DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–1229–P]

RIN 0938–AM12

Medicare Program; Payment Reform for Part B Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise, based on one of four approaches, the current payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. We are seeking comments on which of these proposed approaches we should implement. This proposed rule would also make changes to Medicare payment for furnishing or administering certain drugs and biologicals.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 14, 2003.

ADDRESSES: In commenting, please refer to file code CMS–1229–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1229–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850. (Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (410) 786–0548.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call (410) 786–7197.

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To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

Alphabetical List of Acronyms in the Proposed Rule

AMP Average Manufacturer's Price
APC Ambulatory Payment Classification
ASCO American Society of Clinical Oncology
ASP Average Sale Price
AWP Average Wholesale Price
BBA Balanced Budget Act of 1997
BBRA Balanced Budget Refinement Act of 1999
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CMS Centers for Medicare & Medicaid Services
DHHS Department of Health and Human Services
DME Durable Medical Equipment
DMERC Durable Medical Equipment Regional Carrier
DOJ Department of Justice
EAC Estimated Acquisition Cost
EPO Erythropoietin
ESRD End-Stage Renal Disease
FSS Federal Supply Schedule
GAO General Accounting Office
MEDPAC Medicare Payment Advisory Commission
NDC National Drug Code
NOC Not Otherwise Classified
OIG Department of Health and Human Services Office of Inspector General
OMB Office of Management and Budget
OPPS Outpatient Prospective Payment System
PPO Preferred Provider Organization
PRA Paperwork Reduction Act of 1995
SDP Single Drug Pricer
VA Department of Veterans Affairs
WAMP Widely Available Market Price

I. Background

A. Covered Drugs and Biologicals

Medicare Part B currently covers a limited number of prescription drugs. For the purposes of this proposed rule, the term ''drugs'' will hereafter refer to both drugs and biologicals. Currently covered Medicare drugs generally fall into three categories: drugs furnished incident to a physician's service, durable medical equipment (DME) drugs, and statutorily covered drugs and other drugs.

1. Drugs Furnished Incident to a Physician's Service

These are injectable or intravenous drugs that are administered incident to a physician's service (section 1861(s)(2) of the Social Security Act (the Act)). The Act limits coverage to drugs that are not usually self-administered. Under the ''incident-to'' provision, the physician must incur a cost for the drug, and must bill for it. Examples include injectable prostate cancer drugs (lupron acetate for depot suspension, goserelin acetate implant), injectable drugs used in connection with treatment of cancer (epoetin alpha), intravenous drugs used to treat cancer (paclitaxel and docetaxel

used to treat breast cancer), injectable anti-emetic drugs used to treat the nausea resulting from chemotherapy, infliximab used to treat rheumatoid arthritis, and rituximab used to treat non-Hodgkin's lymphoma.

2. Durable Medical Equipment (DME) Drugs

These are drugs that are administered through a covered item of DME such as a nebulizer or pump. Two of the most common drugs in this category are the inhalation drugs albuterol sulfate and ipratropium bromide.

3. Statutorily Covered Drugs and Other Drugs

Certain drugs are specifically covered by statute including: immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis vaccines; antigens; erythropoietin for trained home dialysis patients; certain other drugs separately billed by end stage renal disease (ESRD) facilities (for example, iron dextran, vitamin D injections); and osteoporosis drugs.

4. Types of Providers

Types of providers and suppliers that are paid based on average wholesale price (AWP) for all or some of the Medicare covered drugs they furnish include: physicians, pharmacies, DME suppliers, hospital outpatient departments, and ESRD facilities.

5. Drugs Paid on a Cost or Prospective Payment Basis

Drugs paid on a cost or prospective payment basis that are generally outside of the scope of this proposed rule include: drugs furnished during an inpatient hospital stay (except clotting factor); drugs packaged under the outpatient prospective payment system (OPPS); drugs furnished by ESRD facilities whose payments are included in Medicare's composite rate; and drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and federally qualified health centers.

B. Current Medicare Drug Spending

In 2002, the preliminary estimate of allowed charges for the approximately 450 drugs paid by Medicare carriers is $8.4 billion. The majority of these expenditures were for drugs administered incident to a physician's service and drugs furnished in conjunction with DME. Spending growth for Medicare drugs has been substantial. Medicare allowed charges for drugs were approximately $3.3 billion in 1998. As indicated above, we estimate 2002 Medicare spending for drugs at approximately $8.4 billion or nearly three times the 1998 levels or an average of 27 percent per year. Because during this time period Medicare fee-for-service enrollment grew by an average of only 1.4 percent per year, other factors such as price increases and additional utilization played a greater role in this expenditure growth. More than 77 percent of Medicare spending for drugs goes to oncologists and urologists for cancer drugs and pharmacies and other medical suppliers of DME drugs. Medicare spending for drugs billed by oncologists has more than tripled between 1998 and 2002 growing from $1.2 billion to $3.8 billion. Between 2001 and 2002, Medicare spending for drugs billed by oncologists increased by 41 percent. Growth in spending for the two highest expenditure DME drugs, albuterol and ipratropium bromide, has increased from $393 million in 1998 to nearly $1.0 billion in 2002.

Much of the current Medicare spending is concentrated in relatively few of the approximately 450 covered drugs. For example, of the $8.4 billion for carrier paid drugs, 7 drugs account for 49 percent of spending ($4.0 billion), 19 drugs account for 75 percent of spending ($6.2 billion) and 33 drugs account for 86 percent of spending ($7.1 billion). The top drug code, epoetin alpha (Q0136), accounts for 13 of carrier spending. Two prostate cancer drugs, lupron acetate for depot suspension (J9217) and goserelin acetate implant (J9202), combined, account for 14 of carrier paid drugs. Two generic drugs furnished via a covered item of DME, albuterol and ipratropium bromide, account for 13 percent of carrier drug spending.

Intermediaries and not carriers process ESRD facility claims for drugs paid outside the ESRD composite rate. In 2000, allowed charges for ESRD facilities for these drugs were $1.4 billion for erythropoietin, $0.1 billion for iron dextran, $0.1 billion for vitamin D injections, and $0.4 billion for all other separately billed drugs. Section 1881(b)(11)(B) of the Act provides a statutory formula to determine the payment amount for erythropoietin separately billed by ESRD facilities. The other drugs furnished and separately billed by ESRD facilities are paid 95 percent of the AWP under section 1842(o) of the Act.

C. History of the Current Payment System

In the June 5, 1991 physician fee schedule proposed rule (56 FR 25792), we proposed that the drug payment limit be based on 85 percent of the national AWP of the drug. For very high volume drugs, we proposed that the drug payment limits be based on the estimated acquisition cost (EAC) of the drugs. The EAC was to be determined from survey data. We received many comments, primarily from oncologists, indicating that an 85 percent standard was inappropriate. In response to these comments, the 1992 physician fee schedule final rule established a payment limit based on the lower of 100 percent of AWP or the EAC. However, because of statistical sampling concerns generated by a lack of information on the variation in acquisition costs between low and high volume providers, the EAC was never implemented. Various legislative proposals were submitted to move away from payment based on 100 percent of AWP, including changing the percentage of AWP to a lower amount. In 1997, the Congress, responding in part to one of these proposals, amended the Act to limit payment for drugs not paid on a cost or prospective payment basis to the lower of the actual charge or 95 percent of AWP (section 1842(o)(1) of the Act as added by section 4556 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33)). The statutory term, average wholesale price, is not defined in law or regulation. In creating payment limits for Medicare covered drugs, Medicare currently relies on the list AWP. The term ''list AWP'' will hereafter refer to the AWP published in commercial compendia such as Red Book, Price Alert, and Medispan.

D. List AWP and Widely Available Market Prices

Numerous reports by the General Accounting Office (GAO), and the Office of Inspector General (OIG), as well as data collected by the Department of Justice (DOJ), discussed below, have indicated that 95 percent of list AWP reflected in published compendia is significantly higher than the prices that drug manufacturers, wholesalers, physician supply houses, specialty pharmacies, and similar entities actually charge to physicians and suppliers purchasing these drugs.

Differences between Medicare's payment based on 95 percent of list AWP and the widely available market prices creates what has been referred to as the ''spread''. The presence of a

substantial ''spread'' or a difference between the price that physicians and suppliers actually pay to acquire drugs in the market and Medicare's reimbursement at 95 percent of list AWP, means that the Medicare program and Medicare beneficiaries often overpay for drugs. For a few drugs, the ''spread'' is so large that the amount that the Medicare beneficiary pays the physician or supplier for coinsurance is greater than the physician or supplier's payment to acquire the drug. For example, leucovorin calcium (J0640) has a list AWP of $18.44. Based on GAO and OIG studies, the widely available market price is 15 percent of the list AWP or $2.77. The Medicare payment is 95 percent of the list AWP, or $17.52. The beneficiary coinsurance is 20 percent of the Medicare payment or $3.69. The beneficiary is paying more in coinsurance ($3.69) than the physician is paying to purchase the drug ($2.77).

E. Studies and Developments Since the Balanced Budget Act of 1997 (BBA)

This section discusses developments since BBA and provides an overview of some of the relevant studies that have been performed illustrating the excessive payments that occur under the current payment methodology.

In September 2000, the Medicare program attempted to allow carriers to consider data provided by DOJ as another and more accurate data source than the list AWP in the published compendia. The use of another data source would allow us to set more accurate AWP payment limits for certain drugs (Program Memorandum ''An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program,'' (AB–00–86, (change request #1232), published September 8, 2000). However, we deferred implementation of this program memorandum in November 2000 since, although we continued to believe that the list AWP reported in the published compendia was inaccurate and inflated, congressional action pending at that time would have precluded the immediate use of this data. We wanted to avoid the disruption that would result from a decrease in payment allowances followed by an immediate increase due to congressional action. In addition to the payment disruption, we also received numerous public comments asserting that drug payments for chemotherapy drugs subsidize payments for services related to the administration of these drugs. The deferral of the use of the DOJ data was published in our program memorandum titled, ''Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program,'' AB–00–115 (change request #1447) published November 17, 2000.

In December 2000, the Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554). Section 429(a) of BIPA mandated that the GAO conduct a study on the payment for drugs under the current Medicare methodology. Section 429(c) established a moratorium on reductions in Medicare payments rates for drugs until after the Secretary reviewed the GAO report. In the study, the GAO was required to—

- Identify the average prices at which Medicare drugs are acquired by physicians and other suppliers;
- Quantify the difference between such average prices and the Medicare payment amount; and
- Determine the extent to which Medicare payment is adequate to compensate physicians, providers of services, or other suppliers of these drugs for costs incurred related to administrative costs of furnishing drugs and biologicals.

In addition, BIPA required the GAO to provide specific recommendations for revised methodologies for payment of drugs and for related services under the Medicare program. In making these recommendations, BIPA instructed the GAO to consider—

- If appropriate, new or adjusted payments for costs incurred in the administration, handling, or storage of certain categories of drugs;
- The method and amount of payment for similar drugs made by large group health plans;
- The potential for patients to receive inpatient or outpatient hospital services in lieu of services in a physician's office as a result of any revised payment methodology;
- The effect of any revised payment methodology on the delivery of drug therapies by hospital outpatient departments; and
- The results of a previously mandated GAO study (GAO–02–053) on the adequacy of Medicare's physician payments to oncologists.

Additionally, the Congress required that the GAO, in making their recommendations, ''shall ensure that any proposed revised payment methodology be designed to ensure that Medicare beneficiaries continue to have appropriate access to health care services under the Medicare program.''

Section 429(b) of BIPA requires us, notwithstanding any other provision of law, to revise the Medicare payment methodology for drugs under sections 1842(o) of the Act based on the GAO report to the Congress. We may, to the extent appropriate, provide new or adjusted payments for the costs incurred in the administration, handling, and storage of drugs. However, the estimated aggregate payments for drugs under the revised system (including additional payments for the administration, handling, and storage of drugs) cannot exceed payments as projected by the Secretary under section 1842(o) of the Act.

Prior to the completion of the GAO report, the OIG published a report in January 2001 titled ''Medicare Reimbursement of Prescription Drugs'' (OEI–03–00–00310) that revealed excessive payments for Medicare covered drugs. This study was a follow-up to a prior 1997 OIG Study: ''Excessive Medicare Payments for Prescription Drugs'' (OEI–03–97–00290) in which the OIG found that payments based on 95 percent of list AWP were substantially greater than the prices widely available to the physician community. In this January 2001 study, the OIG compared calendar year (CY) 1999 Medicare payments for 24 high expenditure drugs to prices available to the physician and supplier community, the Department of Veterans Affairs (VA), and Medicaid. In determining the prices available to the physician supplier community, the OIG reviewed print and online catalogs from five drug wholesalers and one group purchasing organization. The report indicated that we would have saved $761 million a year by paying for drugs based on the actual wholesale prices available to physicians and suppliers rather than paying 95 percent of list AWP.

In September 2001, the GAO presented its study to the Congress in a report titled, ''Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs'' (GAO–01–1118). The report contained some significant findings and also confirmed previous OIG reports on drug payments.

- Physicians and suppliers are able to obtain Medicare-covered drugs at prices significantly below 95 percent of list AWP. (*See* Table 1 in Appendix A for a reprint of the table from the GAO report summarizing some of these findings.)
- For most physician-administered drugs, the average discount from list AWP ranged from 13 percent to 34 percent; two physician-administered drugs had discounts of 65 and 86 percent. That is, physicians paid an average of 66 to 87 percent of the list AWP, and for two drugs physicians paid 14 percent and 35 percent of the list AWP.

• For two high expenditure drugs provided by pharmacies, ipratropium bromide and albuterol, discounts from list AWP averaged 78 percent and 85 percent, respectively. In other words, suppliers paid 15 and 22 percent of the list AWP.

• While physician practices that purchase large volumes of drugs may have access to larger discounts and rebates, low volume providers can also purchase drugs for markedly less than list AWP, and often at additional discounts below widely available prices. In particular, physicians who bill Medicare for low volumes of drugs used in cancer treatment receive discounted prices for many of these drugs similar to or greater than widely available discounts. (*See* Table 2 in Appendix A for a reprint of the table from the GAO report summarizing some of these findings.)

• Private health plans use their drug-purchase and patient volume to negotiate favorable prices for drugs and the physician and supplier services related to supplying or delivering the drugs.

• Public payers, such as the VA, use their purchasing volume along with information about actual transaction prices from private payers to lower their drug payments.

Based on its studies, the GAO concluded that our current payment methodology is flawed because current payment rates (that is, 95 percent of the list AWP) do not reflect market prices. The GAO recommended that we take the following actions with regard to the payment for drugs and related services.

• Establish Medicare payment levels for Part B drugs that are more closely related to their costs. Payments for drugs should be set at levels that reflect actual market transaction prices and the likely acquisition cost to providers.

• Pay appropriately for drug delivery and administration and not allow potential overpayments for drugs to subsidize payments for related services.

• Examine the benefits and risks of expanding the current competitive bidding demonstration projects for drugs covered under Part B.

• Institute a process to monitor access to Part B covered drugs to ensure that payment changes do not negatively affect access for particular drugs or groups of beneficiaries or for certain geographic areas.

F. Implications of GAO and OIG Studies

Table 4 provides a summary of the reports on Medicare prescription drugs published by OIG between 1997 through 2001. The 1997 report indicated that for 22 drugs studied by the OIG, Medicare's allowances for these drugs exceeded wholesale prices by $447 million in 1996. For 1998 the report indicated that Medicare would have saved $1 billion if the allowed amounts for the 34 drugs studied were equal to prices obtained by the VA through the Federal Supply Schedule (FSS). Additionally, the report indicated that Medicare would have saved $1.6 billion for 24 drugs studied if Medicare had paid for these drugs based on the FSS. Although the savings estimates vary, for example due to differences in the particular drugs studied, OIG concluded based on the reports that the potential savings for Medicare and its beneficiaries from reforming the current payment policy to a system based on FSS is substantial.

In table 3, we have combined the findings of the GAO and OIG reports displaying the prices that they found as a percent of list AWP. For the GAO report, we used the findings from their widely available drug prices. We examined but did not use the separate survey of low volume billers. Although many low volume biller prices were below the widely available drug prices, they were compiled through a small phone survey of physicians. The widely available drug prices were based on price lists from wholesalers and GPOs. We believe that the widely available drug prices are a better reflection of the prices available to physicians and suppliers. In addition, there was much more consistency between the GAO's widely available drug prices and the OIG's finding.

Table 3 separately presents the findings for brand name drugs and for generic drugs. The ''spread,'' computed as a percent of Medicare's payment at 95 percent of list AWP, is also displayed for each drug based on the average of the GAO and OIG findings. The lower the price found by GAO or OIG as a percent of list AWP, the larger the spread between that price and Medicare's current payment. In effect, the ''spread'' is the difference between the Medicare allowed charge (95 percent of the list AWP) and the actual purchase price paid by the physicians and suppliers. The percent spread is the difference between the Medicare payment and the market price expressed as a percentage of the Medicare payment. For example, the list AWP for granisetron hcl (J1626) is $19.52. The Medicare payment is 95 percent of the list AWP or $18.54. The average of the GAO and OIG data indicates that the market price is 71 of the list AWP or $13.86. The 25 percent spread is calculated as ($18.54 – $13.86) / $18.54 = $4.68 / $18.54 = .25 = 25 percent.

A review of Table 3 shows that in general the ''spread,'' in percentage terms, is larger for the generic drugs examined in the studies than for brand drugs. This is consistent with our understanding that when actual market prices decline with the introduction of generic competition, the list AWPs do not usually experience a corresponding decline of the same magnitude. With one exception, among the brand name drugs studied, physicians and suppliers could obtain these drugs at 71 percent to 87 percent of list AWP, which translates into a spread of 25 percent and 8 percent, respectively. For the generic drugs examined, there was considerably more variability. For six of the drugs examined, physicians or suppliers could purchase at a price between 15 percent and 46 percent of list AWP, translating into a spread of 84 percent and 52 percent, respectively. The other three drugs examined had spreads more in line with that for brand drugs.

A general conclusion reached in reviewing the GAO and OIG data is that there is a level of overstatement in the list AWP for all drugs beyond the 5 percent currently accounted for in Medicare's policy. Using the average of the GAO and OIG findings, every drug studied was available at a price not greater than 87 percent of list AWP. Most drugs could be obtained at an even lower price, sometimes substantially lower.

If we examine the data in the aggregate, the difference between Medicare's payment and widely available market prices was $1.5 billion in 2002 for the 29 drugs where we have GAO and OIG data. That is, if Medicare had paid widely available market prices instead of 95 percent of list AWP in 2002 for these 29 drugs, Medicare and its beneficiaries would have paid nearly $1.5 billion less for drugs or nearly 17 percent less than total estimated payments of $8.4 billion. Of this amount, Medicare and its beneficiaries would have paid approximately $475 million less to oncologists and $760 million less to suppliers of DME drugs. Assuming that widely available market prices were between 80 percent and 90 percent of list AWP for all other drugs, the total savings to Medicare and its beneficiaries in 2002 from paying in this way would have been between $1.7 and $2.0 billion.

II. Provisions of the Proposed Rule

A. Approaches to Revising the Current Payment System

Given the serious and well-documented flaws in the current

Medicare payment system identified by the GAO, OIG, and our own analyses, we are seeking comments on four different approaches to revising the Medicare drug payment system: (1) Basing our reform efforts on the comparability provision in the statute; (2) applying an average list AWP discount to the list AWPs as of April 1, 2003; (3) utilizing existing sources of market-based prices and developing additional sources for market monitoring; and (4) establishing a competitive acquisition program and Average Sales Price system. We are proposing to select one of these options.

Option 1—Comparability Provision

One option we are proposing is to base our reform efforts on the ''comparability'' provision in the Act, section 1842(b)(3)(B) of the Act. Specifically, this provision limits Medicare payment for a drug to what our contractors pay when the same drug is provided to their private policyholders and subscribers under comparable circumstances. As described below, we are proposing additional guidance to our contractors in identifying comparable circumstances with respect to the drug payments they make in their private sector business. While comparability applies to all charge-based services, we are proposing to focus its application on drugs given the excessive payments by the Medicare program and our beneficiaries under the current methodology, as reflected in several OIG and GAO reports.

Section 1842 of the Act authorizes us to enter into contracts with carriers for the administration of Part B benefits. Section 1842(b)(3) of the Act mandates that each contract with a carrier provide that the carrier:

> ''* * * will take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to policyholders and subscribers of the carrier * * *.''

Section 1842 of the Act sets forth general provisions applicable to part B payment determinations, including drug payments. The comparability provision requires a carrier to take action, when necessary, to ensure that Part B charges are reasonable and ''not higher than the charge applicable for a comparable service in comparable circumstances'' to its own policyholders. This limitation is a principle set forth by the Congress at the outset of the Medicare program, providing that Medicare beneficiaries should not be charged more than private pay patients for a comparable service provided under comparable circumstances. To this end, the Congress mandated that, where payment for a service to a Medicare beneficiary is on a charge basis, as opposed to a cost basis, the carrier's private plan, if it has one, should be assessed to determine whether the service in question and the circumstances under which the service is provided are ''comparable'' to Medicare. If the service is comparable, then the applicable charge under the carrier's private insurance plan may serve as a limitation on the amount that we pay. In accordance with these provisions, we have broad authority to make comparability adjustments with respect to Part B payment determinations based on charges.

At the time the Congress legislated the current drug payment methodology, it did not amend our authority to make comparability adjustments or provide any indication that the other provisions of section 1842(b) of the Act with respect to Part B payment calculations were no longer applicable.

Section 1842(b)(3) of the Act requires carriers, including Durable Medical Equipment Regional Carriers (DMERCs), to limit payment rates for Medicare covered drugs to the amounts that the carriers pay when these drugs are provided to their private policyholders and subscribers under comparable circumstances. We are proposing to issue additional guidance to our contractors indicating that comparability would exist with drug payments made in the same geographic area under the carrier's indemnity health insurance products or broad network preferred provider organization (PPO) products that do not rely on selective contracting. We are seeking comments on this proposed guidance.

Consistent with § 405.508(c), the responsibility for determining that a carrier's indemnity product or PPO product is comparable would in the first instance fall upon the carrier in reporting pertinent information about its programs to us. When the pertinent information has been reported, we will advise the carrier whether any of its products has comparability. If we determine that a carrier's lower private payment for a drug has comparability in a given locality, the lower private payment limit would apply to the Medicare payment in that locality.

Contractors would inform physicians, suppliers and other impacted parties about the new lower payment limit through their usual means of provider education (for example, bulletins, newsletters, Web site postings.)

As an example of how this approach would apply to a specific drug using hypothetical data, we will examine docetaxol (J9170). Suppose the national payment limit for docetaxol in 2004 was $358. If one of our carriers was paying $325 for docetaxol in one of its localities in its comparable private side business, the Medicare payment limit for docetaxol in that locality would be set at $325. This lower payment amount would only apply in that locality and would not be the national payment limit. If, however, the carrier was paying $375 for docetaxol in this locality, the Medicare payment would be based on the current national limit of $358.

We understand that to the extent private sector drug payments vary by geographic region, the application of comparability may result in regional variation in drug payments. We seek comment on this aspect of the policy.

It is our understanding that historically many private insurers have focused more on payments for oral drugs and inhalation drugs than injectable drugs, although this is changing due to the rapid growth in expenditures for injectable drugs. MedPAC discussed this in their June 2003 report to Congress titled ''Report to the Congress: Variation and Innovation in Medicare,'' which stated that ''Only as expenditures have sharply increased in the past few years have payers begun to focus on more efficient methods of paying for these drugs.'' We are seeking information on these new methods of paying for injectable drugs and comments on any implications for Medicare drug payment limits under the comparability provision.

Option 2—Average AWP Discount

a. Existing Drugs

Another option we are proposing is to apply an average AWP discount to the AWPs published in commercial compendia as of April 1, 2003. Specifically, we would lock-in and reduce the AWP published as of April 1, 2003 in the national drug pricing compendia by an average price discount from AWP. Our analysis of the available data from the GAO and OIG studies indicates that the majority of drugs examined had a discount of approximately 10 to 20 percent off of the AWP, with the remaining drugs having larger discounts. The Medicare payment limit, therefore, would be set at between 80 percent and 90 percent of the AWP published as of April 1, 2003. We are seeking comment on the appropriate uniform reduction to make in this range. This policy would be effective January 1, 2004. In future years, these prices would be updated on an annual basis by the increase in the consumer price index for medical care

for the 12-month period ending June of the prior year.

As an example of how this approach might apply to a specific drug assuming an average AWP discount of 15 percent, we will again examine docetaxol (J9170). The April 1, 2003 AWP published in the commercial compendia for docetaxol is $377. Applying an average AWP discount of 15 percent, the Medicare 2004 payment limit for J9170 would be $320. Assuming a 4.0 percent increase in the consumer price index (CPI) for medical care for the 12-month period ending June 2004, the 2005 payment limit for J9170 would be $333, regardless of the list AWP at that time.

b. New Drugs and Drugs With Patent Expirations

The reimbursement rate for new drugs and drugs coming off of patent would be determined for the first year based on our review of information provided by the manufacturer about the expected widely available market price for that year. As a condition of obtaining a HCPCS code for billing purposes (in the case of new drugs) or continuing to recognize a HCPCS code for billing purposes (in the case of drugs coming off patent), manufacturers would be required to provide information on the anticipated widely available market price that a prudent physician or prudent supplier would pay for the drug and a rationale for the new price. We expect that drug manufacturers in the normal course of conducting their business have determined the prices that physicians and suppliers would pay for the drug when sold through a distributor or via direct distribution.

If we suspect that a manufacturer has knowingly supplied misleading pricing information to generate or maintain a ''spread'' between Medicare payment and the widely available market price, we will refer the matter to the OIG. As stated by the OIG in their Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers (68 FR 23737) that was published on May 5, 2003:

''If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product.''

During the first year the HCPCS code is used for billing, the manufacturer would provide updated information to us on the actual prices that physicians and suppliers are paying to purchase the drug. Again, we expect manufacturers would collect this information in the normal course of conducting their business.

We would review this data and other available data sources on the widely available market price of the drug to determine if an adjustment to the Medicare payment limit would be required for the second year. In the absence of a second year adjustment, the first year payment would be updated by the increase in the medical component of the CPI for the 12-month period ending six months prior to the year. For the third year and all subsequent years, the Medicare payment limit would be updated on an annual basis by the increase in the CPI for medical care for the 12-month period ending June of the prior year.

Option 3—Market Monitoring

Another option we are proposing is to utilize existing sources of market-based prices in developing Medicare payment limits and to develop additional sources of this information for market monitoring. Under this option, we would define AWP to be the widely available market price. Initially, we would use the market analyses available to us from GAO and OIG studies to transition widely available market prices into the Medicare payments. As discussed below, over time we may expand our data sources for these market prices. Although the GAO and OIG performed market analyses on drugs covering the majority of Medicare expenditures, they did not study all of the approximately 450 Medicare drugs. As described earlier in section I.B, Medicare drug spending is concentrated in relatively few drugs; 33 drugs account for 86 percent of the spending. Initially, for those drugs where we do not have GAO and OIG information on which to base a market price, we would proceed as in option 2 and base the payment limit on an average AWP discount off of the list AWP reported to the commercial compendia as of April 1, 2003.

a. Definition of Average Wholesale Price

In implementing sections 1842(o) of the Act and 429 of BIPA, we propose to define the AWP of a drug to be the widely available market price. The widely available market price would be the price that a prudent physician or prudent supplier would pay when purchasing the drug from common sources. Common sources that a prudent physician or supplier might utilize when purchasing a drug include, but are not limited to, wholesalers, manufacturers, repackagers, physician supply houses, pharmacies, specialty pharmacies, and group purchasing organizations. The widely available market price would not be a list price that is commonly discounted, but would be the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers.

The widely available market price would reflect prices in programs where a manufacturer, a manufacturer's subsidiary or related company, or a repackager sells drugs to physicians and suppliers directly or through buying groups or other mechanisms. For example, if a drug manufacturer establishes a buying group easily accessed by prudent physicians, the lower price offered to the buying group should be reflected as the widely available market price.

It is not our intent to set the Medicare payment limit below the widely available market price. Under the current system, the Medicare allowed charge is the lower of the actual charge and 95 percent of the AWP. Using the authority granted to the Secretary under section 429(b) of BIPA, the Medicare allowed charge in a fully phased-in revised payment methodology would be the lower of the actual charge or the widely available market price. We would not pay at 95 percent of the widely available market price since we wish to consider further the issue of beneficiary access at 95 percent of the widely available market price. As described in section II.D, we do not expect any beneficiary access issues with payment at the widely available market price.

b. Use of existing sources of market based prices

As described earlier in section I.F, both the GAO and OIG have performed market analyses of the widely available market prices for the top Medicare drugs in terms of expenditures. While the market analyses differed in their methodologies, for example the GAO used averages of drug prices from their data sources and the OIG used medians, in general the results were consistent for these drugs. To begin to incorporate this information into the Medicare payment limits for the drugs that have been studied, we would take the average discount between the GAO and OIG data for the drug and apply it to the list AWP reported in the published

compendia as of April 1, 2003. Although as noted the results of the GAO and OIG market analyses are generally consistent, we seek comment on our proposed approach of averaging these two data sources.

For example, one drug studied by both the GAO and OIG is rituximab (J9310). The April 1, 2003 list AWP published in the commercial compendia for rituximab is $501.13 for 100 mg. The GAO study indicates the average market price for rituximab is 81 percent of the list AWP. The OIG study indicates the average market price for rituximab is 80 percent of AWP. The average of these two data sources rounded to nearest percent is 81 percent of the list AWP. Under this option, the Medicare payment limit for J9310 would be $405.92 (that is, 81 percent of $501.13) effective January 1, 2004.

Clotting factor was the subject of a separate GAO report entitled ''Payment for Blood Clotting Factor Exceeds Providers' Acquisition Costs'' (GAO–03–184). This report found that the market price for clotting factor was 59 percent of list AWP for hemophilia treatment centers and 69 percent of list AWP for homecare companies. We are proposing to transition these market prices into the Medicare payment limit for clotting factor at the average of these two figures, 64 percent, with an initial transition amount of 80 percent in 2004. (*see* section 3.f. for further discussion on the transition to market prices). We are requesting comments on the appropriate payment limit rate. The limit would apply for all clotting factor HCPCS codes, including both the human and recombinant forms.

c. Drugs Without Market-Based Price Information

Initially, for those drugs where we do not have GAO and OIG information on which to base a market price, we would proceed as in option 2 and base the payment limit on the average AWP discount off of the list AWP reported to the commercial compendia as of April 1, 2003.

As an example of how this approach might apply to a specific drug assuming an average AWP discount of 15 percent, we will examine ifosfamide (J9208). The OIG and GAO did not study ifosfamide. The April 1, 2003 list AWP published in the commercial compendia for ifosfamide is $158. The Medicare payment limit for J9208 would be $135 (that is, 85 percent of $158) effective January 1, 2004.

d. Exceptions Process for First Year Reductions

A manufacturer could seek an exception from the application of these reductions on January 1, 2004 to one or more of its drugs if it would furnish us before October 1, 2003 with verifiable data on the widely available market price, as described earlier in section II.A.3.a, of the drug as of April 1, 2003 and certify the accuracy of this data. We will review the data and determine if it should be incorporated into the Medicare payment limit. Note that all data submitted as part of comments on this proposed rule would be available to the public. Also note that we would base any changes to our proposed payment policy only on data that we could make available to the public.

e. Future Years

As discussed in section 3.f below, we expect to develop additional sources of market-based prices in future years for the purpose of market monitoring. We also recognize that the OIG may perform updated market analyses on drugs previously studied or additional drugs. If the OIG performs a new market analysis, we expect to incorporate this information into the Medicare payment limits. As we develop additional sources of widely available market prices and sufficient new valid information becomes available from these sources, we expect to incorporate this information into the Medicare payment limits based on the methodology described above. In the absence of additional valid data sources indicating a change in the widely available market price, the Medicare payment limits would be updated on an annual basis by the increase in the CPI for medical care for the 12-month period ending June of the prior year.

f. Transition for Existing Drugs

For existing drugs where the widely available market price based on the OIG and GAO studies is less than 80 percent of list AWP, we would transition to the market-based payment in 15 percentage point increments. This is similar to the approach taken by the Congress in specifying the incremental payment changes under the inherent reasonableness authority (section 1842(b)(8) of the Act). For example, one drug studied by both the GAO and OIG is ipratropium bromide (J7644). The April 1, 2003 AWP published in the commercial compendia for ipratropium bromide is $3.52. The GAO study indicates the average market price for ipratropium bromide is 33 percent of list AWP. The OIG study indicates the average market price for ipratropium bromide is 34 percent of list AWP. The average of these two data sources rounded to the nearest percent is 34 percent of AWP. Because this is lower than 80 percent of list AWP, the Medicare payment limit for ipratropium bromide effective January 1, 2004 would be 80 percent of the list AWP or $2.82. The Medicare payment limit for ipratropium bromide effective January 1, 2005 would be 65 percent of the list AWP published in the commercial compendia as of April 1, 2003 updated by the medical CPI. The Medicare payment limits for CY 2006 and CY 2007 would be 50 percent and 35 percent, respectively, of the April 1, 2003 list AWP updated by the medical CPI. In 2008, the transition to the widely available market price would be complete and the payment limit would be 34 percent of the April 1, 2003 list AWP updated by the medical CPI.

To the extent that the OIG performs a new market analysis or additional data sources are developed as described in section 3.h, the target widely available market price might change.

g. New Drugs and Drugs with Patent Expirations

The payment limit for new drugs and drugs coming off of patent would be determined as described under option 2. The only difference would be that under the market monitoring approach the out year payment limit might change to the extent that the OIG performs a market analysis or additional data sources are developed as described in the next section.

h. Additional Sources of Market-Based Prices

We are considering additional sources of market-based price information. These sources could include drug distributors (for example, wholesalers, physician supply houses, specialty pharmacies, retail pharmacies, manufacturers, repackagers) physicians, suppliers, and group purchasing organizations (GPOs). To the extent that payments by private insurers and health plans reflect widely available market prices, we are considering inclusion of these sources.

The general approach we will use is to take the median price among valid available sources of information on widely available market prices, after making any adjustments required to make the information comparable. We are considering whether to restrict the median calculation to those information sources that reflect significant market share. We are proposing to rely on a single information source if we determine that the source is representative of the widely available market price for a drug.

We are considering the acquisition of this market-based price information through market research firms, contractors, consultants, the OIG, and/or by directly obtaining such data.

If we obtain additional sources of market-based prices and if we determine

these sources are valid for the purposes of determining payment limits based on widely available prices, we will provide an opportunity for public comment on the sources.

1. Data from Distributors and Manufacturers

We would seek to acquire data from drug distributors and manufacturers. Although there may be many distributors for a given drug, our understanding is that most physicians and suppliers tend to use the same distributors over a given time period and that the majority of these purchases, at least for injectable drugs, are concentrated in a small number of distributors. We are considering whether to focus our efforts initially on these distributors and we are seeking comment on this focused approach.

Our market analyses would also include pricing information from manufacturers' direct distribution programs since, as discussed earlier, we understand that many of these programs are easily accessible to physicians and suppliers and that the prices offered in these programs are often lower than the prices available through other distribution channels.

2. Data From Physicians and Suppliers

We would also seek to obtain acquisition cost information from physician and suppliers. Although individual invoice pricing may not necessarily be reflective of the widely available market price, for example due to the presence of volume related rebates and price concessions, this information could be informative in developing the widely available market price.

While issues have been raised in the past concerning the use of invoice prices due to the potential presence of volume discounting, we note that the GAO study found that physicians who billed for low amounts of chemotherapy drugs were still able to obtain significant price discounts. We seek comment on this issue.

3. Data from Private Insurers and Health Plans

We are considering obtaining data from private insurers and health plans, including Medicare carriers' private businesses. As discussed earlier, it is our understanding that while many private insurers pay widely available market prices for oral drugs and inhalation drugs, they have not historically paid widely available market prices for injectable drugs. Given this, we are considering initially seeking private business prices for oral and inhalation drugs. For example, we are considering whether to request our four DMEPOS contractors to supply us with oral and inhalation drug pricing and related information from their private side business.

For injectable drugs, as private insurers develop alternative payment approaches that reflect widely available market prices, we could seek this information from them. For example, similar to the approach suggested for oral and inhalation drugs, we are considering asking our carriers to furnish us with their private business payments for these drugs.

4. Approaches to Acquiring Market-Based Pricing Information

We are considering the acquisition of this market-based price information through market research firms, consultants, contractors, the OIG, and/or directly obtaining such data. It is our understanding that many manufacturers use market research firms to gather information on their products. For example, they conduct surveys of physician practices and compile pricing information. We are considering contracting with one of these firms to perform a market analysis of physician practices. We also understand that a few private health plans have begun to use consultants, at least for injectable drugs, to assist them in developing market-based payment structures. We are considering contracting with these consultants. We are considering an attempt to obtain pricing information directly from distributors using full or part-time CMS employed or contracted physicians. We are considering the selection of one or more contractors to acquire this information for us and maintain updated pricing information. The OIG may also update market analyses of drugs they have previously studied and examine additional drugs.

Option 4—Competitive Acquisition Program and Average Sales Prices

A fourth option we are considering is the establishment of a competitive acquisition program for drugs covered under section 1842(o) of the Act coupled with the establishment of a process for determining Average Sales Price (ASP). Under this option, we would establish competitive acquisition areas and entities would bid to supply drugs to physicians in one or more of these areas. A physician could choose annually to acquire drugs from one of these entities and the entity would be responsible for billing Medicare. Alternatively, a physician could choose to purchase drugs and bill Medicare. If a physician elected to purchase drugs, we would pay the physician the ASP for the drug. Manufacturers would be required to furnish us with the ASP for each of their drugs quarterly. This option is consistent with the GAO's recommendation that we evaluate expanding competitive bidding approaches to obtain lower drug prices (GAO–01 1118, p.5) and is consistent with our understanding of Congressional intent with respect to section 429 of BIPA.

Below we describe our proposed competitive acquisition program and ASP-based payment systems. We seek comment on any additional elements that need to be considered in the establishment of these payment systems. We also note that for some drugs, such as those currently provided directly from the manufacturer to the physician, we may be potentially introducing an additional distribution level in the form of the bidding entity. Therefore, we have explicitly identified safeguards under the competitive acquisition program that are more implicit under our alternative payment reform proposals. While we believe that section 429 of BIPA contemplates (and section 1842(o) of the Act could be defined to permit) the use of such a competitive acquisition model, coupled with the implementation of an ASP setting function described below, we specifically solicit comments on the extent of the authority to implement the option set forth below either in its entirety or in a modified fashion.

A. Competitive Acquisition

1. Categories of Drugs

Under this proposal, we would bid two categories of drugs in each competitive acquisition area: oncology and non-oncology. The oncology category would consist of covered drugs typically billed by oncologists or otherwise used to treat cancer. The non-oncology category would consist of all other covered drugs with the exception of DME drugs, clotting factors, drugs furnished to individuals in connection with the treatment of end stage renal disease, and vaccines. Payment for excepted drugs would be based on the ASP. We may propose subcategories of non-oncology drugs in the future. We seek comment on any additional categories of drugs that may be inappropriate for competitive bidding due to low utilization, a unique method of delivery, or similar reasons.

2. Bidding Entity Qualifications

a. Capacity

Bidding entities would be required to demonstrate sufficient capacity to

supply the drugs in the drug category in accordance with all applicable state requirements and pharmacy laws. The entity would need to have sufficient arrangements to acquire and to deliver drugs within the category at the bid price for all physicians that may elect such entity in a competitive acquisition area.

b. Shipment

Bidding entities would be required to have arrangements in effect for the shipment of drugs at least 5 days each week and for the timely delivery (including emergency situations) of drugs in the competitive acquisition area. The shipments would be made to the physician and not directly to the beneficiary, except under circumstances where a beneficiary currently receives the drug in the home or other nonphysician office setting. The contractor would not deliver drugs to a physician except upon receipt of a prescription.

c. Integrity of the distribution system.

Bidding entities would need to demonstrate that the drugs provided in the competitive acquisition program would be acquired directly from the manufacturer or from a distributor that has acquired the drugs directly from the manufacturer.

d. Inquiries and dispute resolution.

Bidding entities would be required to establish procedures for the prompt response and resolution of physician and beneficiary inquiries regarding the shipment of drugs and to establish a grievance process for the resolution of disputes. For disputes that are not resolved at the bidding entity, we propose to establish a national ombudsman to oversee and review complaints under the competitive acquisition program.

3. Bidding Process

a. Evaluation of bids.

We propose to select one or more winning bidders for each category based on the bid prices for the drugs, the ability to ensure product integrity, customer service, and past experience in the distribution of drugs. We also propose to reject any bid that we estimate would result in aggregate payments that exceed the payments that would have been made if the drugs in the category were paid at the ASP.

b. Timing of bidding process.

We expect to have the initial bidding process complete and the winning entities selected in time for the competitive acquisition program to be implemented for oncology drugs beginning in 2005 and non-oncology drugs beginning in 2006. We propose to select subsequent contractors on a periodic basis and seek comment on the appropriate time between bidding periods and the appropriate length of the contracts.

c. Bid prices.

The prices bid by an entity would be the prices in effect and available for the supply of contracted drugs in the area through the entity for the entire contract period. The bid price would not vary within a competitive acquisition area. The bid price would include all costs related to carrying out the contract provisions, including costs related to the delivery, dispensing, and shipping of the drug.

d. Bidding on a national or regional basis.

We would propose, but not require, entities to bid for contracts in more than one competitive acquisition area.

4. Competitive Acquisition Areas

We seek comment on the appropriate geographic regions to establish for a competitive acquisition program.

5. Billing and Coinsurance Under Competitive Acquisition

We propose that a successful bidder would be responsible for billing Medicare and collecting coinsurance for the drugs they supply that are subsequently administered to Medicare beneficiaries.

B. Average Sales Price

Under the competitive acquisition model option, a physician would make an annual election to obtain drugs in a given category through a winning bidder or could purchase the drugs and bill Medicare. If a physician chooses to purchase drugs, they would be paid under the ASP-based system described below. Manufacturers would be required to report the ASP to us on a quarterly basis.

1. Definition of Average Sales Price

Under this proposed option we would propose to define the ASP for a drug for a quarter as a manufacturer's total sales for the quarter less any sales exempted from the ASP calculation divided by the total number of units of such drug sold by the manufacturer in such quarter less any units from sales exempted from the ASP calculation. We seek comment on this definition as well as on the appropriate categories of sales that should be exempted from the ASP calculation.

2. Discounts

Under this proposal, in calculating the ASP, the manufacturer would take into account volume discounts, prompt pay discounts, cash discounts, the free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug is reduced as a consequence of such rebate.

3. Payments.

We propose to pay for multi-source drugs at an appropriate markup above ASP and seek comment on a markup in the range of 101 to 112 percent of ASP. We propose to pay for single source drugs at the lesser of an appropriate markup of ASP in the range of 101 to 112 percent or the Wholesale Acquisition Cost (WAC).

a. Wholesale Acquisition Cost (WAC).

Under this competitive acquisition model option we would propose defining the WAC as the manufacturer's list price for the drug to wholesalers and direct purchasers in the United States as reported in wholesale price guides or other publications of drug pricing data. The WAC would not include prompt pay or other discounts, rebates or reductions in price.

B. Increases in Payments Related to the Costs of Furnishing or Administering Drugs

As described earlier, section 429(b) of BIPA requires us to revise the Medicare payment methodology for drugs under section 1842(o) of the Act based on the GAO report to the Congress. Under section 429(b), to the extent the Secretary determines appropriate, the Secretary may make adjustments to the practice expense component of the physician fee schedule for costs incurred in the administration, handling, or storage of certain categories of such drugs and biologicals. Section 429(b) also authorizes the Secretary to make proposals for new payments to providers of services or suppliers for such costs, if appropriate. However, the estimated aggregate payments for drugs under the revised system (including additional payments for related costs of furnishing or administering the drug) cannot exceed payments as projected by the Secretary under the current system. Below, we discuss payment issues associated with furnishing or administering Medicare covered drugs. To the extent appropriate, we are proposing increased payments for the administration of drugs or new payments to providers or suppliers for

furnishing Medicare covered drugs and seek comment on the applicability of these payments under each of our four options for reforming the current payment system.

1. Proposed Changes in Physician Fee Schedule Payment for the Administration of Medicare Covered Drugs

a. SMS and Supplemental Survey Data

An important element in calculation of the practice expense relative value units (RVUs) for all services paid using the physician fee schedule is specialty-specific practice expenses per hour of patient care. We use the American Medical Association's (AMA's) Socioeconomic Monitoring System (SMS) survey of actual aggregate cost data by specialty as the major source of data for these expenses per hour. However, not every specialty is included in the SMS data and several other specialties have commented that the SMS data were not adequately representative of the costs incurred by their specialty. (63 FR 58824–58826) Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) directed us to establish a process under which we would accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by organizations. In an interim final rule published on May 3, 2000 (65 FR 25664) we set forth our criteria for accepting such supplemental surveys. In the December 31, 2002 **Federal Register** that contained the 2003 physician fee schedule final rule (67 FR 79972), in response to comments, we made some modifications to these criteria. In this year's physician schedule proposed rule (68 FR 49030), we proposed changes to the deadline for submitting supplemental survey information to our contractor, the Lewin Group.

Using the SMS data, we calculated a total practice expense per hour of $99.30 for oncology. We are currently using this practice expense per hour for CMS specialty codes 83 (Hematology/Oncology) and 90 (Medical Oncology). However, the American Society of Clinical Oncology (ASCO) submitted a supplemental survey in 2002 with a practice expense per hour of $189.00. In the 2003 physician fee schedule final rule (67 FR 79973), we discussed the practice expense survey submitted by the ASCO. Although the survey met our stated criteria, we did not use it in the calculation of the 2003 practice expense RVUs because of concerns about the data. Our contractor, the Lewin Group evaluated the data and indicated that average compensation (including salaries and fringes) for clinical and administrative staff reported in the ASCO survey averaged $71,014 and $87,253 respectively and appear inconsistent with other available data on wage rates for such staff. Furthermore, the Lewin Group indicated that the category of ''other professional expenses'' was 349 percent higher than the SMS survey. The Lewin Group suggested that we seek an explanation for the high values in the ASCO survey before incorporating it into the practice expense methodology. In the December 31, 2002 physician fee schedule final rule we indicated that we intended to meet with ASCO to discuss our concerns and that we would consider using the data in the future if our concerns were addressed. We have subsequently held such discussions with ASCO and understand that the high values for average compensation for clinical and administrative staff are largely due to a limited number of practices with very high values that raise the average values calculated across all respondents to the survey. At this time, we are proposing to incorporate the survey into the methodology. Since our practice has been to use all survey data and not eliminate practices with high values, we are including all respondents in the supplemental practice expense per hour.

As we note in more detail below, section 429(b) authorizes the Secretary to provide for adjustments to payments for the costs incurred in the administration of certain categories of drugs. While we believe the provision allows the Secretary to make changes to practice expense payments in a non-budget neutral manner, we also believe that it anticipates that the Secretary will make adjustments to payments for drug administration services at the same time the Secretary revises the payment methodology for drugs. Otherwise, we would be unable to compare the aggregate costs of the changes authorized by section 429. We are, therefore, proposing only to incorporate the oncology survey data into the practice expense methodology at the same time proposed changes in Medicare payment for drugs are adopted.

ASCO, the GAO, and OIG have all indicated that Medicare overpays for drugs and revisions to the payment methodology for drugs should coincide with increase in practice expense payments for drug administration services. In testimony before the House Ways and Means Committee on October 3, 2002, ASCO acknowledged the need for comprehensive reform of Medicare payment for drugs and physician practice expenses. ASCO testified:

> We do not relish being targets for those who correctly point out that some drugs are reimbursed by Medicare at a rate that exceeds the acquisition cost * * * reform must be comprehensive, encompassing both overpayments for drugs and underpayments for the costs of administering the drugs.

The GAO echoed this view in testimony before the House Energy and Commerce Subcommittee on Health Oversight and Investigations on September 21, 2001 testifying: ''it should be a principle of Medicare payment policy to pay for each service appropriately.'' OIG testified:

> Our reports have shown time after time that Medicare pays too much for drugs * * * We agree that physicians need to be properly reimbursed for patient care. However, we do not believe that the payment of artificially inflated drug prices is an appropriate mechanism to compensate them.

At the same hearing, Subcommittee Chair James C. Greenwood stated:

> We will need to develop a solution that results in Medicare paying prices for drugs that are closer to the actual prices paid by health care providers. Similarly we will need to take steps to ensure that health care providers are sufficiently reimbursed for all of their services.

Furthermore, we remain concerned about high practice expense per hour values from the ASCO survey. Even when practices with extremely high values are eliminated from the calculations, the supplemental survey practice expense per hour would remain 174 percent higher than the all physician average and more than 45 percent higher than the next highest specialty. We will continue investigating why oncology practice expenses would be so far above other specialties. For the reasons above, we believe the supplemental survey should only be incorporated into the practice expense methodology at the same time that Medicare revises the payment methodology for drugs.

b. Weight Averaging Supplemental Survey and SMS Data

When we use supplemental survey data, we have generally blended the supplemental data with SMS data for the specialty in order to use the maximum number of survey responses in calculating a practice expense per hour. However, the argument has been made that specialty societies would only undertake a survey because of the belief that the existing SMS data were not sufficiently representative of the specialty's practice expenses. According to this argument, blending the

supplemental data with existing SMS data were not appropriate. We agree and propose to use supplemental survey data without blending it with the SMS data.

On only one previous occasion have we used blended data in the calculation of a specialty's practice expense per hour. In the 1999 physician fee schedule final rule (64 FR 59391), we blended the survey data from the Society of Thoracic Surgeons (STS) with the older SMS data for cardiac and thoracic surgery. Consistent with the proposed change to use supplemental survey data for oncologists' practice expenses without blending it with the SMS data, we are proposing to recalculate the practice expense per hour for cardiac and thoracic surgery using the data from only the STS survey which will result in a modest increase in their practice expense per hour. We are proposing to use the following revised data for oncology and cardiac and thoracic surgery:

REVISED PRACTICE EXPENSE PER HOUR

[Dollar]

Specialty	Clin. staff	Admin. staff	Office expense	Med. supplies	Med. equip.	Other	Total
Cardiac/Thoracic	19.5	18.0	17.2	2.1	2.1	14.2	73.1
Oncology	53.4	34.7	34.4	16.9	7.4	42.2	189.0

c. Nonphysician Work Pool

The nonphysician work pool is a special methodology that we used to determine practice expense RVUs for many services that do not have physician work RVUs. We created the nonphysician work pool as an interim measure until we could further analyze the effect of the basic practice expense methodology on Medicare payment for services that do not have physician work RVUs. While the nonphysician work pool is of benefit to many of the services that were originally included, we have allowed specialties to request that their services be removed from the pool. Because the nonphysician work pool includes a variety of services performed by many different specialties, we use the ''all physician'' average practice expense per hour in place of a specialty-specific practice expense per hour.

Oncologists currently receive approximately 23 percent of their Medicare physician fee schedule revenues from drug administration services that are in the nonphysician work pool. For drug administration codes to benefit from the increase in oncology's practice expense per hour, it would be necessary to remove them from the nonphysician work pool and use the general top-down methodology to establish their practice expense RVUs. For this reason, we are proposing to remove therapeutic and diagnostic infusions (CPT codes 90780 and 90781), therapeutic, prophylactic or diagnostic injections (CPT codes 90782 through 90788) and chemotherapy administration (CPT codes 96408 through 96549) from the nonphysician work pool. Practice expense RVUs for these services will be computed utilizing the standard practice expense methodology used for computing practice expense RVUs for other services outside the nonphysician work pool. (CPT code 96400, chemotherapy injection, is not listed above because it has already been removed from the nonphysician work pool at the request of the American Urological Association. See the December 31, 2002 final rule, 67 FR 79981. This service is primarily provided by urologists and increased in payment by 640 percent between 2002 and 2003 as a result of being removed from the nonphysician work pool).

As we state above, we use the all physician average practice expense per hour in calculating the aggregate practice expense pool for services included in the nonphysician work pool. Once drug administration services are removed from the nonphysician work pool, nearly 98 percent of Medicare allowed charges for services affected by the nonphysician work pool calculations are diagnostic tests provided by radiologists, cardiologists and internists and therapeutic radiation oncology services. Because there is a less heterogeneous group of services remaining in the nonphysician work pool once drug administration services are removed and to minimize the impact of the removal of these services, we are proposing to revise the practice expense per hour based on a weighted average of the specialties that perform the services affected by its calculations. We are proposing to use the following revised data in the practice expense methodology for services remaining in the nonphysician work pool:

REVISED PRACTICE EXPENSE PER HOUR

Specialty	Clin. staff	Admin. staff	Office expense	Med. supplies	Med. equip	Other	Total
Nonphysician Work Pool	$15.8	$17.4	$21.5	$7.9	$4.9	$15.0	$82.6

In the practice expense methodology, the practice expense per hour for each category of costs is multiplied by the physician time per procedure and summed to the specialty level to create aggregate cost pools. By definition, nonphysician work pool services do not involve the physician and have no physician time. To create the nonphysician work pool, we have used clinical staff time per procedure in the computation. In the June 28, 2002 proposed rule (67 FR 43851), we proposed to use the maximum staff time where multiple staff are involved in providing the service. By using the maximum staff time, we are assuming that clinical staff are working concurrently. However, it is possible that clinical staff are working sequentially and it would be appropriate to use the total staff time for each service. We believe the staff time arrangement will likely differ based on the specific service and it is not possible to adopt a rule that will address every situation. Nevertheless, we are proposing to use the total staff time in place of the maximum staff time for developing the 2004 physician fee schedule. As we stated earlier, the nonphysician work pool was adopted as an interim step until we could further

analyze the effect of the top-down methodology on nonphysician work pool services. We have performed these analyses and are optimistic about being able to address nonphysician work pool issues as part of developing the 2005 physician fee schedule. At that time, we will no longer need to use staff time in the creation of the aggregate cost pools and this issue will be resolved.

We have modeled the effect of removing drug administration services from the nonphysician work pool in combination with the change to the practice expense per hour and clinical staff time changes described above. These changes will increase the practice expense RVUs for the nonphysician work pool by approximately 3 percent relative to the practice expense RVUs shown in the physician fee schedule proposed rule published on August 15, 2003.

d. Crosswalk Issues

As stated above, we are currently using the oncology practice expense per hour for CMS specialties 83 (Hematology/Oncology) and 90 (Medical Oncology). We have reviewed 2002 Medicare data for specialty 82 (Hematology). The mix of services provided by physicians billing under specialty 82 is similar to those of specialties 83 and 90. For this reason, we are proposing to change the specialty practice expense per hour crosswalk for specialty 82 from internal medicine to oncology.

e. Issues Related to Budget Neutrality

Section 1848(c)(2)(B)(ii)(II) of the Act requires that the additional expenditures resulting from changes in RVUs be budget-neutral. We normally adjust the practice expense RVUs so that the aggregate amount of expenditures is the same before and after a change to the methodology or data that are used to develop the practice expense RVUs. However, section 429(b)(1) of the BIPA indicates that, ''Notwithstanding *any* other provision of law'' * * *. (emphasis added) the Secretary is required to revise payments for drugs and is allowed to provide for adjustments to payment amounts for the practice expense component of the physician fee schedule (or new payments to providers or suppliers) for the costs incurred in the administration, handling, or storage of certain categories of drugs and biologicals). The additional physician fee schedule payment and the new payments to providers and suppliers cannot exceed savings from revising payments for drugs. We believe that BIPA section 429(b) provides authority for us to increase physician fee schedule expenditures (that is, not apply the budget-neutrality requirement in section 1848(c)(2)(B)(ii)(II) of the Act) for adjustments made to the practice expense RVUs for drug administration. We have modeled all of the changes described above and determined that payments for the drug administration services will increase by $190 million ($150 million to oncologists and $40 million to other specialties that provide drug administration services such as rheumatology, gastroenterology and infectious disease). Because section 429(b) of BIPA provides authority to increase physician fee schedule expenditures for the adjustments to the practice expense RVUs for drug administration services, the proposed adjustments to practice expense RVUs will increase physician fee schedule allowed charges by $190 million or the amount of increased payments for drug administration services. In general, the proposed adjustments to practice expense RVUs will result in increases in payment for those specialties that provide drug administration services and minimal net payment effects on other specialties. We believe that BIPA allows us not to apply the physician fee schedule budget-neutrality requirements in the context of revising payment rates for drugs and only if the additional expenditures from these and other changes described below do not exceed savings from revising prices for drugs. If we increased physician fee schedule expenditures for the adjustments made to the practice expense RVUs for drug administration without simultaneously revising payments for drugs, we would be spending more on Medicare drugs and drug administration services than we would be in the absence of making the payment changes. Such a policy is clearly prohibited by BIPA.

As we stated earlier, we believe the statute anticipates that we would make drug administration payment changes in conjunction with adopting a revised payment methodology for Medicare drugs. Therefore, we are also proposing not to make the drug administration payment changes, even if we were to make them budget neutral under section 1848(c)(2)(B)(ii)(II) of the Act with respect to other physician fee schedule service unless the drug payment changes are also made. If these proposed changes are adopted the increased costs will be reflected in the sustainable growth rate.

f. Multiple Pushes

In the November 25, 1991 **Federal Register** (56 FR 59541), we indicated that Medicare will allow CPT code 96408 (Chemotherapy administration, intravenous; push technique) to be reported only once per day even if the physician administers multiple drugs. Since this code is in the nonphysician work pool, its payment amount is established based on charge-based practice expense RVUs. However, because we are establishing resource-based practice expense RVUs and there are additional resources involved in administering each subsequent drug, we are proposing to change our policy and allow for 96408 to be reported once per day for each drug administered. Using 2002 Medicare utilization data and the payment amounts resulting from the proposed changes described above, we estimate a $25 million increase in Medicare allowed charges to oncologists. We will reflect any increased costs associated with paying for multiple drug administrations on the same day in the sustainable growth rate. However, as discussed previously, we do not believe the statute permits us to adopt this proposal without revising Medicare's payment methodology for drugs since aggregate payments for drugs and drug administration services would exceed payments that would be made in the absence of such changes.

g. Summary of Physician Fee Schedule Proposals

We are proposing to: (1) Use the ASCO survey data without blending it with existing SMS data to determine practice expenses per hour for use in the top-down methodology (resulting in increased payment rates for drug administration codes provided by oncologists, rheumatologists, gastroenterologists, infectious disease specialties and all other physicians that provide these services); (2) revise the cardiac/thoracic surgery practice expense per hour to use supplemental survey data without blending with SMS data; (3) remove drug administration codes from the nonphysician work pool and instead use our general top-down methodology to establish practice expense relative values units (RVUs); (4) revise the practice expense per hour and clinical staff time used to determine the nonphysician work pool; (5) change the specialty practice expense crosswalk for specialty 82 (Hematology) from internal medicine to oncology; (6) increase physician fee schedule expenditures for the adjustments made to the practice expense RVUs for drug administration services (but only if there are accompanying revisions in payment for drugs discussed elsewhere in this proposed rule) resulting in minimal net payment effects on any specialty that does not provide drug administration services; and (7) revise our policy on payment for multiple pushes.

We have modeled the above proposals as though they were in effect in 2002 to determine the specialty-level impact on

Medicare revenues for oncologists. In 2002, oncologists received approximately $3.8 billion in Medicare revenues for drugs, $1.1 billion for physician fee schedule services and $0.1 billion for all other services. Taken together, oncologists received approximately $5.0 billion in 2002 Medicare revenues for all services. Using 2002 utilization, we estimate that total physician fee schedule payments to oncologists would have increased by $150 million as a result of using oncology survey data and other changes to the practice expense methodology. Allowing payment for multiple drug administration by the push technique would have increased oncology payments another $25 million. The estimated additional payment of $175 million to oncologists represents a 17 percent increase in their physician fee schedule revenues and a 58 percent increase in their payments for drug administration services. If we had adopted one of the proposals described above to revise drug payments in 2002, Medicare revenues to oncologists would have increased $80 million or 2 percent from applying comparability. Medicare revenues to oncologists would have declined by $570 million or 8 percent from applying an average list AWP discount of 80 percent.

2. Clotting Factor

As mentioned earlier, in January 2003 the GAO issued a report entitled ''MEDICARE: Payment for Blood Clotting Factor Exceeds Providers'' Acquisition Costs'' (GAO–03–184). GAO recommended that we establish Medicare payment levels for clotting factor that are more closely related to providers' acquisition costs and then establish a separate payment for the cost of delivering clotting factor to Medicare beneficiaries by hemophilia treatment centers and homecare companies. In following the GAO's recommendation, at the same time that we establish an appropriate price for clotting factor, we plan to establish a separate payment to hemophilia treatment centers and homecare companies for the administrative costs associated with furnishing the clotting factor. GAO estimated that total delivery costs in 2000 and 2001 ranged from $0.03 to $0.08 per unit of clotting factor sold by hemophilia treatment centers. GAO did not receive enough data from homecare companies to estimate their costs. We are proposing to create a payment of $0.05 per unit of clotting factor provided to Medicare beneficiaries by hemophilia treatment centers and homecare companies to appropriately pay for the administrative costs associated with furnishing the clotting factor. Note that we are not proposing the creation of separate payment for furnishing the clotting factor for individuals or entities other than hemophilia treatment centers and homecare companies, for example hospitals. The administrative costs of these other individuals or entities associated with furnishing clotting factor are already paid for in their respective payment systems. We also note that GAO indicated that providers may also furnish other services for which they are not separately reimbursed, such as patient education and community outreach. However, these services are not Medicare-covered benefits and they are generally targeted to younger patients who are not Medicare beneficiaries. We are proposing not to include such non-Medicare covered services in the separate payment that we plan to establish for furnishing clotting factor. Section 429(b) of BIPA authorizes the Secretary to establish payment for clotting factor delivery. Therefore, we plan to assure that the total amount of Medicare expenditures for both clotting factor and delivery of such factor does not exceed the amount that Medicare would otherwise spend for clotting factor in the absence of adjustment in payment for the drug and establishment of a separate fee for furnishing the drug. We are seeking public comment and data related to the appropriateness of a fee for furnishing clotting factor under each of our four options for revising the current payment methodology.

3. Separately Billable ESRD Drugs

Medicare pays ESRD facilities a prospective payment, the composite rate, for each hemodialysis treatment furnished. The composite rate is designed to cover the facility's costs of ESRD services furnished to beneficiaries. ESRD facilities can also bill Medicare separately for certain drugs paid outside the composite rate, including erythropoietin, vitamin D analogue, and calcitrol. By law, Medicare payment for erythropoietin furnished by ESRD facilities is $10 per 1,000 units. The other separately billable drugs are paid under the current 95 percent of list AWP methodology.

In its March 2003 report to Congress, MedPAC concludes that after taking into account the combined payments to ESRD facilities for both the dialysis treatment and the separately billable drugs, the aggregate Medicare payments for outpatient dialysis services appear to be adequate. However, MedPAC found that in 2001, Medicare's composite rate payment did not cover the costs of providing dialysis services. MedPAC indicated that the profitability of erythropoietin and other separately billable drugs is subsidizing the lower margins under the composite rate. The finding regarding the profitability of the separately billable drugs is consistent with two earlier studies by the OIG. The OIG also found that Medicare's payment rates for these drugs were high relative to providers' costs and the rates paid by the VA and Medicaid programs.

We believe that it is important to pay appropriately for the composite rate and separately billable drugs and not have payments for one cross-subsidize the other. It is our preference for the Congress to provide explicit authority to increase the composite rate when we reduce payments for ESRD separately billable drugs. However, we believe that Congress intended for us to establish additional payments for ESRD facilities to account for increased costs resulting from revised drug payment rates. Section 429(b) provides that the Secretary may provide for additional payments to providers or suppliers for the administration, handling, and storage of drugs and biologicals. While the citation in section 429(b) is to a provision of the statute that no longer exists, we believe that in light of other provisions in section 429, Congress intended the Secretary to provide for additional payments to ESRD facilities for increased costs related to the administration of drugs and biologicals to offset revised Part B payments rates if the Secretary determined it was appropriate. We believe based on the MedPAC analysis that it is appropriate to increase ESRD payments to offset the savings that will occur as we reform drug payments under the current methodology. This would result in the same amount of money being paid to ESRD facilities in 2004, but with more accurate payment for separately billable drugs. This would not involve the bundling of payment for these drugs or the drug savings into the composite rate, but a separate payment from the composite rate. After we have selected an AWP reform option, we would determine the average first year savings from the ESRD separately billable drugs per hemodialysis treatment and create a separate ESRD facility payment per hemodialysis treatment equal to this amount. As stated earlier, we would prefer for Congress to provide explicit authority for us to bundle the savings from reforming the separately billable ESRD drug payments into the composite rate.

We are requesting comments from the public on our interpretation of the BIPA

provisions as well as our proposal for additional ESRD payments.

4. Inhalation and Home Infusion Drugs

For inhalation drugs furnished in connection with an item of DME, Medicare currently pays for: (i) The DME itself, (ii) servicing of the DME, and (iii) the inhalation or infusion drug. For inhalation drugs, Medicare also pays a dispensing fee.

Inhalation equipment, such as nebulizers and home infusion pumps, are paid under the DME benefit under the capped rental category. The supplier furnishes the equipment to a beneficiary and the supplier is paid 10 percent of the purchase price for the first three months and 7.5 percent of the purchase price for months 4 through 15 (that is, up to 120 percent) of the purchase price of the equipment. The supplier furnishes the equipment for as many months as the beneficiary needs it. The statute also provides for a purchase option for the beneficiary. If a beneficiary does not purchase the equipment, the supplier retains title to the equipment and could furnish it to another beneficiary. In this case, the payment occurs in a similar fashion and the supplier could be paid up to another 120 percent of the purchase price of the equipment. Medicare's payment includes delivery of the equipment to the patient and any necessary setup and training of the beneficiary in its use.

The statute specifies that Medicare also make payments for maintenance and servicing the equipment. Such maintenance and servicing payments cover 6-month periods beginning 7 months after initial use of the equipment. By statute, Medicare's payment for maintenance and servicing is equal to the lesser of a reasonable and necessary maintenance and servicing fee, or 10 percent of the total purchase price of the equipment.

In their September 2001 report described earlier (GAO–01–1118), the GAO noted that although there have been no recent analyses of the adequacy of Medicare DME payments, there are indications that the payments may be above market rates. We are unaware of any studies indicating that absent excessive Medicare payments for DME drugs, payment for the DME itself is inadequate. Nevertheless, we are interested in receiving convincing and comprehensive data from the public about any underpayment for inhalation and infusion durable medical equipment believed to exist and the applicability of that data under each of our four options revising the current payment methodology.

We note that it has been suggested that the current excessive Medicare payments for DME drugs are used to pay for inhalation and infusion services provided by DME suppliers that are not covered by the Medicare program. We believe it is inappropriate for excessive drug payments to subsidize these non-covered services.

5. Oral Drugs Provided by Pharmacies

Medicare makes no separate payment to pharmacies for dispensing covered Medicare drugs such as oral immunosuppressive and oral anti-emetic drugs. The GAO report did not make a recommendation with respect to dispensing fees for pharmacies. We are seeking public comment and data related to the appropriateness of dispensing fees under each of our four options for revising the current payment methodology.

C. Beneficiary Access to Drugs

Given our intent to pay appropriately for drugs and our proposed increases in payments for the costs related to furnishing and administering drugs, we do not believe that any beneficiaries will experience drug access issues as a result of our four proposed options. For the drugs (for example, the inhalation drugs) where we are not currently proposing changes in payments related to the administrative costs of furnishing the drugs, we are seeking comments and data supporting the appropriateness of any payment changes.

Although we do not believe any drug access issues will result from this proposed rule, we intend to monitor beneficiary access closely and may propose additional changes to our payment system in the future if necessary. The data sources we might examine in our access monitoring effort include claims data, surveys and focus groups, beneficiary inquiries to the 1–800-Medicare number, and environmental scanning activities.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- 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.

Requirement:

Under proposed option 2 and option 3 for this regulation, a manufacturer of a new drug or a drug coming off patent would have to submit detailed information and a rationale to us for a new price, in order to receive a HCPCS code or continue the use of a HCPCS code, respectively. During the first year, the manufacturer would also have to provide updated information on the actual prices that Medicare physicians and supplier pay to purchase the drug.

The burden associated with these requirements is the time involved in providing us the information the first time and in providing us the updates. The burden of submitting the data should be minimal, as most of it will undoubtedly be electronically stored and transmitted. Submitting information should take no longer than 1 hour; updates would take no more than 30 minutes per year. Assuming a maximum of 50 Medicare Part B covered drugs per year either new, coming off patent, or subject to a manufacturer update in the first year based on actual sales, we expect the maximum aggregate burden per year would not exceed 150 hours. In addition, under option 3 a manufacturer could request an exception to price reduction in the first year. We believe that it would take an average of one hour to submit the request and the necessary data and certification. Given the universe of approximately 450 Medicare drug codes and assuming an average of 10 manufacturers per drug code, the maximum aggregate burden associated with this activity would be 4500 hours.

For proposed option 3 for this regulation we would collect, through various means, market-based price information. This information would be collected from any of the following: manufacturers, distributors, physicians and suppliers, and private insurers and health plans.

The burden associated with these requirements is the time involved in providing us the information. We expect it would take an average of one hour to provide us with this information. We expect the burden will not vary significantly regardless of the number of codes requested since this information

is predominately stored electronically by these entities. Assuming a maximum of 1000 of the above entities are requested to provide information in a given year, the maximum aggregate burden associated with this information in 1000 hours per year.

Under option 4, bidders would have to submit a bid. They would have to demonstrate that they have sufficient capacity, that the source of the drugs is the wholesaler or distributor for the wholesaler, and that they have arrangements for shipment within a specified time frame. They would be required to have a procedure for resolving disputes.

The burden associated with the competitive acquisition program would be the time it would take a bidder to submit the bid and to document that it has met the requirements. We expect it would take an average of approximately 40 hours to collect the information for competitive bidding under option 4. Given that we are seeking comment on the number of geographic areas to conduct the competitive bidding, it is not possible to estimate the aggregate burden.

Also under option 4 we are requesting information from manufacturers on the Average Sales Price of a drug. We believe that it would take an average of one hour to collect this information. Given the universe of approximately 450 Medicare drug codes and assuming an average of 10 manufacturers per drug code, the maximum aggregate burden associated with this activity would be 4500 hours per quarter.

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

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, DRDI, DRD–B, Attn: Julie Brown, Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be emailed to the following address: email: *baguilar@omb.eop.gov;* or faxed to OMB at (202) 395–6974.

IV. Response to Public Comments

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

V. 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 reassigns responsibility 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 described below, we have simulated the effect of changes in payment resulting from the implementation of each of the four options for revising the current drug payment methodology. We have also simulated the impact of our proposed increase in payments for the administrative costs related to furnishing drugs.

Since this rule is considered to be a major rule because it is economically significant, 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.

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of $8.5 million or less. Approximately 96 percent of physicians are considered to be small entities. There are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. These physicians are more concentrated in the specialties of oncology, urology, and rheumatology. 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 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 DME, prosthetics, orthotics, surgical dressings, and other equipment and supplies each year. Total Medicare expenditures for DME are approximately $7 billion per year, of which approximately $1 billion are for DME drugs.

The impact of this proposed rule on an individual physician or DME supplier is dependent on the mix of drugs they provide to Medicare beneficiaries. For example, under the market monitoring option a physician could: (1) Determine the quantities of drugs that the physician provides to Medicare beneficiaries; (2) determine the proposed impact on that physician for drugs which have been studied by GAO and OIG based on the quantities the physician provides, the information in Table 3, and our proposed transition as described in section II.A.3.f; and, (3) determine the proposed impact on that physician for drugs which have not been studied by GAO and OIG based on the quantities the physician provides and our proposal to pay 80 percent to 90 percent of AWP as discussed earlier in section II.A.3.c. Different impacts will result from this calculation depending on the mix of drugs provided.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. To the extent changes in drug payments would have any impact on small rural hospitals, it would be limited to the few drugs they might furnish with pass-through status

under the Outpatient Prospective Payment System.

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 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined that this proposed rule will have no consequential effect on State, local, or tribal governments.

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.

A. Anticipated Effects

We have prepared the following analysis, related to the 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 are using to minimize the burden on small entities. As indicated elsewhere, we are making changes to payments for drugs and related services in response to the requirements of section 429(b) of BIPA and section 1842(o) of the Act. It is our intent to revise our drug payment system and pay appropriately for the administrative costs related to furnishing drugs. We provide information for each of the policy changes in the relevant sections in this rule. The provisions of this rule are changing only our payment rates for drugs and related services. This rule does not impose reporting, record keeping, and other compliance requirements except as described in section II.A.2.b New Drugs and Drugs with Patent Expirations and section II.A.4.b Average Sales Price. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule.

B. Impact of Approaches to Revising the Current Payment System

The proposed approach of basing our reform efforts on the comparability provision (Option 1) in the statute and issuing additional guidance to our contractors would result in decreases in Medicare expenditures for drugs of $4.1 billion over the ten-year period FY 2004 through 2013. The effect of implementing an average list AWP discount (Option 2) is dependent on the level of the discount. We are seeking comment on the appropriate discount in the range of 10 percent to 20 percent. At 10 percent, the impact of this proposal is $5.1 billion for FY 2004 through 2013. At 20 percent the impact is $14.3 billion for FY 2004 through 2013. The implementation of market monitoring (Option 3) is also dependent on the list AWP discount since the discount impacts the drugs that have not been studied by the OIG and GAO. At a 10 percent discount for the drugs that have not been studied, the impact of this proposal is $16.1 billion for FY 2004 through 2013. At 20 percent, the impact is $19.4 billion for FY 2004 through 2013. The proposed approach of basing our reform efforts on the establishment of a competitive acquisition program and Average Sales Price system (Option4) is dependent on the ASP markup. At a 1 percent markup the impact of this proposal for FY 2004 through 2013 is $13.5 billion excluding DME drugs and $27.6 billion including DME drugs. At a 12 percent markup the impact of this proposal for FY 2004 through 2013 is $7.6 billion excluding DME drugs and $21.2 billion including DME drugs.

C. Impact on Payments Related to Furnishing or Administering Drugs

We have simulated the impact of our proposed increase in payments for the costs of furnishing or administering drugs. Medicare payments for physician fee schedule services are estimated to increase by $1.6 billion over the ten-year period FY 2004 through 2013. For ESRD facility costs related to furnishing separately billable ESRD drugs, we would set payments budget neutral to the reductions in drug payments. For DME inhalation, DME home infusion, and oral drugs provided by pharmacies, we are seeking comment on the appropriateness of any changes to the payments for the administrative costs of furnishing these drugs.

D. Alternatives Considered

This proposed rule contains the four alternative approaches to reforming the current payment methodology that we considered, each of which has been discussed in detail. We are seeking comment on these approaches. We expect to select one of these approaches after reviewing all public comments received on the proposed rule and making any necessary modifications.

E. Impact on Beneficiaries

We have simulated the effect of changes in beneficiary copayments for drugs and related changes in beneficiary Part B premium payments resulting from the implementation of the four options for reforming the AWP system. The proposed approach of basing our reform efforts on the comparability provision in the statute and issuing additional guidance to our contractors would result in decreases in these payments by beneficiaries of $2.6 billion over the ten-year period FY 2004 through 2013. The effect on beneficiary payments resulting from the implementation of an average list AWP discount is dependent on the level of the discount. At 10 percent, the proposal will save beneficiaries $3.2 billion for FY 2004 through 2013. At 20 percent, the proposal will save beneficiaries $9.1 billion for FY 2004 through 2013. The implementation of market monitoring is also dependent on the list AWP discount since this impacts the drugs that have not been studied by the OIG and GAO. At a 10 percent discount for the drugs that have not been studied, the proposal will save beneficiaries $10.3 billion for FY 2004 through 2013. At 20 percent, the proposal will save beneficiaries $12.3 billion for FY 2004 through 2013. The proposed approach of basing our reform efforts on the establishment of a competitive acquisition program and Average Sales Price system is dependent on the ASP markup. At a 1 percent markup the proposal will save beneficiaries $8.6 billion excluding DME drugs and $17.6 billion including DME drugs. At a 12 percent markup this proposal will save beneficiaries $4.8 billion excluding DME drugs and $13.5 billion including DME drugs.

Beneficiaries will pay an additional $1.1 billion in copayments and related Part B premium increases as a result of the proposed changes to the Medicare physician fee schedule.

As described in section II.C, we do not believe that any beneficiaries will experience drug access issues as a result of our four proposed options. We intend to monitor beneficiary access closely and may propose additional changes to our payment system in the future if necessary.

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

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 27, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 13, 2003.

Tommy G. Thompson,

Secretary.

Addendum A

TABLE 1.—REPRINT OF ''TABLE 3: WIDELY AVAILABLE DISCOUNTS FROM AWP FOR MEDICARE-COVERED DRUGS BILLED PRIMARILY BY PHYSICIANS, 2001'' FROM THE GAO REPORT

Drug name	Specialty most frequently billing for drug	Average AWP [a]	Average widely available discount from AWP (percentage) [b]
Leuprolide acetate (for depot suspension)	urology	$618.93	17.6
Rituximab	oncology [c]	478.47	19.2
Goserelin acetate implant	urology	469.99	21.9
Docetaxel	oncology	313.51	22.0
Filgrastim (G–CSF) 480 mcg	oncology	300.40	[d] 18.0
Pamidronate disodium	oncology	279.86	16.8
Hylan G–F 20	orthopedic surgery	225.13	[d] 17.7
Filgrastim (G–CSF) 300mcg	oncology	193.62	[d] 18.4
Paclitaxel	oncology	180.57	19.0
Irinotecan	oncology	141.32	22.9
Carboplatin	oncology	120.48	20.3
Gemcitabine HCl	oncology	112.34	21.3
Dolasetron mesylate, injection	oncology	45.02	[d] 65.0
Granisetron HCl, injection	oncology	19.52	29.3
Leucovorin calcium	oncology	18.44	85.6
Epoetin alpha for non-ESRD use	oncology	12.91	15.2
Ondansetron HCl, injection	oncology	6.41	12.8
Botulinum toxin type A	neurology	4.86	[e] n/a
Imiglucerase	oncology	3.95	[e] n/a
Dexamethasone sodium phosphate	oncology	1.44	14.2
Heparin sodium	oncology	0.43	34.4

Source: GAO Report ''Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost'' (GAO–01–1118)

[a] ''Average AWP'' is the average of AWP of each NDC for that product adjusted to the HCPCS-defined dosage.

[b] ''Average widely available discount from AWP'' for each drug was calculated by (1) determining the average widely available price(s) for each NDC for that drug, (2) determining the percentage difference between the average widely available price(s) and the AWP for each NDC for that drug, and (3) averaging the percentage differences for all NDCs for that drug.

[c] ''Oncology'' specialty includes hematology/oncology and medical oncology.

[d] ''Average widely available discount from AWP'' in 2001 for this drug is based on a price or prices from a single wholesaler. For these four drugs, we had 2000 data from two or more sources. Those data showed that the average widely available discount from AWP in 2000 was 18.8 percent for Filgrastim (G–CSF) 480 mcg, 17.6 percent for Hylan G–F 20, 19.0 percent for Filgrastim (G–CSF) 300mcg, and 42.2 percent for Dolasetron mesylate, injection.

[e] We (GAO) were unable to obtain wholesaler or GPO prices for these products.

Source: GAO analysis of data from BESS, the Medical Economics Drug Topics Red Book CD–ROM vol. 21, and wholesaler and GPO price lists.

TABLE 2.—REPRINT OF ''TABLE 4: DISCOUNTS FROM AWP OBTAINED BY PHYSICIANS WHO BILLED MEDICARE FOR A LOW VOLUME OF SELECTED DRUGS, COMPARED TO WIDELY AVAILABLE DISCOUNTS, 2001'' FROM THE GAO REPORT

Drug name	Low volume billers' average discount from AWP (percentage)	Average widely available discount from AWP [a] (percentage)
Leuprolide acetate (for depot suspension)	32.8	17.6
Rituximab	15.7	19.2
Goserelin acetate implant	[b] 22.3	21.9
Docetaxel	22.0	22.0
Filgrastim (G–CSF) (480 mcg)	22.4	[c] 18.0
Pamidronate disodium	18.0	16.8
Filgrastim (G–CSF) (300mcg)	21.7	[c] 18.4
Paclitaxel	25.8	19.0
Irinotecan	27.1	22.9
Carboplatin	[b] 20.0	20.3
Gemcitabine HCl	16.1	21.3
Dolasetron mesylate, injection	62.0	[c] 65.0
Granisetron HCl, injection	28.1	29.3
Leucovorin calcium	90.4	85.6
Epoetin alpha for non-ESRD use	22.1	15.2
Ondansetron HCl, injection	26.4	12.8

Source: GAO Report ''Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost'' (GAO–01–1118)

[a] ''Average widely available discount from AWP'' for each drug was calculated by (1) determining the average widely available price(s) for each NDC for that drug, (2) determining the percentage difference between the average widely available price(s) and the AWP for each NDC for that drug, and (3) averaging the percentage differences for all NDCs for that drug.

[b] ''Low-volume billers' average discount from AWP'' for this drug is based on a price from a single physician.

[c] ''Average widely available discount from AWP'' for this drug is based on a price or prices from a single wholesaler.

Notes: Out of our sample of 108 physicians, 14 provided us with acquisition cost data for 16 of the 18 cancer treatment drugs we examined. An additional 37 physicians belonged to large, hospital-based or national chain oncology practices that likely had access to widely available drug price discounts. Fifty-six physicians could not be contacted or refused to participate. One physician in the sample did not purchase drugs.

Source: GAO telephone survey of a sample of physicians who billed Medicare for a low volume of cancer drugs in 1999 and AWPs listed in a contemporaneous wholesaler catalog.

TABLE 3.—MEDICARE PART B DRUGS IN THE MOST RECENT GAO AND OIG STUDIES

Brand drugs [c]	HCPCS	Medicare allowed charges (CY '02, run thru 2/03)	Rank in terms of medicare allowed charges across all part B drugs	GAO average widely available price as a percent of AWP [a] (2001)	OIG median catalogue price as a percent of AWP [b] (2000)	Average of GAO and OIG data (percent)	"Spread" [j] (percent)
EPOETIN ALFA (PROCRIT)	Q0136	$928	1	85	89	87	8
LEUPROLIDE ACETATE (LUPRON)	J9217	627	2	82	80	81	15
GOSERELIN ACETATE (ZOLADEX)	J9202	441	4	78	80	79	17
RITUXIMAB (RITUXAN)	J9310	377	6	81	80	81	15
PACLITAXEL [c] (TAXOL)	J9265	226	9	81	80	81	15
DOCETAXEL (TAXOTERE)	J9170	221	10	78	80	79	17
CARBOPLATIN (PARAPLATIN)	J9045	189	11	80	82	81	15
IRINOTECAN (CAMPTOSAR)	J9206	170	12	77	80	79	17
GEMCITABINE HCL (GEMZAR)	J9201	159	13	79	80	80	16
PAMIDRONATE DISODIUM [c] (AREDIA)	J2430	126	14	83	87	85	11
DOLASETRON MESYLATE (ANZEMET)	J1260	125	15	[d] 58	[d] 53	56	41
FILGRASTIM (NEUPOGEN) 480mcg	J1441	99	17	[d] 81	[d] 80	81	15
HYLAN G–F 20 (SYNVISC)	J7320	93	18	[d] 82	.....	[f] 82	14
MYCOPHENOLATE MOFETIL (CELLCEPT)	J7517	64	20	[e] 86	.....	86	9
FILGRASTIM (NEUPOGEN) 300mcg	J1440	53	26	[d] 81	[d] 80	81	15
GRANISETRON HCL (KYTRIL)	J1626	47	28	71	71	71	25
ONDANSETRON (ZOFRAN)	J2405	45	29	87	86	87	8
VINORELBINE TARTATE [c] (NAVELBINE)	J9390	38	33	81	[g] 81	15	
SARGRAMOSTIM (LEUKINE)	J2820	35	35	80	.....	[g] 80	16
TOPOTECAN (HYCAMTIM)	J9350	34	36	.....	84	[g] 84	12
Generic Drugs							
IPRATROPIUM BROMIDE	J7644	550	3	[d] 33	[(d)(i)] 34	34	64
ALBUTEROL SULFATE	J7619	381	5	15	[(i)] 18	17	82
IMMUNE GLOBULIN [h]	J1561 J1563	105	.....	.....	72	[g] 72	24
LEUCOVORIN CALCIUM	J0640	61	22	14	15	15	84
DOXORUBICIN HCL	J9000	29	41	.....	22	[g] 22	77
DEXAMETHOSONE SODIUM PHOSPHATE	J1100	3	104	86	.....	[f] 86	9
HEPARIN SODIUM LOCK-FLUSH	J1642	3	105	66	[f] 66	.....	31
CROMOLYN SODIUM	J7631	3	106	31	[f] 31	67	
ACETYLCYSTEINE	J7608	2	129	[e] 28	64	46	52

Sources: GAO, "Medicare Payments for Covered Outpatient Drugs Exceed Providers' Costs," September 2001. OIG, "Medicare Reimbursement of Prescription Drugs," January 2001. OIG, "Excessive Medicare Reimbursement for Albuterol," March 2002. OIG, "Excessive Medicare Reimbursement for Ipratromium Bromide," March 2002.

[a] GAO estimated the average widely available discount from AWP. We converted that figure into the average widely available price as percent of AWP by subtracting the GAO average widely available discount from 100 percent.

[b] The OIG studies report the median Medicare payment amount and the median catalogue price for each HCPCS code. Based on the OIG data, we divided the OIG Medicare payment amount by 95 percent to estimate AWP and then divided the median catalogue price by the estimated AWP.

[c] PACLITAXEL and PAMIDRONATE DISODIUM became generic drugs in 2002 and VINORELBINE TARTATE became generic in 2003, however, the pricing information in the GAO and OIG studies covers the time period when they were brand drugs only.

[d] For these drugs, GAO only had data from 1 wholesaler in 2001, but had data from 2 or more sources in 2000. The widely available price as a % of AWP shown above for these drugs is the 2000 estimate. The figures for 2000 and 2001, respectively, were: DOLASETRON MESYLATE (58% and 35%), FILGRASTIM 480mcg (81% and 82%), HYLAN G–F 20 (82% and 82%) FILGRASTIM 300mcg (81% and 82%), and IPRATROPIUM BROMIDE (33% and 22%).

[e] GAO data are for 2000.

[f] Only based on GAO data.

[g] Only based on OIG data.

[h] Immune globulin was included in the generic category because it is a multisource biologic. OIG collected data on Immune Globulin HCPCs J1562. That Jcode is no longer in use and now corresponds to Jcodes 1561 and 1563.

[i] The price estimates based on OIG data for ALBUTEROL AND IPRATROPIUM BROMIDE include more than just catalogue prices. OIG conducted special studies on these two drugs in 2002. The studies provided data on the median Medicare payment amount in 2001, the median wholesale catalogue price in 2001, the median invoice price (data gathered by OIG reflecting the time period 1998—August 2000), and the median wholesale acquisition cost reported in the April 2001 Drug Topics Redbook. For these 2 drugs, we calculated the median price across OIG's three data sources, and then divided it by our estimate of AWP (OIG's Medicare median payment amount divided by 95%).

[j] The "spread" is the percent difference between the Medicare reimbursement price (*i.e.*, 95 percent of AWP) and the average GAO/OIG widely available/catalogue price.

[k] Top 20 w/combined Jcodes.

TABLE 4.—SUMMARY OF OIG REPORTS ON MEDICARE PRESCRIPTION DRUGS

Year of Report	1997	1998	2000			2001		2002
Drugs reviewed	22 drugs	34 drugs	5 ESRD drugs	Albuterol	24 drugs	Albuterol	24 drugs	Ipratropium Bromide
Year Reviewed	1996	1997	1998	1999	1999	2000	2000	2000
Medicare Expenditures for Reviewed Drugs	[3] $1.5	[3] $2.1	[4] $379	[4] $246	[3] $3.1	[4] $296	[3] $3.7	[4] $348
Excessive Payments Based On:								
VA	.....	[3] $1	[4] $162	[4] $209	[3] $1.6	[4] $264	[3] $1.9	[4] $279
Catalogs	[4] $447	.....	.....	.....	[4] $761	[4] $245	[4] $887	[4] $262
Medicaid	.....	.....	[4] $42	[4] $120	[4] $425	.....	.....	.....
Beneficiary Share of Excessive Payments:								
VA	.....	.....	[4] $32	[4] $42	[4] $320	[4] $53	[4] $380	[4] $56
Catalogs	[4] $89	[4] $200	.....	.....	[4] $152	[4] $49	[4] $177	[4] $52

TABLE 4.—SUMMARY OF OIG REPORTS ON MEDICARE PRESCRIPTION DRUGS—Continued

Year of Report	1997	1998	2000			2001		2002
Drugs reviewed	22 drugs	34 drugs	5 ESRD drugs	Albuterol	24 drugs	Albuterol	24 drugs	Ipratropium Bromide
Medicaid	.....	.....	[4]$8	[4]$24	[4]$85	.....	.....	

Sources:
[1] OIG, ''Testimony of George F. Grob, Deputy Inspector General for Evaluation and Inspections, HHS Office of Inspector General,'' House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations and Subcommittee on Health, Joint Hearing September 21, 2001.
[2] OIG, ''Excessive Reimbursement for Ipratropium Bromide,'' Report Number: OEI–03–01–00411, March 2002.
[3] Billion.
[4] Million.

LIST OF MEDICARE DRUG HCPCS CODES

HCPCS*	Description
90371	HEPATITIS B IG, IM
90375	RABIES IG, IM/SC
90376	RABIES IG, HEAT TREATED
90379	RESPIRATORY SYNCYTIAL VIRUS IG, IV
90385	RHO(D) IG (RHLG), MINIDOSE, IM
90389	TETANUS IG, IM
90585	BACILLUS CALMETTE-GUERIN VACCINE, PERCUTANEOUS
90632	HEPATITIS A VACCINE, ADULT IM
90633	HEPATITIS A VACCINE, PED/ADOL, 2 DOSE
90634	HEPATITIS A VACCINE, PED/ADOL, 3 DOSE
90645	HEMOPHILUS INFLUENZA B VACCINE, HBOC, IM
90675	RABIES VACCINE, IM
90691	TYPHOID VACCINE, IM
90700	DIPTHERIA, TETANUS TOXOIDS VACCINE, IM
90703	TETANUS VACCINE, IM
90704	MUMPS VACCINE, SC
90705	MEASLES VACCINE, SC
90706	RUBELLA VACCINE, SC
90707	MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, SC
90713	POLIOVIRUS VACCINE, IPV, SC
90716	CHICKEN POX VACCINE, SC
90717	YELLOW FEVER VACCINE, SC
90718	TETANUS AND DIPTHERIA TOXOIDS VACCINE > 7, IM
90721	DIPTHERIA, TETANUS TOXOIDS, & ACELLULAR PERTUSSIS VACCINE & HEMOPHILUS INFLUENZA B VACCINE, IM
90733	MENINGOCOCCAL VACCINE, SC
90740	HEPATITIS B VACCINE, DIALYSIS OR IMMUNOSUPPRESSED PATIENT, 3 DOSE, IM
90743	HEPATITIS B VACCINE, ADOL, 2 DOSE, IM
90744	HEPATITIS B VACCINE, PED/ADOL 3 DOSE, IM
90746	HEPATITIS B VACCINE, ADULT, IM
90747	HEPATITIS B VACCINE, DIALYSIS OR IMMUNOSUPPRESSED PATIENT, 4 DOSE, IM
J0130	INJECTION, ABCIXIMAB, 10 MG
J0150	INJECTION, ADENOSINE, 6 MG (NOT TO BE USED TO REPORT ANY ADENOSINE PHOSPHATE)
J0151	INJECTION, ADENOSINE, 90 MG (NOT TO BE USED TO REPORT ANY ADENOSINE PHOSPHATE)
J0170	INJECTION, ADRENALIN, EPINEPHRINE, UP TO 1 ML AMPULE
J0200	INJECTION, ALATROFLOXACIN MESYLATE, 100 MG
J0205	INJECTION, ALGLUCERASE, PER 10 UNITS
J0207	INJECTION, AMIFOSTINE, 500 MG
J0210	INJECTION, METHYLDOPATE HCL, UP TO 250 MG
J0256	INJECTION, ALPHA 1-PROTEINASE INHIBITOR—HUMAN, 10 MG
J0280	INJECTION, AMINOPHYLLIN, UP TO 250 MG
J0282	INJECTION, AMIODARONE HYDROCHLORIDE, 30 MG
J0285	INJECTION, AMPHOTERICIN B, 50 MG
J0287	INJECTION, AMPHOTERICIN B LIPID COMPLEX, 10 MG
J0288	INJECTION, AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX, 10 MG
J0289	INJECTION, AMPHOTERICIN B LIPOSOME, 10 MG
J0290	INJECTION, AMPICILLIN SODIUM, 500 MG
J0295	INJECTION, AMPICILLIN SODIUM/SULBACTAM SODIUM, PER 1.5 GM
J0300	INJECTION, AMOBARBITAL, UP TO 125 MG
J0330	INJECTION, SUCCINYLCHOLINE CHLORIDE, UP TO 20 MG
J0360	INJECTION, HYDRALAZINE HCL, UP TO 20 MG
J0380	INJECTION, METARAMINOL BITARTRATE, PER 10 MG
J0390	INJECTION, CHLOROQUINE HYDROCHLORIDE, UP TO 250 MG
J0395	INJECTION, ARBUTAMINE HCL, 1 MG
J0456	INJECTION, AZITHROMYCIN, 500 MG
J0460	INJECTION, ATROPINE SULFATE, UP TO 0.3 MG
J0470	INJECTION, DIMERCAPROL, PER 100 MG
J0475	INJECTION, BACLOFEN, 10 MG
J0476	INJECTION, BACLOFEN, 50 MCG FOR INTRATHECAL TRIAL
J0500	INJECTION, DICYCLOMINE HCL, UP TO 20 MG
J0515	INJECTION, BENZTROPINE MESYLATE, PER 1 MG
J0520	INJECTION, BETHANECHOL CHLORIDE, MYOTONACHOL OR URECHOLINE, UP TO 5 MG
J0530	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, UP TO 600,000
J0540	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, UP TO 1,200,000

LIST OF MEDICARE DRUG HCPCS CODES—Continued

HCPCS*	Description
J0550	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, UP TO 2,400,000
J0560	INJECTION, PENICILLIN G BENZATHINE, UP TO 600,000 UNITS
J0570	INJECTION, PENICILLIN G BENZATHINE, UP TO 1,200,000 UNITS
J0580	INJECTION, PENICILLIN G BENZATHINE, UP TO 2,400,000 UNITS
J0585	BOTULINUM TOXIN TYPE A, PER UNIT
J0587	BOTULINUM TOXIN TYPE B, PER 100 UNITS
J0592	INJECTION, BUPRENORPHINE HYDROCHLORIDE, 0.1 MG
J0600	INJECTION, EDETATE CALCIUM DISODIUM, UP TO 1000 MG
J0610	INJECTION, CALCIUM GLUCONATE, PER 10 ML
J0620	INJECTION, CALCIUM GLYCEROPHOSPHATE AND CALCIUM LACTATE, PER 10 ML
J0630	INJECTION, CALCITONIN SALMON, UP TO 400 UNITS
J0636	INJECTION, CALCITRIOL, 0.1 MCG
J0637	INJECTION, CASPOFUNGIN ACETATE, 5 MG
J0640	INJECTION, LEUCOVORIN CALCIUM, PER 50 MG
J0670	INJECTION, MEPIVACAINE HYDROCHLORIDE, PER 10 ML
J0690	INJECTION, CEFAZOLIN SODIUM, 500 MG
J0692	INJECTION, CEFEPIME HYDROCHLORIDE, 500 MG
J0694	INJECTION, CEFOXITIN SODIUM, 1 GM
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG
J0697	INJECTION, STERILE CEFUROXIME SODIUM, PER 750 MG
J0698	INJECTION, CEFOTAXIME SODIUM, PER GM
J0702	INJECTION, BETAMETHASONE ACETATE AND BETAMETHASONE SODIUM PHOSPHATE, PER 3 MG
J0704	INJECTION, BETAMETHASONE SODIUM PHOSPHATE, PER 4 MG
J0706	INJECTION, CAFFEINE CITRATE, 5MG
J0713	INJECTION, CEFTAZIDIME, PER 500 MG
J0715	INJECTION, CEFTIZOXIME SODIUM, PER 500 MG
J0720	INJECTION, CHLORAMPHENICOL SODIUM SUCCINATE, UP TO 1 GM
J0725	INJECTION, CHORIONIC GONADOTROPIN, PER 1,000 USP UNITS
J0735	INJECTION, CLONIDINE HYDROCHLORIDE, 1 MG
J0740	INJECTION, CIDOFOVIR, 375 MG
J0743	INJECTION, CILASTATIN SODIUM; IMIPENEM, PER 250 MG
J0744	INJECTION, CIPROFLOXACIN FOR INTRAVENOUS INFUSION, 200 MG
J0745	INJECTION, CODEINE PHOSPHATE, PER 30 MG
J0760	INJECTION, COLCHICINE, PER 1 MG
J0770	INJECTION, COLISTIMETHATE SODIUM, UP TO 150 MG
J0780	INJECTION, PROCHLORPERAZINE, UP TO 10 MG
J0800	INJECTION, CORTICOTROPIN, UP TO 40 UNITS
J0835	INJECTION, COSYNTROPIN, PER 0.25 MG
J0850	INJECTION, CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN), PER VIAL
J0880	INJECTION, DARBEPOETIN ALFA, 5 MCG
J0895	INJECTION, DEFEROXAMINE MESYLATE, 500 MG
J0900	INJECTION, TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE, UP TO 1 CC
J0945	INJECTION, BROMPHENIRAMINE MALEATE, PER 10 MG
J0970	INJECTION, ESTRADIOL VALERATE, UP TO 40 MG
J1000	INJECTION, DEPO-ESTRADIOL CYPIONATE, UP TO 5 MG
J1020	INJECTION, METHYLPREDNISOLONE ACETATE, 20 MG
J1030	INJECTION, METHYLPREDNISOLONE ACETATE, 40 MG
J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG
J1051	INJECTION, MEDROXYPROGESTERONE ACETATE, 50 MG
J1056	INJECTION, MEDROXYPROGESTERONE ACETATE/ESTRADIOL CYPIONATE, 5MG/25MG
J1060	INJECTION, TESTOSTERONE CYPIONATE AND ESTRADIOL CYPIONATE, UP TO 1 ML
J1070	INJECTION, TESTOSTERONE CYPIONATE, UP TO 100 MG
J1080	INJECTION, TESTOSTERONE CYPIONATE, 1 CC, 200 MG
J1094	INJECTION, DEXAMETHASONE ACETATE, 1 MG
J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG
J1110	INJECTION, DIHYDROERGOTAMINE MESYLATE, PER 1 MG
J1120	INJECTION, ACETAZOLAMIDE SODIUM, UP TO 500 MG
J1160	INJECTION, DIGOXIN, UP TO 0.5 MG
J1165	INJECTION, PHENYTOIN SODIUM, PER 50 MG
J1170	INJECTION, HYDROMORPHONE, UP TO 4 MG
J1180	INJECTION, DYPHYLLINE, UP TO 500 MG
J1190	INJECTION, DEXRAZOXANE HYDROCHLORIDE, PER 250 MG
J1200	INJECTION, DIPHENHYDRAMINE HCL, UP TO 50 MG
J1205	INJECTION, CHLOROTHIAZIDE SODIUM, PER 500 MG
J1212	INJECTION, DMSO, DIMETHYL SULFOXIDE, 50 percent, 50 ML
J1230	INJECTION, METHADONE HCL, UP TO 10 MG
J1240	INJECTION, DIMENHYDRINATE, UP TO 50 MG
J1245	INJECTION, DIPYRIDAMOLE, PER 10 MG
J1250	INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG
J1260	INJECTION, DOLASETRON MESYLATE, 10 MG
J1270	INJECTION, DOXERCALCIFEROL, 1 MCG
J1320	INJECTION, AMITRIPTYLINE HCL, UP TO 20 MG
J1325	INJECTION, EPOPROSTENOL, 0.5 MG
J1327	INJECTION, EPTIFIBATIDE, 5 MG
J1364	INJECTION, ERYTHROMYCIN LACTOBIONATE, PER 500 MG
J1380	INJECTION, ESTRADIOL VALERATE, UP TO 10 MG
J1390	INJECTION, ESTRADIOL VALERATE, UP TO 20 MG
J1410	INJECTION, ESTROGEN CONJUGATED, PER 25 MG
J1435	INJECTION, ESTRONE, PER 1 MG
J1436	INJECTION, ETIDRONATE DISODIUM, PER 300 MG
J1438	INJECTION, ETANERCEPT, 25 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG

LIST OF MEDICARE DRUG HCPCS CODES—Continued

HCPCS*	Description
J1440	INJECTION, FILGRASTIM (G–CSF), 300 MCG
J1441	INJECTION, FILGRASTIM (G–CSF), 480 MCG
J1450	INJECTION FLUCONAZOLE, 200 MG
J1452	INJECTION, FOMIVIRSEN SODIUM, INTRAOCULAR, 1.65 MG
J1455	INJECTION, FOSCARNET SODIUM, PER 1000 MG
J1460	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 1 CC
J1470	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 2 CC
J1480	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 3 CC
J1490	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 4 CC
J1500	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 5 CC
J1510	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 6 CC
J1520	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 7 CC
J1530	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 8 CC
J1540	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 9 CC
J1550	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 10 CC
J1563	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, 1G
J1564	INJECTION, IMMUNE GLOBULIN, 10 MG
J1565	INJECTION, RESPIRATORY SYNCYTIAL VIRUS IMMUNE GLOBULIN, INTRAVENOUS, 50 MG
J1570	INJECTION, GANCICLOVIR SODIUM, 500 MG
J1580	INJECTION, GARAMYCIN, GENTAMICIN, UP TO 80 MG
J1590	INJECTION, GATIFLOXACIN, 10MG
J1600	INJECTION, GOLD SODIUM THIOMALATE, UP TO 50 MG
J1610	INJECTION, GLUCAGON HYDROCHLORIDE, PER 1 MG
J1620	INJECTION, GONADORELIN HYDROCHLORIDE, PER 100 MCG
J1626	INJECTION, GRANISETRON HYDROCHLORIDE, 100 MCG
J1630	INJECTION, HALOPERIDOL, UP TO 5 MG
J1631	INJECTION, HALOPERIDOL DECANOATE, PER 50 MG
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS
J1645	INJECTION, DALTEPARIN SODIUM, PER 2500 IU
J1650	INJECTION, ENOXAPARIN SODIUM, 10 MG
J1652	INJECTION, FONDAPARINUX SODIUM, 0.5 MG
J1655	INJECTION, TINZAPARIN SODIUM, 1000 IU
J1670	INJECTION, TETANUS IMMUNE GLOBULIN, HUMAN, UP TO 250 UNITS
J1700	INJECTION, HYDROCORTISONE ACETATE, UP TO 25 MG
J1710	INJECTION, HYDROCORTISONE SODIUM PHOSPHATE, UP TO 50 MG
J1720	INJECTION, HYDROCORTISONE SODIUM SUCCINATE, UP TO 100 MG
J1730	INJECTION, DIAZOXIDE, UP TO 300 MG
J1742	INJECTION, IBUTILIDE FUMARATE, 1 MG
J1745	INJECTION, INFLIXIMAB, 10 MG
J1750	INJECTION, IRON DEXTRAN, 50 MG
J1756	INJECTION, IRON SUCROSE, 1 MG
J1785	INJECTION, IMIGLUCERASE, PER UNIT
J1790	INJECTION, DROPERIDOL, UP TO 5 MG
J1800	INJECTION, PROPRANOLOL HCL, UP TO 1 MG
J1810	INJECTION, DROPERIDOL AND FENTANYL CITRATE, UP TO 2 ML AMPULE
J1815	INJECTION, INSULIN, PER 5 UNITS
J1835	INJECTION, ITRACONAZOLE, 50 MG
J1840	INJECTION, KANAMYCIN SULFATE, UP TO 500 MG
J1850	INJECTION, KANAMYCIN SULFATE, UP TO 75 MG
J1885	INJECTION, KETOROLAC TROMETHAMINE, PER 15 MG
J1890	INJECTION, CEPHALOTHIN SODIUM, UP TO 1 GRAM
J1910	INJECTION, KUTAPRESSIN, UP TO 2 ML
J1940	INJECTION, FUROSEMIDE, UP TO 20 MG
J1950	INJECTION, LEUPROLIDE ACETATE (FOR DEPOT SUSPENSION), PER 3.75 MG
J1955	INJECTION, LEVOCARNITINE, PER 1 GM
J1956	INJECTION, LEVOFLOXACIN, 250 MG
J1960	INJECTION, LEVORPHANOL TARTRATE, UP TO 2 MG
J1980	INJECTION, HYOSCYAMINE SULFATE, UP TO 0.25 MG
J1990	INJECTION, CHLORDIAZEPOXIDE HCL, UP TO 100 MG
J2000	INJECTION, LIDOCAINE HCL, 50 CC
J2010	INJECTION, LINCOMYCIN HCL, UP TO 300 MG
J2020	INJECTION, LINEZOLID, 200MG
J2060	INJECTION, LORAZEPAM, 2 MG
J2150	INJECTION, MANNITOL, 25 percent IN 50 ML
J2175	INJECTION, MEPERIDINE HYDROCHLORIDE, PER 100 MG
J2180	INJECTION, MEPERIDINE AND PROMETHAZINE HCL, UP TO 50 MG
J2210	INJECTION, METHYLERGONOVINE MALEATE, UP TO 0.2 MG
J2250	INJECTION, MIDAZOLAM HYDROCHLORIDE, PER 1 MG
J2260	INJECTION, MILRINONE LACTATE, 5 MG
J2270	INJECTION, MORPHINE SULFATE, UP TO 10 MG
J2271	INJECTION, MORPHINE SULFATE, 100MG
J2275	INJECTION, MORPHINE SULFATE (PRESERVATIVE-FREE STERILE SOLUTION), PER 10 MG
J2300	INJECTION, NALBUPHINE HYDROCHLORIDE, PER 10 MG
J2310	INJECTION, NALOXONE HYDROCHLORIDE, PER 1 MG
J2320	INJECTION, NANDROLONE DECANOATE, UP TO 50 MG
J2321	INJECTION, NANDROLONE DECANOATE, UP TO 100 MG
J2322	INJECTION, NANDROLONE DECANOATE, UP TO 200 MG
J2324	INJECTION, NESIRITIDE, 0.5 MG
J2355	INJECTION, OPRELVEKIN, 5 MG
J2360	INJECTION, ORPHENADRINE CITRATE, UP TO 60 MG

LIST OF MEDICARE DRUG HCPCS CODES—Continued

HCPCS*	Description
J2370	INJECTION, PHENYLEPHRINE HCL, UP TO 1 ML
J2400	INJECTION, CHLOROPROCAINE HYDROCHLORIDE, PER 30 ML
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG
J2410	INJECTION, OXYMORPHONE HCL, UP TO 1 MG
J2430	INJECTION, PAMIDRONATE DISODIUM, PER 30 MG
J2440	INJECTION, PAPAVERINE HCL, UP TO 60 MG
J2460	INJECTION, OXYTETRACYCLINE HCL, UP TO 50 MG
J2501	INJECTION, PARICALCITOL, 1 MCG
J2510	INJECTION, PENICILLIN G PROCAINE, AQUEOUS, UP TO 600,000 UNITS
J2515	INJECTION, PENTOBARBITAL SODIUM, PER 50 MG
J2540	INJECTION, PENICILLIN G POTASSIUM, UP TO 600,000 UNITS
J2543	INJECTION, PIPERACILLIN SODIUM/TAZOBACTAM SODIUM, 1 GRAM/0.125 GRAMS (1.125)
J2545	PENTAMIDINE ISETHIONATE, INHALATION SOLUTION, PER 300 MG, ADMINISTERED THROUGH
J2550	INJECTION, PROMETHAZINE HCL, UP TO 50 MG
J2560	INJECTION, PHENOBARBITAL SODIUM, UP TO 120 MG
J2590	INJECTION, OXYTOCIN, UP TO 10 UNITS
J2597	INJECTION, DESMOPRESSIN ACETATE, PER 1 MCG
J2650	INJECTION, PREDNISOLONE ACETATE, UP TO 1 ML
J2670	INJECTION, TOLAZOLINE HCL, UP TO 25 MG
J2675	INJECTION, PROGESTERONE, PER 50 MG
J2680	INJECTION, FLUPHENAZINE DECANOATE, UP TO 25 MG
J2690	INJECTION, PROCAINAMIDE HCL, UP TO 1 GM
J2700	INJECTION, OXACILLIN SODIUM, UP TO 250 MG
J2710	INJECTION, NEOSTIGMINE METHYLSULFATE, UP TO 0.5 MG
J2720	INJECTION, PROTAMINE SULFATE, PER 10 MG
J2725	INJECTION, PROTIRELIN, PER 250 MCG
J2730	INJECTION, PRALIDOXIME CHLORIDE, UP TO 1 GM
J2760	INJECTION, PHENTOLAMINE MESYLATE, UP TO 5 MG
J2765	INJECTION, METOCLOPRAMIDE HCL, UP TO 10 MG
J2770	INJECTION, QUINUPRISTIN/DALFOPRISTIN, 500 MG (150/350)
J2780	INJECTION, RANITIDINE HYDROCHLORIDE, 25 MG
J2788	INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, MINIDOSE, 50 MCG
J2790	INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, FULL DOSE, 300 MCG
J2792	INJECTION, RHO D IMMUNE GLOBULIN, INTRAVENOUS, HUMAN, SOLVENT DETERGENT, 100 IU
J2795	INJECTION, ROPIVACAINE HYDROCHLORIDE, 1 MG
J2800	INJECTION, METHOCARBAMOL, UP TO 10 ML
J2820	INJECTION, SARGRAMOSTIM (GM-CSF), 50 MCG
J2910	INJECTION, AUROTHIOGLUCOSE, UP TO 50 MG
J2912	INJECTION, SODIUM CHLORIDE, 0.9 percent, PER 2 ML
J2916	INJECTION, SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE INJECTION, 12.5 MG
J2920	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 40 MG
J2930	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 125 MG
J2940	INJECTION, SOMATREM, 1 MG
J2941	INJECTION, SOMATROPIN, 1 MG
J2950	INJECTION, PROMAZINE HCL, UP TO 25 MG
J2993	INJECTION, RETEPLASE, 18.1 MG
J2995	INJECTION, STREPTOKINASE, PER 250,000 IU
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG
J3000	INJECTION, STREPTOMYCIN, UP TO 1 GM
J3010	INJECTION, FENTANYL CITRATE, 0.1 MG
J3030	INJECTION, SUMATRIPTAN SUCCINATE, 6 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG)
J3070	INJECTION, PENTAZOCINE, 30 MG
J3100	INJECTION, TENECTEPLASE, 50MG
J3105	INJECTION, TERBUTALINE SULFATE, UP TO 1 MG
J3120	INJECTION, TESTOSTERONE ENANTHATE, UP TO 100 MG
J3130	INJECTION, TESTOSTERONE ENANTHATE, UP TO 200 MG
J3140	INJECTION, TESTOSTERONE SUSPENSION, UP TO 50 MG
J3150	INJECTION, TESTOSTERONE PROPIONATE, UP TO 100 MG
J3230	INJECTION, CHLORPROMAZINE HCL, UP TO 50 MG
J3240	INJECTION, THYROTROPIN ALPHA, 0.9 MG, PROVIDED IN 1.1 MG VIAL
J3245	INJECTION, TIROFIBAN HYDROCHLORIDE, 12.5 MG
J3250	INJECTION, TRIMETHOBENZAMIDE HCL, UP TO 200 MG
J3260	INJECTION, TOBRAMYCIN SULFATE, UP TO 80 MG
J3265	INJECTION, TORSEMIDE, 10 MG/ML
J3280	INJECTION, THIETHYLPERAZINE MALEATE, UP TO 10 MG
J3301	INJECTION, TRIAMCINOLONE ACETONIDE, PER 10 MG
J3302	INJECTION, TRIAMCINOLONE DIACETATE, PER 5 MG
J3303	INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5 MG
J3305	INJECTION, TRIMETREXATE GLUCURONATE, PER 25 MG
J3315	INJECTION, TRIPTORELIN PAMOATE, 3.75 MG
J3320	INJECTION, SPECTINOMYCIN DIHYDROCHLORIDE, UP TO 2 GM
J3360	INJECTION, DIAZEPAM, UP TO 5 MG
J3364	INJECTION, UROKINASE, 5000 I.U. VIAL
J3365	INJECTION, IV, UROKINASE, 250,000 I.U. VIAL
J3370	INJECTION, VANCOMYCIN HCL, 500 MG
J3395	INJECTION, VERTEPORFIN, 15 MG
J3410	INJECTION, HYDROXYZINE HCL, UP TO 25 MG
J3420	INJECTION, VITAMIN B–12 CYANOCOBALAMIN, UP TO 1000 MCG
J3430	INJECTION, PHYTONADIONE (VITAMIN K), PER 1 MG
J3475	INJECTION, MAGNESIUM SULFATE, PER 500 MG
J3480	INJECTION, POTASSIUM CHLORIDE, PER 2 MEQ

LIST OF MEDICARE DRUG HCPCS CODES—Continued

HCPCS*	Description
J3485	INJECTION, ZIDOVUDINE, 10 MG
J3487	INJECTION, ZOLEDRONIC ACID, 1 MG
J7030	INFUSION, NORMAL SALINE SOLUTION , 1000 CC
J7040	INFUSION, NORMAL SALINE SOLUTION, STERILE (500 ML=1 UNIT)
J7042	5 percent DEXTROSE/NORMAL SALINE (500 ML = 1 UNIT)
J7050	INFUSION, NORMAL SALINE SOLUTION, 250 CC
J7051	STERILE SALINE OR WATER, UP TO 5 CC
J7060	5 percent DEXTROSE/WATER (500 ML = 1 UNIT)
J7070	INFUSION, D5W, 1000 CC
J7100	INFUSION, DEXTRAN 40, 500 ML
J7110	INFUSION, DEXTRAN 75, 500 ML
J7120	RINGERS LACTATE INFUSION, UP TO 1000 CC
J7130	HYPERTONIC SALINE SOLUTION, 50 OR 100 MEQ, 20 CC VIAL
J7190	FACTOR VIII (ANTIHEMOPHILIC FACTOR, HUMAN) PER I.U.
J7191	FACTOR VIII (ANTIHEMOPHILIC FACTOR (PORCINE)), PER I.U.
J7192	FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U.
J7193	FACTOR IX (ANTIHEMOPHILIC FACTOR, PURIFIED, NON-RECOMBINANT) PER I.U.
J7194	FACTOR IX, COMPLEX, PER I.U.
J7195	FACTOR IX (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U.
J7197	ANTITHROMBIN III (HUMAN), PER I.U.
J7198	ANTI-INHIBITOR, PER I.U.
J7310	GANCICLOVIR, 4.5 MG, LONG-ACTING IMPLANT
J7317	SODIUM HYALURONATE, PER 20 TO 25 MG DOSE FOR INTRA-ARTICULAR INJECTION
J7320	HYLAN G–F 20, 16 MG, FOR INTRA ARTICULAR INJECTION
J7330	AUTOLOGOUS CULTURED CHONDROCYTES, IMPLANT
J7340	DERMAL AND EPIDERMAL TISSUE OF HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR
J7342	DERMAL TISSUE, OF HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR
J7500	AZATHIOPRINE, ORAL, 50 MG
J7501	AZATHIOPRINE, PARENTERAL, 100 MG
J7502	CYCLOSPORINE, ORAL, 100 MG
J7504	LYMPHOCYTE IMMUNE GLOBULIN, ANTITHYMOCYTE GLOBULIN, EQUINE, PARENTERAL, 250 MG
J7505	MUROMONAB–CD3, PARENTERAL, 5 MG
J7506	PREDNISONE, ORAL, PER 5 MG
J7507	TACROLIMUS, ORAL, PER 1 MG
J7508	TACROLIMUS, ORAL, PER 5 MG
J7509	METHYLPREDNISOLONE ORAL, PER 4 MG
J7510	PREDNISOLONE ORAL, PER 5 MG
J7511	LYMPHOCYTE IMMUNE GLOBULIN, ANTITHYMOCYTE GLOBULIN, RABBIT, PARENTERAL, 25 MG
J7513	DACLIZUMAB, PARENTERAL, 25 MG
J7515	CYCLOSPORINE, ORAL, 25 MG
J7516	CYCLOSPORIN, PARENTERAL, 250 MG
J7517	MYCOPHENOLATE MOFETIL, ORAL, 250 MG
J7520	SIROLIMUS, ORAL, 1 MG
J7525	TACROLIMUS, PARENTERAL, 5 MG
J7599	IMMUNOSUPPRESSIVE DRUG, NOT OTHERWISE CLASSIFIED
J7608	ACETYLCYSTEINE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER GRAM
J7618	ALBUTEROL, ALL FORMULATIONS INCLUDING SEPARATED ISOMERS, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER 1 MG (ALBUTEROL) OR PER 0.5 MG (LEVALBUTEROL)
J7619	ALBUTEROL, ALL FORMULATIONS INCLUDING SEPARATED ISOMERS, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE, PER 1 MG (ALBUTEROL) OR PER 0.5 MG (LEVALBUTEROL)
J7626	BUDESONIDE INHALATION SOLUTION, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 0.25 TO 0.50 MG
J7628	BITOLTEROL MESYLATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7631	CROMOLYN SODIUM, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS
J7639	DORNASE ALPHA, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7644	IPRATROPIUM BROMIDE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7648	ISOETHARINE HCL, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7649	ISOETHARINE HCL, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7668	METAPROTERENOL SULFATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER 10 MILLIGRAMS
J7669	METAPROTERENOL SULFATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS
J7682	TOBRAMYCIN, UNIT DOSE FORM, 300 MG, INHALATION SOLUTION, ADMINISTERED THROUGH DME
J7699	NOC DRUGS, INHALATION SOLUTION ADMINISTERED THROUGH DME
J8499	PRESCRIPTION DRUG, ORAL, NON CHEMOTHERAPEUTIC, NOS
J8510	BUSULFAN; ORAL, 2 MG
J8520	CAPECITABINE, ORAL, 150 MG
J8521	CAPECITABINE, ORAL, 500 MG
J8530	CYCLOPHOSPHAMIDE; ORAL, 25 MG
J8560	ETOPOSIDE; ORAL, 50 MG
J8600	MELPHALAN; ORAL, 2 MG
J8610	METHOTREXATE; ORAL, 2.5 MG
J8700	TEMOZOLMIDE, ORAL, 5 MG
J8999	PRESCRIPTION DRUG, ORAL, CHEMOTHERAPEUTIC, NOS
J9000	DOXORUBICIN HCL, 10 MG
J9001	DOXORUBICIN HYDROCHLORIDE, ALL LIPID FORMULATIONS, 10 MG
J9010	ALEMTUZUMAB, 10 MG
J9015	ALDESLEUKIN, PER SINGLE USE VIAL
J9017	ARSENIC TRIOXIDE, 1MG
J9020	ASPARAGINASE, 10,000 UNITS
J9031	BCG (INTRAVESICAL) PER INSTILLATION
J9040	BLEOMYCIN SULFATE, 15 UNITS
J9045	CARBOPLATIN, 50 MG

LIST OF MEDICARE DRUG HCPCS CODES—Continued

HCPCS*	Description
J9050	CARMUSTINE, 100 MG
J9060	CISPLATIN, POWDER OR S0LUTION, PER 10 MG
J9062	CISPLATIN, 50 MG
J9065	INJECTION, CLADRIBINE, PER 1 MG
J9070	CYCLOPHOSPHAMIDE, 100 MG
J9080	CYCLOPHOSPHAMIDE, 200 MG
J9090	CYCLOPHOSPHAMIDE, 500 MG
J9091	CYCLOPHOSPHAMIDE, 1.0 GRAM
J9092	CYCLOPHOSPHAMIDE, 2.0 GRAM
J9093	CYCLOPHOSPHAMIDE, LYOPHILIZED, 100 MG
J9094	CYCLOPHOSPHAMIDE, LYOPHILIZED, 200 MG
J9095	CYCLOPHOSPHAMIDE, LYOPHILIZED, 500 MG
J9096	CYCLOPHOSPHAMIDE, LYOPHILIZED, 1.0 GRAM
J9097	CYCLOPHOSPHAMIDE, LYOPHILIZED, 2.0 GRAM
J9100	CYTARABINE, 100 MG
J9110	CYTARABINE, 500 MG
J9120	DACTINOMYCIN, 0.5 MG
J9130	DACARBAZINE, 100 MG
J9140	DACARBAZINE, 200 MG
J9150	DAUNORUBICIN, 10 MG
J9151	DAUNORUBICIN CITRATE, LIPOSOMAL FORMULATION, 10 MG
J9160	DENILEUKIN DIFTITOX, 300 MCG
J9165	DIETHYLSTILBESTROL DIPHOSPHATE, 250 MG
J9170	DOCETAXEL, 20 MG
J9180	EPIRUBICIN HYDROCHLORIDE, 50 MG
J9181	ETOPOSIDE, 10 MG
J9182	ETOPOSIDE, 100 MG
J9185	FLUDARABINE PHOSPHATE, 50 MG
J9190	FLUOROURACIL, 500 MG
J9200	FLOXURIDINE, 500 MG
J9201	GEMCITABINE HCL, 200 MG
J9202	GOSERELIN ACETATE IMPLANT, PER 3.6 MG
J9206	IRINOTECAN, 20 MG
J9208	IFOSFAMIDE, 1 GM
J9209	MESNA, 200 MG
J9211	IDARUBICIN HYDROCHLORIDE, 5 MG
J9212	INJECTION, INTERFERON ALFACON–1, RECOMBINANT, 1 MCG
J9213	INTERFERON, ALFA–2A, RECOMBINANT, 3 MILLION UNITS
J9214	INTERFERON, ALFA–2B, RECOMBINANT, 1 MILLION UNITS
J9215	INTERFERON, ALFA–N3, (HUMAN LEUKOCYTE DERIVED), 250,000 IU
J9216	INTERFERON, GAMMA 1–B, 3 MILLION UNITS
J9217	LEUPROLIDE ACETATE (FOR DEPOT SUSPENSION), 7.5 MG
J9218	LEUPROLIDE ACETATE, PER 1 MG
J9219	LEUPROLIDE ACETATE IMPLANT, 65 MG
J9230	MECHLORETHAMINE HYDROCHLORIDE, (NITROGEN MUSTARD), 10 MG
J9245	INJECTION, MELPHALAN HYDROCHLORIDE, 50 MG
J9250	METHOTREXATE SODIUM, 5 MG
J9260	METHOTREXATE SODIUM, 50 MG
J9265	PACLITAXEL, 30 MG
J9266	PEGASPARGASE, PER SINGLE DOSE VIAL
J9268	PENTOSTATIN, PER 10 MG
J9270	PLICAMYCIN, 2.5 MG
J9280	MITOMYCIN, 5 MG
J9290	MITOMYCIN, 20 MG
J9291	MITOMYCIN, 40 MG
J9293	INJECTION, MITOXANTRONE HYDROCHLORIDE, PER 5 MG
J9300	GEMTUZUMAB OZOGAMICIN, 5MG
J9310	RITUXIMAB, 100 MG
J9320	STREPTOZOCIN, 1 GM
J9340	THIOTEPA, 15 MG
J9350	TOPOTECAN, 4 MG
J9355	TRASTUZUMAB, 10 MG
J9357	VALRUBICIN, INTRAVESICAL, 200 MG
J9360	VINBLASTINE SULFATE, 1 MG
J9370	VINCRISTINE SULFATE, 1 MG
J9375	VINCRISTINE SULFATE, 2 MG
J9380	VINCRISTINE SULFATE, 5 MG
J9390	VINORELBINE TARTRATE, PER 10 MG
J9600	PORFIMER SODIUM, 75 MG
P9041	INFUSION, ALBUMIN (HUMAN), 5percent, 50 ML
P9043	INFUSION, PLASMA PROTEIN FRACTION (HUMAN), 5percent, 50 ML
P9045	INFUSION, ALBUMIN (HUMAN), 5percent, 250 ML
P9046	INFUSION, ALBUMIN (HUMAN), 25percent, 20 ML
P9047	INFUSION, ALBUMIN (HUMAN), 25percent, 50 ML
P9048	INFUSION, PLASMA PROTEIN FRACTION (HUMAN), 5percent, 250ML
Q0136	INJECTION, EPOETIN ALPHA, (FOR NON ESRD USE), PER 1000 UNITS
Q0163	DIPHENHYDRAMINE HYDROCHLORIDE, 50 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT TIME OF CHEMOTHERAPY TREATMENT NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0164	PROCHLORPERAZINE MALEATE, 5 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN

LIST OF MEDICARE DRUG HCPCS CODES—Continued

HCPCS*	Description
Q0165	PROCHLORPERAZINE MALEATE, 10 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0166	GRANISETRON HYDROCHLORIDE, 1 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 24 HOUR DOSAGE REGIMEN
Q0167	DRONABINOL, 2.5 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0168	DRONABINOL, 5 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0169	PROMETHAZINE HYDROCHLORIDE, 12.5 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0170	PROMETHAZINE HYDROCHLORIDE, 25 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0171	CHLORPROMAZINE HYDROCHLORIDE, 10 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0172	CHLORPROMAZINE HYDROCHLORIDE, 25 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0173	TRIMETHOBENZAMIDE HYDROCHLORIDE, 250 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0174	THIETHYLPERAZINE MALEATE, 10 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0175	PERPHENAZINE, 4 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0176	PERPHENAZINE, 8MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0177	HYDROXYZINE PAMOATE, 25 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0178	HYDROXYZINE PAMOATE, 50 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0179	ONDANSETRON HYDROCHLORIDE 8 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0180	DOLASETRON MESYLATE, 100 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 24 HOUR DOSAGE REGIMEN
Q0181	UNSPECIFIED ORAL DOSAGE FORM, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR A IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0183	DERMAL TISSUE, OF HUMAN ORIGIN, WITH AND WITHOUT OTHER BIOENGINEERED OR
Q0187	FACTOR VIIA (COAGULATION FACTOR, RECOMBINANT) PER 1.2 MG
Q2022	VON WILLEBRAND FACTOR COMPLEX, HUMAN, PER IU
Q3025	INJECTION, INTERFERON BETA–1A, 11 MCG FOR INTRAMUSCULAR USE
Q4052	INJECTION, OCTREOTIDE, DEPOT FORM FOR INTRAMUSCULAR INJECTION, 1 MG
Q4053	INJECTION, PEGFILGRASTIM, PER 1 MG
Q9920	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 20 OR LESS
Q9921	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 21
Q9922	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 22
Q9923	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 23
Q9924	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 24
Q9925	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 25
Q9926	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 26
Q9927	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 27
Q9928	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 28
Q9929	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 29
Q9930	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 30
Q9931	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 31
Q9932	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 32
Q9933	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 33
Q9934	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 34
Q9935	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 35
Q9936	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 36
Q9937	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 37
Q9938	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 38
Q9939	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 39
Q9940	INJECTION OF EPO, PER 1000 UNITS, AT PATIENT HCT OF 40 OR ABOVE

*Under HIPAA, pharmacies must use NDC codes, not HCPCS codes, to bill for drugs effective October 16, 2003.

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