaluation and consultation services specified under this section.

(2) *Services provided.* The hospice pre-election services include an evaluation of an individual's need for pain and symptom management and counseling regarding hospice and other care options. In addition, the services may include advising the individual regarding advanced care planning.

(3) *Provision of pre-election hospice services.*

(i) The services must be furnished by a physician.

(ii) The physician furnishing these services must be an employee or medical director of the hospice billing for this service.

(iii) The services cannot be furnished by hospice personnel other than employed physicians, such as but not limited to nurse practitioners, nurses, or social workers, physicians under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice.

(iv) If the beneficiary's attending physician is also the medical director or a physician employee of the hospice, the attending physician may not provide nor may the hospice bill for this service because that physician already possesses the expertise necessary to furnish end-of-life evaluation and management, and counseling services.

(4) *Documentation.* (i) If the individual's physician initiates the request for services of the hospice medical director or physician, appropriate documentation is required.

(ii) The request or referral must be in writing, and the hospice medical

director or physician employee is expected to provide a written note on the patient's medical record.

(iii) The hospice agency employing the physician providing these services is required to maintain a written record of the services furnished.

(iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the services and documentation that communication between the hospice medical director or physician and the beneficiary's physician occurs, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

■ 34. Section 418.304 is amended by adding paragraph (d) to read as follows.

§ 418.304 Payment for physician services.

* * * * *

(d) *Payment for hospice pre-election evaluation and counseling services.* The intermediary makes payment to the hospice for the services established in § 418.205. Payment for this service is set at an amount established under the physician fee schedule, for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decision-making of low complexity other than the portion of the amount attributable to the practice expense component. Payment for this pre-election service does not count towards the hospice cap amount.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 35. The authority citation for part 424 continues to read as follows:

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

■ 36. Section 424.55 is amended by adding new paragraph (c) to read as follows:

§ 424.55 Payment to the supplier.

* * * * *

(c) *Exception.* In situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

■ 37. Section 424.71 is amended as follows:

■ A. The definition of ''Health care delivery system or system'' is removed.

■ B. The definition of the term ''Entity'' is added in alphabetical order.

The addition reads as follows:

§ 424.71 Definitions.

* * * * *

Entity means a person, group, or facility that is enrolled in the Medicare program.

* * * * *

■ 38. Section 424.80 is amended by—

■ A. Revising paragraph (a).

■ B. Revising paragraph (b)(2).

■ C. Removing paragraph (b)(3).

■ D. Redesignating paragraphs (b)(4) through (6) as paragraphs (b)(3) through (5), respectively.

■ E. Revising paragraph (c).

■ F. Adding a new paragraph (d).

The revisions and addition read as follows:

§ 424.80 Prohibition of reassignment of claims by suppliers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a supplier under an assignment to any other person under reassignment, power of attorney, or any other direct arrangement. Nothing in this section alters a party's obligations under the anti-kickback statute (section 1128B(b) of the Act), the physician self-referral prohibition (section 1877 of the Act), the rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter), the rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter), or other laws, rules, and regulations.

(b) * * *

(1) * * *

(2) *Payment to an entity under a contractual arrangement.* Medicare may pay an entity enrolled in the Medicare program if there is a contractual arrangement between the entity and the supplier under which the entity bills for the supplier's services, subject to the provisions of paragraph (d) of this section.

* * * * *

(c) *Rules applicable to an employer or entity.* An employer or entity that may receive payment under paragraph (b)(1) or (b)(2) of this section is considered the supplier of those services for purposes of subparts C, D, and E of this part, subject to the provisions of paragraph (d) of this section.

(d) *Reassignment to an entity under a contractual arrangement: Conditions and limitations.* (1) *Liability of the parties.* An entity enrolled in the Medicare program that receives payment under a contractual arrangement under paragraph (b)(2) of this section and the supplier that otherwise receives payment are jointly and severally responsible for any Medicare overpayment to that entity.

(2) *Access to records.* The supplier furnishing the service has unrestricted access to claims submitted by an entity for services provided by that supplier.

PART 484—HOME HEALTH SERVICES

■ 39. The authority citation for part 484 continues to read as follows:

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

§ 484.4 [Amended]

■ 40. In § 484.4 in the definition of physical therapy assistant the term ''physical therapy assistant'' is removed and the term ''physical therapist assistant'' is added in its place wherever it appears.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 41. The authority citation for part 486 continues to read as follows:

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

Subpart D—[Removed and Reserved]

■ 42. Part 486 subpart D, consisting of § 486.150 through § 486.163, is removed and reserved.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 1, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 1, 2004.

Tommy G. Thompson,

Secretary.

Note: These addenda will not appear in the Code of Federal Regulations.

Addendum A—Explanation and Use of Addenda B

The addenda on the following pages provide various data pertaining to the Medicare fee schedule for physicians' services furnished in 2005. Addendum B contains the RVUs for work, non-facility practice expense, facility practice expense, and malpractice expense, and other information for all services included in the physician fee schedule.

In previous years, we have listed many services in Addendum B that are not paid under the physician fee schedule. To avoid publishing as many pages of codes for these services, we are not including clinical laboratory codes and most alphanumeric

codes (Healthcare Common Procedure Coding System (HCPCS) codes not included in CPT) in Addendum B.

Addendum B—2005 Relative Value Units and Related Information Used in Determining Medicare Payments for 2005

This addendum contains the following information for each CPT code and alphanumeric HCPCS code, except for alphanumeric codes beginning with B (enteral and parenteral therapy), E (durable medical equipment), K (temporary codes for nonphysicians' services or items), or L (orthotics), and codes for anesthesiology.

1. *CPT/HCPCS code.* This is the CPT or alphanumeric HCPCS number for the service. Alphanumeric HCPCS codes are included at the end of this addendum.

2. *Modifier.* A modifier is shown if there is a technical component (modifier TC) and a professional component (PC) (modifier -26) for the service. If there is a PC and a TC for the service, Addendum B contains three entries for the code: one for the global values (both professional and technical); one for modifier -26 (PC); and one for modifier TC. The global service is not designated by a modifier, and physicians must bill using the code without a modifier if the physician furnishes both the PC and the TC of the service.

Modifier -53 is shown for a discontinued procedure. There will be RVUs for the code (CPT code 45378) with this modifier.

3. *Status indicator.* This indicator shows whether the CPT/HCPCS code is included in the physician fee schedule and whether it is separately payable if the service is covered.

A = Active code. These codes are separately payable under the fee schedule if covered. There will be RVUs for codes with this status. The presence of an ''A'' indicator does not mean that Medicare has made a national decision regarding the coverage of the service. Carriers remain responsible for coverage decisions in the absence of a national Medicare policy.

B = Bundled code. Payment for covered services is always bundled into payment for other services not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are incident. (An example is a telephone call from a hospital nurse regarding care of a patient.)

C = Carrier-priced code. Carriers will establish RVUs and payment amounts for these services, generally on a case-by-case basis following review of documentation, such as an operative report.

E = Excluded from physician fee schedule by regulation. These codes are for items or services that we chose to exclude from the physician fee schedule payment by regulation. No RVUs are shown, and no payment may be made under the physician fee schedule for these codes. Payment for them, if they are covered, continues under reasonable charge or other payment procedures.

I = Not valid for Medicare purposes. Medicare uses another code for the reporting of, and the payment for these services. (Code not subject to a 90-day grace period.)

N = Noncovered service. These codes are noncovered services. Medicare payment may not be made for these codes. If RVUs are shown, they are not used for Medicare payment.

P = Bundled or excluded code. There are no RVUs for these services. No separate payment should be made for them under the physician fee schedule.

—If the item or service is covered as incident to a physician's service and is furnished on the same day as a physician's service, payment for it is bundled into the payment for the physician's service to which it is incident (an example is an elastic bandage furnished by a physician incident to a physician's service).

—If the item or service is covered as other than incident to a physician's service, it is excluded from the physician fee schedule (for example, colostomy supplies) and is paid under the other payment provisions of the Act.

R = Restricted coverage. Special coverage instructions apply. If the service is covered and no RVUs are shown, it is carrier-priced.

T = Injections. There are RVUs for these services, but they are only paid if there are no other services payable under the physician fee schedule billed on the same date by the same provider. If any other services payable under the physician fee schedule are billed on the same date by the same provider, these services are bundled into the service(s) for which payment is made.

X = Exclusion by law. These codes represent an item or service that is not within the definition of ''physicians' services'' for physician fee schedule payment purposes. No RVUs are shown for these codes, and no payment may be made under the physician fee schedule. (Examples are ambulance services and clinical diagnostic laboratory services.)

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

5. *Physician work RVUs.* These are the RVUs for the physician work for this service in 2005. Codes that are not used for Medicare payment are identified with a ''+.''

6. *Facility practice expense RVUs.* These are the fully implemented resource-based practice expense RVUs for facility settings.

7. *Non-facility practice expense RVUs.* These are the fully implemented resource-based practice expense RVUs for non-facility settings.

8. *Malpractice expense RVUs.* These are the RVUs for the malpractice expense for the service for 2005.

9. *Facility total.* This is the sum of the work, fully implemented facility practice expense, and malpractice expense RVUs.

10. *Non-facility total.* This is the sum of the work, fully implemented non-facility practice expense, and malpractice expense RVUs.

11. *Global period.* This indicator shows the number of days in the global period for the code (0, 10, or 90 days). An explanation of the alpha codes follows:

MMM = The code describes a service furnished in uncomplicated maternity cases including antepartum care, delivery, and postpartum care. The usual global surgical concept does not apply. See the 1999 Physicians' Current Procedural Terminology for specific definitions.

XXX = The global concept does not apply.

YYY = The global period is to be set by the carrier (for example, unlisted surgery codes).

ZZZ = Code related to another service that is always included in the global period of the other service. (Note: Physician work and practice expense are associated with intra-service time and in some instances the post-service time.)

BILLING CODE 4120–01–P

ADDENDUM B. - RELATIVE VALUE UNITS(RVUs) AND RELATED INFORMATION -

CPT[1]/ HCPCS[2]	Mod	Status	Description	Physician work RVUs[3]	Non- facility PE RVUs	Facility PE RVUs	Mal- practice RVUs	Non-facility Total	Facility Total	Global
0003T		C	Cervicography	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0008T		C	Upper gi endoscopy w/suture	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0010T		C	Tb test, gamma interferon	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0016T		C	Thermotx choroid vasc lesion	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0017T		C	Photocoagulat macular drusen	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0018T		C	Transcranial magnetic stimul	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0019T		I	Extracorp shock wave tx, ms	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0020T		C	Extracorp shock wave tx, ft	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0021T		C	Fetal oximetry, trnsvag/cerv	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0023T		C	Phenotype drug test, hiv 1	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0024T		C	Transcath cardiac reduction	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0026T		C	Measure remnant lipoproteins	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0027T		C	Endoscopic epidural lysis	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0028T		C	Dexa body composition study	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0029T		C	Magnetic tx for incontinence	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0030T		C	Antiprothrombin antibody	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0031T		C	Speculoscopy	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0032T		C	Speculoscopy w/direct sample	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0033T		C	Endovasc taa repr incl subcl	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0034T		C	Endovasc taa repr w/o subcl	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0035T		C	Insert endovasc prosth, taa	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0036T		C	Endovasc prosth, taa, add-on	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0037T		C	Artery transpose/endovas taa	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0038T		C	Rad endovasc taa rpr w/cover	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0039T		C	Rad s/i, endovasc taa repair	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0040T		C	Rad s/i, endovasc taa prosth	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0041T		C	Detect ur infect agnt w/cpas	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0042T		C	Ct perfusion w/contrast, cbf	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0043T		C	Co expired gas analysis	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0044T		C	Whole body photography	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0045T		C	Whole body photography	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0046T		C	Cath lavage, mammary duct(s	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0047T		C	Cath lavage, mammary duct(s)	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0048T		C	Implant ventricular device	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0049T		C	External circulation assist	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0050T		C	Removal circulation assist	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0051T		C	Implant total heart system	0.00	0.00	0.00	0.00	0.00	0.00	XXX

3 +Indicates RVUs are not used for Medicare payment.

ADDENDUM B. - RELATIVE VALUE UNITS(RVUs) AND RELATED INFORMATION -

CPT[1]/ HCPCS[2]	Mod	Status	Description	Physician work RVUs[3]	Non- facility PE RVUs	Facility PE RVUs	Mal- practice RVUs	Non-facility Total	Facility Total	Global
0052T		C	Replace component heart syst	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0053T		C	Replace component heart syst	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0054T		C	Bone surgery using computer	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0055T		C	Bone surgery using computer	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0056T		C	Bone surgery using computer	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0058T		C	Cryopreservation, ovary tiss	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0059T		C	Cryopreservation, oocyte	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0060T		C	Electrical impedance scan	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0061T		C	Destruction of tumor, breast	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0062T		C	Rep intradisc annulus;1 lev	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0063T		C	Rep intradisc annulus;>1lev	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0064T		C	Spectroscop eval expired gas	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0065T		C	Ocular photoscreen bilat	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0066T		C	Ct colonography;screen	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0067T		C	Ct colonography;dx	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0068T		C	Interp/rept heart sound	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0069T		C	Analysis only heart sound	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0070T		C	Interp only heart sound	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0071T		C	U/s leiomyomata ablate <200	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0072T		C	U/s leiomyomata ablate >200	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0073T		A	Delivery, comp imrt	0.00	18.02	NA	0.13	18.15	NA	XXX
0074T		C	Online physician e/m	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0075T		C	Perq stent/chest vert art	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0076T		C	S&i stent/chest vert art	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0077T		C	Cereb therm perfusion probe	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0078T		C	Endovasc aort repr w/device	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0079T		C	Endovasc visc extnsn repr	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0080T		C	Endovasc aort repr rad s&i	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0081T		C	Endovasc visc extnsn s&i	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0082T		C	Stereotactic rad delivery	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0083T		C	Stereotactic rad tx mngmt	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0084T		C	Temp prostate urethral stent	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0085T		C	Breath test heart reject	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0086T		C	L ventricle fill pressure	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0087T		C	Sperm eval hyaluronan	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0088T		C	Rf tongue base vol reduxn	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0500F		I	Initial prenatal care visit	0.00	0.00	0.00	0.00	0.00	0.00	XXX

3 +Indicates RVUs are not used for Medicare payment.

ADDENDUM B. - RELATIVE VALUE UNITS(RVUs) AND RELATED INFORMATION -

CPT[1]/ HCPCS[2]	Mod	Status	Description	Physician work RVUs[3]	Non- facility PE RVUs	Facility PE RVUs	Mal- practice RVUs	Non-facility Total	Facility Total	Global
0501F		I	Prenatal flow sheet	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0502F		I	Subsequent prenatal care	0.00	0.00	0.00	0.00	0.00	0.00	XXX
0503F		I	Postpartum care visit	0.00	0.00	0.00	0.00	0.00	0.00	XXX
1000F		I	Tobacco use, smoking, assess	0.00	0.00	0.00	0.00	0.00	0.00	XXX
1001F		I	Tobacco use, non-smoking	0.00	0.00	0.00	0.00	0.00	0.00	XXX
10021		A	Fna w/o image	1.27	2.15	0.54	0.10	3.52	1.91	XXX
10022		A	Fna w/image	1.27	2.54	0.42	0.08	3.89	1.77	XXX
1002F		I	Assess anginal symptom/level	0.00	0.00	0.00	0.00	0.00	0.00	XXX
10040		A	Acne surgery	1.18	1.01	0.79	0.06	2.25	2.03	010
10060		A	Drainage of skin abscess	1.17	1.21	0.93	0.12	2.50	2.22	010
10061		A	Drainage of skin abscess	2.40	1.82	1.50	0.26	4.48	4.16	010
10080		A	Drainage of pilonidal cyst	1.17	3.10	1.11	0.11	4.38	2.39	010
10081		A	Drainage of pilonidal cyst	2.45	4.07	1.50	0.25	6.77	4.20	010
10120		A	Remove foreign body	1.22	2.17	0.97	0.12	3.51	2.31	010
10121		A	Remove foreign body	2.69	3.51	1.78	0.32	6.52	4.79	010
10140		A	Drainage of hematoma/fluid	1.53	1.77	1.29	0.19	3.49	3.01	010
10160		A	Puncture drainage of lesion	1.20	1.60	1.08	0.14	2.94	2.42	010
10180		A	Complex drainage, wound	2.25	2.98	1.98	0.33	5.56	4.56	010
11000		A	Debride infected skin	0.60	0.58	0.22	0.07	1.25	0.89	000
11001		A	Debride infected skin add-on	0.30	0.23	0.11	0.03	0.56	0.44	ZZZ
11004		A	Debride genitalia & perineum	10.31	NA	3.90	0.67	NA	14.88	000
11005		A	Debride abdom wall	13.75	NA	5.56	0.96	NA	20.27	000
11006		A	Debride genit/per/abdom wall	12.61	NA	4.85	1.28	NA	18.74	000
11008		A	Remove mesh from abd wall	5.00	NA	2.02	0.61	NA	7.63	ZZZ
11010		A	Debride skin, fx	4.19	6.87	2.62	0.60	11.66	7.41	010
11011		A	Debride skin/muscle, fx	4.94	8.16	2.34	0.70	13.80	7.98	000
11012		A	Debride skin/muscle/bone, fx	6.87	12.10	3.84	1.12	20.09	11.83	000
11040		A	Debride skin, partial	0.50	0.52	0.21	0.06	1.08	0.77	000
11041		A	Debride skin, full	0.82	0.66	0.33	0.10	1.58	1.25	000
11042		A	Debride skin/tissue	1.12	0.97	0.44	0.13	2.22	1.69	000
11043		A	Debride tissue/muscle	2.38	3.38	2.59	0.29	6.05	5.26	010
11044		A	Debride tissue/muscle/bone	3.06	4.45	3.75	0.40	7.91	7.21	010
11055		R	Trim skin lesion	0.43	0.56	0.17	0.05	1.04	0.65	000
11056		R	Trim skin lesions, 2 to 4	0.61	0.64	0.23	0.07	1.32	0.91	000
11057		R	Trim skin lesions, over 4	0.79	0.74	0.30	0.10	1.63	1.19	000
11100		A	Biopsy, skin lesion	0.81	1.25	0.37	0.04	2.10	1.22	000
11101		A	Biopsy, skin add-on	0.41	0.33	0.19	0.02	0.76	0.62	ZZZ

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ADDENDUM B. - RELATIVE VALUE UNITS(RVUs) AND RELATED INFORMATION -

CPT[1]/ HCPCS[2]	Mod	Status	Description	Physician work RVUs[3]	Non- facility PE RVUs	Facility PE RVUs	Mal-practice RVUs	Non-facility Total	Facility Total	Global
11200		A	Removal of skin tags	0.77	1.04	0.76	0.05	1.86	1.58	010
11201		A	Remove skin tags add-on	0.29	0.16	0.12	0.02	0.47	0.43	ZZZ
11300		A	Shave skin lesion	0.51	0.99	0.21	0.03	1.53	0.75	000
11301		A	Shave skin lesion	0.85	1.11	0.38	0.05	2.01	1.28	000
11302		A	Shave skin lesion	1.05	1.30	0.46	0.05	2.40	1.56	000
11303		A	Shave skin lesion	1.24	1.58	0.52	0.07	2.89	1.83	000
11305		A	Shave skin lesion	0.67	0.85	0.27	0.07	1.59	1.01	000
11306		A	Shave skin lesion	0.99	1.10	0.42	0.08	2.17	1.49	000
11307		A	Shave skin lesion	1.14	1.29	0.49	0.08	2.51	1.71	000
11308		A	Shave skin lesion	1.41	1.45	0.59	0.13	2.99	2.13	000
11310		A	Shave skin lesion	0.73	1.11	0.32	0.05	1.89	1.10	000
11311		A	Shave skin lesion	1.05	1.23	0.49	0.06	2.34	1.60	000
11312		A	Shave skin lesion	1.20	1.42	0.55	0.06	2.68	1.81	000
11313		A	Shave skin lesion	1.62	1.80	0.72	0.10	3.52	2.44	000
11400		A	Exc tr-ext b9+marg 0.5 < cm	0.85	1.99	0.88	0.07	2.91	1.80	010
11401		A	Exc tr-ext b9+marg 0.6-1 cm	1.23	2.05	1.02	0.10	3.38	2.35	010
11402		A	Exc tr-ext b9+marg 1.1-2 cm	1.51	2.22	1.08	0.13	3.86	2.72	010
11403		A	Exc tr-ext b9+marg 2.1-3 cm	1.79	2.39	1.32	0.17	4.35	3.28	010
11404		A	Exc tr-ext b9+marg 3.1-4 cm	2.06	2.70	1.40	0.21	4.97	3.67	010
11406		A	Exc tr-ext b9+marg > 4.0 cm	2.76	3.06	1.65	0.32	6.14	4.73	010
11420		A	Exc h-f-nk-sp b9+marg 0.5 <	0.98	1.76	0.93	0.10	2.84	2.01	010
11421		A	Exc h-f-nk-sp b9+marg 0.6-1	1.42	2.06	1.11	0.13	3.61	2.66	010
11422		A	Exc h-f-nk-sp b9+marg 1.1-2	1.63	2.25	1.33	0.15	4.03	3.11	010
11423		A	Exc h-f-nk-sp b9+marg 2.1-3	2.01	2.58	1.45	0.20	4.79	3.66	010
11424		A	Exc h-f-nk-sp b9+marg 3.1-4	2.43	2.80	1.60	0.25	5.48	4.28	010
11426		A	Exc h-f-nk-sp b9+marg > 4 cm	3.77	3.48	2.10	0.42	7.67	6.29	010
11440		A	Exc face-mm b9+marg 0.5 < cm	1.06	2.20	1.31	0.08	3.34	2.45	010
11441		A	Exc face-mm b9+marg 0.6-1 cm	1.48	2.33	1.49	0.13	3.94	3.10	010
11442		A	Exc face-mm b9+marg 1.1-2 cm	1.72	2.54	1.57	0.15	4.41	3.44	010
11443		A	Exc face-mm b9+marg 2.1-3 cm	2.29	2.91	1.81	0.21	5.41	4.31	010
11444		A	Exc face-mm b9+marg 3.1-4 cm	3.14	3.47	2.18	0.29	6.90	5.61	010
11446		A	Exc face-mm b9+marg > 4 cm	4.48	4.04	2.77	0.42	8.94	7.67	010
11450		A	Removal, sweat gland lesion	2.73	5.03	2.02	0.34	8.10	5.09	090
11451		A	Removal, sweat gland lesion	3.94	6.60	2.54	0.51	11.05	6.99	090
11462		A	Removal, sweat gland lesion	2.51	5.11	2.01	0.30	7.92	4.82	090
11463		A	Removal, sweat gland lesion	3.94	6.82	2.68	0.51	11.27	7.13	090
11470		A	Removal, sweat gland lesion	3.25	5.06	2.26	0.39	8.70	5.90	090

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ADDENDUM B. - RELATIVE VALUE UNITS(RVUs) AND RELATED INFORMATION -

CPT[1]/ HCPCS[2]	Mod	Status	Description	Physician work RVUs[3]	Non-facility PE RVUs	Facility PE RVUs	Mal-practice RVUs	Non-facility Total	Facility Total	Global
11471		A	Removal, sweat gland lesion	4.40	6.70	2.76	0.55	11.65	7.71	090
11600		A	Exc tr-ext mlg+marg 0.5 < cm	1.31	2.63	0.97	0.10	4.04	2.38	010
11601		A	Exc tr-ext mlg+marg 0.6-1 cm	1.80	2.70	1.22	0.12	4.62	3.14	010
11602		A	Exc tr-ext mlg+marg 1.1-2 cm	1.95	2.82	1.26	0.13	4.90	3.34	010
11603		A	Exc tr-ext mlg+marg 2.1-3 cm	2.19	3.07	1.33	0.16	5.42	3.68	010
11604		A	Exc tr-ext mlg+marg 3.1-4 cm	2.40	3.37	1.39	0.20	5.97	3.99	010
11606		A	Exc tr-ext mlg+marg > 4 cm	3.42	4.06	1.73	0.36	7.84	5.51	010
11620		A	Exc h-f-nk-sp mlg+marg 0.5 <	1.19	2.59	0.95	0.10	3.88	2.24	010
11621		A	Exc h-f-nk-sp mlg+marg 0.6-1	1.76	2.70	1.24	0.12	4.58	3.12	010
11622		A	Exc h-f-nk-sp mlg+marg 1.1-2	2.09	2.96	1.39	0.14	5.19	3.62	010
11623		A	Exc h-f-nk-sp mlg+marg 2.1-3	2.61	3.33	1.58	0.20	6.14	4.39	010
11624		A	Exc h-f-nk-sp mlg+marg 3.1-4	3.06	3.74	1.77	0.27	7.07	5.10	010
11626		A	Exc h-f-nk-sp mlg+mar > 4 cm	4.29	4.63	2.39	0.44	9.36	7.12	010
11640		A	Exc face-mm malig+marg 0.5 <	1.35	2.65	1.11	0.10	4.10	2.56	010
11641		A	Exc face-mm malig+marg 0.6-1	2.16	3.02	1.53	0.16	5.34	3.85	010
11642		A	Exc face-mm malig+marg 1.1-2	2.59	3.40	1.71	0.19	6.18	4.49	010
11643		A	Exc face-mm malig+marg 2.1-3	3.10	3.80	1.96	0.25	7.15	5.31	010
11644		A	Exc face-mm malig+marg 3.1-4	4.02	4.68	2.45	0.37	9.07	6.84	010
11646		A	Exc face-mm mlg+marg > 4 cm	5.94	5.75	3.47	0.60	12.29	10.01	010
11719		R	Trim nail(s)	0.17	0.25	0.07	0.02	0.44	0.26	000
11720		A	Debride nail, 1-5	0.32	0.34	0.12	0.04	0.70	0.48	000
11721		A	Debride nail, 6 or more	0.54	0.44	0.21	0.07	1.05	0.82	000
11730		A	Removal of nail plate	1.13	1.03	0.43	0.14	2.30	1.70	000
11732		A	Remove nail plate, add-on	0.57	0.44	0.22	0.07	1.08	0.86	ZZZ
11740		A	Drain blood from under nail	0.37	0.55	0.35	0.04	0.96	0.76	000
11750		A	Removal of nail bed	1.86	2.16	1.75	0.22	4.24	3.83	010
11752		A	Remove nail bed/finger tip	2.67	2.99	2.99	0.35	6.01	6.01	010
11755		A	Biopsy, nail unit	1.31	1.57	0.77	0.15	3.03	2.23	000
11760		A	Repair of nail bed	1.58	2.62	1.78	0.20	4.40	3.56	010
11762		A	Reconstruction of nail bed	2.89	2.88	2.34	0.36	6.13	5.59	010
11765		A	Excision of nail fold, toe	0.69	1.78	0.76	0.08	2.55	1.53	010
11770		A	Removal of pilonidal lesion	2.61	3.48	1.50	0.31	6.40	4.42	010
11771		A	Removal of pilonidal lesion	5.73	5.64	3.31	0.73	12.10	9.77	090
11772		A	Removal of pilonidal lesion	6.97	7.50	5.07	0.88	15.35	12.92	090
11900		A	Injection into skin lesions	0.52	0.65	0.21	0.03	1.20	0.76	000
11901		A	Added skin lesions injection	0.80	0.66	0.35	0.03	1.49	1.18	000
11920		R	Correct skin color defects	1.61	3.70	1.09	0.23	5.54	2.93	000

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ADDENDUM B. - RELATIVE VALUE UNITS(RVUs) AND RELATED INFORMATION -

CPT[1]/ HCPCS[2]	Mod	Status	Description	Physician work RVUs[3]	Non-facility PE RVUs	Facility PE RVUs	Mal-practice RVUs	Non-facility Total	Facility Total	Global
11921		R	Correct skin color defects	1.93	3.96	1.27	0.28	6.17	3.48	000
11922		R	Correct skin color defects	0.49	1.14	0.25	0.07	1.70	0.81	ZZZ
11950		R	Therapy for contour defects	0.84	1.14	0.39	0.06	2.04	1.29	000
11951		R	Therapy for contour defects	1.19	1.49	0.51	0.11	2.79	1.81	000
11952		R	Therapy for contour defects	1.69	1.85	0.68	0.16	3.70	2.53	000
11954		R	Therapy for contour defects	1.85	2.44	0.90	0.24	4.53	2.99	000
11960		A	Insert tissue expander(s)	9.07	NA	10.39	1.28	NA	20.74	090
11970		A	Replace tissue expander	7.05	NA	6.13	1.03	NA	14.21	090
11971		A	Remove tissue expander(s)	2.13	9.11	3.79	0.30	11.54	6.22	090
11975		N	Insert contraceptive cap	+1.48	1.42	0.57	0.17	3.07	2.22	XXX
11976		R	Removal of contraceptive cap	1.78	1.72	0.68	0.21	3.71	2.67	000
11977		N	Removal/reinsert contra cap	+3.30	2.27	1.26	0.37	5.94	4.93	XXX
11980		A	Implant hormone pellet(s)	1.48	1.08	0.54	0.13	2.69	2.15	000
11981		A	Insert drug implant device	1.48	1.70	0.68	0.12	3.30	2.28	XXX
11982		A	Remove drug implant device	1.78	1.94	0.83	0.17	3.89	2.78	XXX
11983		A	Remove/insert drug implant	3.30	2.28	1.47	0.24	5.82	5.01	XXX
12001		A	Repair superficial wound(s)	1.70	1.98	0.77	0.16	3.84	2.63	010
12002		A	Repair superficial wound(s)	1.86	2.04	0.90	0.18	4.08	2.94	010
12004		A	Repair superficial wound(s)	2.24	2.32	1.01	0.22	4.78	3.47	010
12005		A	Repair superficial wound(s)	2.86	2.82	1.20	0.28	5.96	4.34	010
12006		A	Repair superficial wound(s)	3.66	3.39	1.51	0.38	7.43	5.55	010
12007		A	Repair superficial wound(s)	4.11	3.82	1.81	0.44	8.37	6.36	010
12011		A	Repair superficial wound(s)	1.76	2.13	0.78	0.17	4.06	2.71	010
12013		A	Repair superficial wound(s)	1.99	2.27	0.93	0.19	4.45	3.11	010
12014		A	Repair superficial wound(s)	2.46	2.57	1.06	0.23	5.26	3.75	010
12015		A	Repair superficial wound(s)	3.19	3.13	1.25	0.30	6.62	4.74	010
12016		A	Repair superficial wound(s)	3.92	3.55	1.52	0.38	7.85	5.82	010
12017		A	Repair superficial wound(s)	4.70	NA	1.89	0.49	NA	7.08	010
12018		A	Repair superficial wound(s)	5.52	NA	2.25	0.61	NA	8.38	010
12020		A	Closure of split wound	2.62	3.82	1.92	0.30	6.74	4.84	010
12021		A	Closure of split wound	1.84	1.82	1.41	0.23	3.89	3.48	010
12031		A	Layer closure of wound(s)	2.15	2.28	0.96	0.18	4.61	3.29	010
12032		A	Layer closure of wound(s)	2.47	3.84	1.79	0.17	6.48	4.43	010
12034		A	Layer closure of wound(s)	2.92	3.19	1.45	0.26	6.37	4.63	010
12035		A	Layer closure of wound(s)	3.42	5.19	2.15	0.38	8.99	5.95	010
12036		A	Layer closure of wound(s)	4.04	5.55	2.54	0.52	10.11	7.10	010
12037		A	Layer closure of wound(s)	4.66	6.09	2.96	0.62	11.37	8.24	010

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ADDENDUM B. - RELATIVE VALUE UNITS(RVUs) AND RELATED INFORMATION -

CPT[1]/ HCPCS[2]	Mod	Status	Description	Physician work RVUs[3]	Non-facility PE RVUs	Facility PE RVUs	Mal-practice RVUs	Non-facility Total	Facility Total	Global
12041		A	Layer closure of wound(s)	2.37	2.54	1.13	0.20	5.11	3.70	010
12042		A	Layer closure of wound(s)	2.74	3.26	1.46	0.19	6.19	4.39	010
12044		A	Layer closure of wound(s)	3.14	3.21	1.60	0.29	6.64	5.03	010
12045		A	Layer closure of wound(s)	3.63	5.26	2.28	0.40	9.29	6.31	010
12046		A	Layer closure of wound(s)	4.24	6.50	2.75	0.51	11.25	7.50	010
12047		A	Layer closure of wound(s)	4.64	6.34	3.08	0.56	11.54	8.28	010
12051		A	Layer closure of wound(s)	2.47	3.27	1.45	0.20	5.94	4.12	010
12052		A	Layer closure of wound(s)	2.77	3.22	1.43	0.19	6.18	4.39	010
12053		A	Layer closure of wound(s)	3.12	3.24	1.53	0.24	6.60	4.89	010
12054		A	Layer closure of wound(s)	3.45	3.56	1.63	0.30	7.31	5.38	010
12055		A	Layer closure of wound(s)	4.42	4.48	2.12	0.45	9.35	6.99	010
12056		A	Layer closure of wound(s)	5.23	6.75	3.05	0.57	12.55	8.85	010
12057		A	Layer closure of wound(s)	5.95	6.13	3.75	0.54	12.62	10.24	010
13100		A	Repair of wound or lesion	3.12	4.05	2.30	0.27	7.44	5.69	010
13101		A	Repair of wound or lesion	3.91	4.66	2.68	0.28	8.85	6.87	010
13102		A	Repair wound/lesion add-on	1.24	1.17	0.57	0.13	2.54	1.94	ZZZ
13120		A	Repair of wound or lesion	3.30	4.14	2.34	0.28	7.72	5.92	010
13121		A	Repair of wound or lesion	4.32	4.85	2.79	0.29	9.46	7.40	010
13122		A	Repair wound/lesion add-on	1.44	1.51	0.63	0.15	3.10	2.22	ZZZ
13131		A	Repair of wound or lesion	3.78	4.36	2.68	0.28	8.42	6.74	010
13132		A	Repair of wound or lesion	5.94	5.90	4.16	0.35	12.19	10.45	010
13133		A	Repair wound/lesion add-on	2.19	1.66	1.03	0.18	4.03	3.40	ZZZ
13150		A	Repair of wound or lesion	3.80	4.87	2.76	0.34	9.01	6.90	010
13151		A	Repair of wound or lesion	4.44	4.80	3.14	0.32	9.56	7.90	010
13152		A	Repair of wound or lesion	6.32	6.03	4.04	0.42	12.77	10.78	010
13153		A	Repair wound/lesion add-on	2.38	1.93	1.14	0.25	4.56	3.77	ZZZ
13160		A	Late closure of wound	10.46	NA	7.16	1.49	NA	19.11	090
14000		A	Skin tissue rearrangement	5.88	7.85	5.46	0.59	14.32	11.93	090
14001		A	Skin tissue rearrangement	8.46	9.41	7.07	0.83	18.70	16.36	090
14020		A	Skin tissue rearrangement	6.58	8.61	6.53	0.64	15.83	13.75	090
14021		A	Skin tissue rearrangement	10.04	9.98	8.28	0.83	20.85	19.15	090
14040		A	Skin tissue rearrangement	7.86	8.80	7.20	0.65	17.31	15.71	090
14041		A	Skin tissue rearrangement	11.47	10.59	8.67	0.76	22.82	20.90	090
14060		A	Skin tissue rearrangement	8.49	8.78	7.43	0.68	17.95	16.60	090
14061		A	Skin tissue rearrangement	12.27	11.60	9.50	0.77	24.64	22.54	090
14300		A	Skin tissue rearrangement	11.74	11.13	9.17	1.16	24.03	22.07	090
14350		A	Skin tissue rearrangement	9.60	NA	7.14	1.32	NA	18.06	090

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