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Medicare: Payments for Covered Part B Prescription Drugs

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Summary

Currently, Medicare does not cover most outpatient prescription drugs. However, beginning in 2006, beneficiaries will be able to obtain assistance with their drug costs under the new Medicare Part D. A few categories of drugs, listed in the Medicare statute, are specifically paid for under the current Part B program. These include immunosuppressive drugs following a transplant paid for by Medicare, certain oral cancer drugs, erythropoietin (EPO) for persons with chronic renal failure who are on dialysis, drugs (which are not self-administered) which are administered "incident to" a physician's professional service, and drugs necessary for the effective use of covered durable medical equipment.

Payment for covered outpatient prescription drugs is made under Medicare Part B. As is the case for most other Part B services, Medicare pays 80% of the recognized amount, while the beneficiary is liable for the remaining 20% (known as coinsurance). Under the Balanced Budget Act of 1997 (BBA 97, P.L. 105-33) the amount payable was set at 95% of the *average wholesale price (AWP)*. This provision was intended to place some controls on Medicare payments. However, many observers contended that the payment system failed to meet this objective. They stated that in many cases Medicare paid substantially in excess of the acquisition price for the drug; further the program was paying more than most other large purchasers. There was widespread agreement that the payment system needed to be reformed.

On December 8, 2003, the President signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173). This legislation established the new prescription drug benefit and made a number of other program changes. One provision revised the way the program pays for drugs currently covered under Medicare Part B. For 2004, MMA reduced payments for most covered drugs to 85% of the AWP. Beginning in 2005, payments for drugs are based on an average sales price (ASP) payment methodology; the Secretary has the authority to reduce the ASP payment amount if the widely available market price is significantly below the ASP. Alternatively, beginning in 2006, drugs could be provided through a newly established competitive acquisition program. In addition, MMA increases the payments for physician practice expenses associated with the administration of covered drugs.

The Centers for Medicare and Medicaid Services (CMS) issued regulations implementing the 2004 and 2005 provisions. Some oncologists have stated that the revised payment methodology will lead to significant payment reductions. Other observers suggest that changes to the AWP system were long overdue and that reductions may be in order given the previous overpayments. Further, they state that estimated payments will still exceed acquisition costs in 2005. This report will be updated as events warrant.

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Medicare: Payments for Covered Part B Prescription Drugs

Introduction

Covered Drugs

Currently, Medicare does not cover most outpatient prescription drugs. However, beginning in 2006, beneficiaries will be able to obtain assistance with their drug costs under the new Medicare Part D, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173).[1] This report focuses on coverage currently available under Medicare.

The current program covers drugs in certain circumstances. Beneficiaries who are inpatients of hospitals or skilled nursing facilities may receive drugs as part of their treatment. Medicare payments made to the facilities cover these costs.

Medicare also makes payments to physicians for drugs or biologicals which *are not usually self-administered by the patient* and are administered "incident to" a physician's service.[2] This means that coverage is generally limited to drugs or biologicals administered by injection. However, if the injection is generally self-administered (e.g., insulin), it is not covered.

Despite the general limitation on coverage for outpatient drugs, the law specifically authorizes coverage for the following:

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[1] See CRS Report RL31966, *Overview of the Medicare Prescription Drug Improvement, and Modernization Act of 2003*, by Jennifer O'Sullivan, Hinda Chaikind, Sibyl Tilson, Jennifer Boulanger, and Paulette Morgan.

[2] Medicare has always covered prescription drugs that cannot be self-administered. In 1997, the Centers for Medicare and Medicaid Services (CMS) issued a memorandum to its claims processors reiterating this policy. However, the memorandum led some contractors to change their policies and discontinue covering some drugs they had previously covered. In response, Congress, in 2000, changed the statutory standard from drugs that "cannot be self-administered" to those that "are not usually self-administered by the patient." In May 2002, CMS issued a program memorandum clarifying how the provision should be implemented. Under the criteria, "usually" would be defined as more than 50% of the time for all Medicare beneficiaries using the drug.

- *Immunosuppressive Drugs*. Drugs used in immunosuppressive therapy (such as cyclosporin) following discharge from a hospital for a Medicare covered organ transplant.[3]
- *Erythropoietin (EPO)*. EPO for the treatment of anemia for persons with end-stage renal disease (ESRD) who are on dialysis.
- *Oral Anti-Cancer Drugs*. Drugs taken orally during cancer chemotherapy provided they have the same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service. Also included are oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen.
- *Hemophilia clotting factors.* Hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors.[4]

The program also pays for supplies (including drugs) that are necessary for the effective use of covered durable medical equipment, including those which must be put directly into the equipment (e.g., tumor chemotherapy agents used with an infusion pump).

Medicare also covers the following immunizations:

- *Pneumococcal pneumonia vaccine.* The vaccine and its administration to a beneficiary if ordered by a physician.
- *Hepatitis B vaccine*. The vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting hepatitis B.
- *Influenza virus vaccine*. The vaccine and its administration when furnished in compliance with any applicable state law. The beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

The distribution of spending and billing patterns reflects the limited nature of Medicare's outpatient drug benefit. The Medicare Payment Advisory Commission (MedPAC) reported that while Medicare covered approximately 450 drugs in 2002, the top 10 drugs accounted for almost 60% of all Part B drug spending in that year. The top drug, Epoetin alpha injections supplied to non-ESRD patients, accounted for

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[3] Coverage for immunosuppressive drugs continues only if the individual continues to be eligible for Medicare. Persons, under age 65, whose Medicare eligibility was based solely on the fact that they had end-stage renal disease, lose their Medicare eligibility (and therefore the drug coverage) three years after a successful kidney transplant.

[4] Medicare also pays for an injectable osteoporosis drug approved for treatment of post-menopausal osteoporosis provided by a home health agency to a homebound individual whose attending physician has certified suffers from a bone fracture related to post-menopausal osteoporosis and the individual is unable to self-administer the drug.

12.8% of the total. Further, 11 of the top 15 drugs treated cancer or the side effects associated with chemotherapy.[5]

For 2001, MedPAC reported[6] that 35 drugs accounted for 88% of Medicare drug spending and 95% of claims. The top 20 drugs accounted for 77% of Part B drug expenditures. Drugs billed by physicians and typically provided in their offices (such as chemotherapy drugs) accounted for more than 80% of total spending in 2001. Most claims were submitted by oncologists, with three specialties (hematology oncology, medical oncology, and urology) accounting for 58% of the total. Payments for drugs represented a substantial portion of their Medicare payments. In 2001, 72% of all Medicare payments to hematology oncologists and medical oncologists were for covered drugs. Drug payments also represented a significant portion of Medicare payments for hematologists (64%), urologists (43%), and rheumatologists (31%).

In contrast to drugs that account for the greatest share of spending, drugs provided through pharmacy suppliers (generally those used with durable medical equipment or infusion devices) accounted for the largest *volume* of drug claims. Two inhalation therapy drugs (ipratropium bromide and albuterol) accounted for 88% of pharmacy billings for home administration in 1999.

Payments

In General. Payment for covered outpatient prescription drugs is made under Medicare Part B. The Balanced Budget Act of 1997 (BBA 97, P.L. 105-33) specified that the amount payable would equal 95% of the *average wholesale price (AWP)*. MMA lowered the amount to 85% in 2004 and provided for the implementation of an *average sales price* (ASP) methodology beginning in 2005. (See MMA discussion below.)

As is the case for most other Part B services, Medicare pays 80% of the recognized amount, while the beneficiary is liable for the remaining 20% (known as coinsurance). These Part B cost-sharing charges do not apply for pneumococcal pneumonia or influenza vaccines.

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA 2000) provided that beneficiaries could not be "balance billed," i.e., they could not be charged for any amounts in excess of the recognized payment amount.

Spending. Medicare spending for outpatient drugs has grown rapidly in recent years. CMS estimated that for 2002, expenditures for Part B drugs totaled $8.45 billion in 2002, an increase of 32% over 2001. These figures did not include drugs provided through hospital outpatient departments or for ESRD patients in dialysis

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[5] Medicare Payment Advisory Commission, *A Data Book: Healthcare Spending and the Medicare Program*, June 2004.

[6] Medicare Payment Advisory Commission, *Variations and Innovation in Medicare*, Report to the Congress, June 2003.

facilities. MedPac estimated that in 2002, freestanding dialysis facilities alone billed Medicare an additional $2.8 billion for drugs.[7]

CMS reported that Medicare spending for drugs billed by oncologists rose from $1.2 billion in 1998 to $3.8 billion in 2002. From 2001 to 2002, spending for drugs billed by oncologists rose by 41%.[8]

Reasons for MMA Changes

For a number of years, Medicare payment has been directly linked to AWPs. AWPs are prices reported by drug manufacturers to organizations that publish them in drug price compendia such as the *Red Book* (published by the Medical Economics Company, Inc.). There are no uniform criteria for reporting these numbers. Further, they do not reflect the discounts that manufactures and wholesalers customarily offer to physicians and other providers such as hospitals and managed care plans. As a result, observers have frequently suggested that AWPs represent neither average prices nor prices charged by wholesalers.

The BBA 97 provision linking Medicare payment to 95% of AWP was intended to place some controls on Medicare payments. However, many observers contended that the system failed to meet this objective. Several studies showed that in many cases Medicare was paying substantially in excess of the acquisition price for the drug; further the program was paying more than most other large purchasers.

Prices

The prices Medicare pays for drugs have frequently been compared with the prices paid by other large public and private purchasers. While much of the information is proprietary, it is clear that many of these purchasers have been able to obtain drugs at prices considerably below those obtained by Medicare. Since 1997, the Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS) has issued a series of reports documenting the difference between what Medicare pays for drugs and what the program would pay if it used either actual wholesale prices or the prices paid by other large purchasers. In 2001, it reviewed payments for 24 drugs accounting for a total of $3.7 billion out of the total $5 billion in Medicare outpatient drug spending. The OIG concluded that excess spending, compared to prices in catalogues used by other third-party purchasers, was $887 million. If Medicare had paid according to the Federal Supply Schedule (FSS, the price schedule negotiated with the Department of Veterans Affairs (VA)), the savings would have totaled $1.9 billion. The OIG noted that if Medicare had paid the lower

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[7] Medicare Payment Advisory Commission, *A Data Book: Healthcare Spending and the Medicare Program*, June 2004.

[8] Department of Health and Human Services, "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule," 68 *Federal Register* 50427, Aug. 20, 2003.

prices, beneficiaries would have benefitted from lower copayments — $175 million if actual catalogue prices had been used and $380 million if the FSS had been used.[9]

In March 2002, the OIG issued reports focusing on two inhalation therapy drugs, which, as noted above, account for the majority of pharmacy-supplier billings. The first report found that the Medicare reimbursement amount for albuterol was more than nine times greater than the median price on the FSS used by the VA ($0.47 per milligram (mg) versus $0.05 per mg). It estimated that Medicare and its beneficiaries would save $264 million if albuterol were paid at the median price paid by the VA. It noted that the program and its beneficiaries would save between $226 million and $245 million if albuterol were reimbursed based on prices available to pharmacy and durable medical equipment suppliers (whose median price ranged from $0.09 to $0.11 per mg). The report further noted that less than 1% of albuterol suppliers received 63% of the Medicare payments for albuterol; it concluded that these suppliers that purchase large quantities of the drug may receive volume discounts from manufacturers and wholesalers.[10] These discounts are not passed along to Medicare because Medicare payments are linked to the AWP.

The second report contained similar findings with respect to ipratropium bromide. It stated that the Medicare reimbursement amount was more than five times greater than the VA price ($3.34 per mg versus $0.66 per mg). Medicare and its beneficiaries could save $279 million a year if ipratropium bromide were reimbursed at the median price paid by the VA and between $223 million and $262 million a year if it were reimbursed at prices available to suppliers. Again, the OIG found that less than 1% of suppliers received the majority (almost 60%) of the Medicare payments for ipratropium bromide in 2000; it concluded that suppliers that purchase large quantities of the drug are likely to receive volume discounts from manufacturers and wholesalers.[11]

Many observers agreed that Medicare paid more than other large purchasers for covered drugs. However, a number of these observers cautioned against using the VA's payments as a basis for Medicare payments. They noted that the VA, unlike Medicare, purchases drugs for its healthcare system directly from manufacturers or wholesalers. Using competitive procedures, contracts are awarded to companies to provide drugs over a specified period of time at the FSS price. In certain cases, the VA is able to negotiate a lower price through such approaches as blanket purchase agreements or VA national contracts. While Medicare suppliers may purchase drugs directly from manufacturers or wholesalers, the program as a whole does not directly purchase drugs; therefore its purchasing clout is diluted.

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[9] U.S. Department of Health and Human Services, Office of the Inspector General, testimony of George F. Grob before the Subcommittees on Health and on Oversight and Investigations of the House Committee on Energy and Commerce, Sept. 21, 2001.

[10] U.S. Department of Health and Human Services, Office of the Inspector General, *Excessive Medicare Reimbursement for Albuterol*, Report OEI-03-01-00410, Mar. 2002.

[11] U.S. Department of Health and Human Services, Office of the Inspector General, *Excessive Medicare Reimbursement for Ipratropium Bromide*, Report OEI-03-01-00411, Mar. 2002.

Implications for Physicians and Beneficiaries

During the 107th Congress, hearings in both the House and Senate focused on the AWP. These hearings highlighted the impact of inflated prices on beneficiaries as well as the Medicare program itself.

One practice was the subject of considerable concern. Some manufacturers were reportedly using inflated AWPs as a marketing device to increase market share. Physicians and suppliers did not pay the inflated AWP but they were reimbursed by Medicare on the basis of the inflated amount. The larger the "spread" between the actual price and 95% of the AWP, the larger the amount the physician or supplier was able to keep. It was thought that some physicians and suppliers might choose the drug with the higher "spread." While the manufacturer did not receive a higher amount for each unit of the drug product, it did increase market share and thus overall drug company profits.[12]

Another concern was the impact of inflated AWPs on beneficiary copayments. Beneficiary copayments equal 20% of Medicare's recognized payment amount (i.e., 95% of AWP). A higher AWP resulted in a higher beneficiary copayment. In some cases the copayment amount might be in excess of the physician's or supplier's total acquisition cost.

Concerns of Oncologists

As noted earlier, payments to physicians for oncology drugs constitute a large portion of Medicare outpatient drug spending. Many oncologists recognized that Medicare payments for drug products were in excess of their actual acquisition costs. However, they claimed that Medicare paid too little for the practice costs associated with administering the oncology drugs. They contended that they were forced to use the higher drug payments to offset inadequate reimbursement for practice expenses. These oncologists contended that the calculation of their practice expenses under the physician fee schedule was flawed. They objected to any changes in the AWP calculation until changes were made in the practice expense calculation. (See discussion below.)

Development of New System

For several years, there was widespread agreement that the existing payment system needed to be reformed. Observers generally agreed that Medicare payments should be brought more in line with market prices that providers actually paid to acquire the drugs. These price determinations should reflect discounts. A number of legislative and administrative activities were undertaken to address these concerns; however, it was difficult to achieve consensus on an alternative.[13] Efforts to design an alternative system were hampered by a number of factors.

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[12] U.S. Department of Health and Human Services, Office of the Inspector General, testimony of Janet Rehnquist before the Senate Committee on Finance, Mar. 14, 2002.

[13] See Appendix A, *Past Efforts to Address Medicare Payment Issues*.

One consideration was what changes were needed under the physician fee schedule to assure that appropriate payments were made for the costs associated with administering the drugs. In particular, oncologists wanted to be assured that any reduction in payment for chemotherapy drugs would be accompanied by an increase in payments for the administration of the drugs.

A key issue in designing the new drug payment system was what should serve as the basis of payment. Underlying this central issue were questions about the availability and accuracy of data, whether manufacturers should be required to report actual price information to CMS, whether physicians and pharmacy suppliers should be required to submit invoices to CMS, and how much additional information CMS would need to collect and verify.

During this period, CMS stated its preference for a legislative solution to the AWP issue. However, at the same time, it continued to develop its own approach. On August 20, 2003, CMS issued proposed rule-making[14] for revising program payments for covered drugs. The rule outlined four proposed approaches that could be used and asked for public comments on which approach should be implemented. This regulation was superseded by the enactment of the MMA provisions.

MMA Drug Payment Requirements

Section 303 of MMA revised the way Medicare pays for covered Part B drugs. In 2004, payments for covered drugs were, in general, equal to 85% of the AWP. Beginning in 2005, payments for drugs are based on an average sales price (ASP) payment methodology. Alternatively, beginning in 2006, drugs can be provided through a new competitive acquisition program.

MMA also revised the calculation of practice expenses associated with the administration of these drugs. The legislation specified that changes in the drug payment methodology could not be made in 2004, unless the Secretary concurrently made the adjustments in practice expense calculations.

2004 Payment Calculations

Eighty-five percent AWP. MMA specified that payments for covered drugs in 2004 were, in general, equal to 85% of the AWP (determined as of April 1, 2003). Certain categories of drugs and biologicals were exempt from the reductions and continued to be paid at 95% of the AWP; these were: blood clotting factors; drugs not available for Medicare payment as of April 2003; pneumococcal, influenza, and hepatitis B vaccines; a drug or biological furnished in connection with the furnishing of renal dialysis services if separately billed by renal facilities; infusion drugs furnished through a covered item of durable medical equipment (based on the price in effect October 1, 2003); and blood and blood products (based on the price in effect October 1, 2003).

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[14] U.S. Department of Health and Human Services, "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule," 68 *Federal Register* 50427, Aug. 20, 2003.

Alternative Amounts. MMA required the Secretary to substitute for the 85% AWP amount a percentage that would apply under a table published in the *Federal Register* on August 20, 2003 for certain specified drugs.[15] This table, entitled "Medicare Part B Drugs in the Most Recent GAO and OIG Studies," included an average of GAO and Office of Inspector General surveyed prices.

In addition, the Secretary was permitted to substitute for the 85% AWP amount a percentage based on data and information submitted by the manufacturer by October 15, 2003. If the manufacturer submitted such data and information between October 16, 2003 and December 31, 2003, the Secretary could use a substitute percentage beginning April 1, 2004.

In no case could the payment be less than 80% of the AWP.

Payment Calculations Beginning in 2005

MMA established new payment methodologies, beginning in 2005. Payments for drugs are based on an average sales price (ASP) payment methodology established under the New Section 1847A of the Social Security Act.[16] Alternatively, beginning in 2006, drugs can be provided through the competitive acquisition program established under the New Section 1847B of the Act. Each year, each physician will be given the opportunity either to receive payment using the ASP methodology or to obtain drugs and biologicals through the competitive acquisition program.

The following are exempt from the new payment provisions and are paid at 95% of the AWP: vaccines; infusion drugs furnished through a covered item of durable medical equipment (based on the price in effect October 1, 2003) and blood and blood products (based on the price in effect October 1, 2003). Beginning in 2007, infusion drugs furnished through a covered item of durable medical equipment in a competitive acquisition area established for durable medical equipment and related items will be paid under such system.

Average Sales Price (ASP). As noted, a physician could elect to be paid for drugs under the New Section 1847A, rather than obtaining drugs and biologicals under the new competition program.

ASP Calculation. Medicare's payment will equal 106% of the applicable price for a multiple source drug or single source drug, subject to the applicable beneficiary deductible and coinsurance. Applicable prices are derived from data reported under the Medicaid program. The applicable price for multiple source drugs is the volume-weighted average of the ASP calculated by National Drug Code (NDC) for each calendar quarter. The applicable price for single source drugs is the lesser of the ASP or the wholesale acquisition cost.

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[15] Beginning Jan. 1, 2004, "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule," 68 *Federal Register* 50428, Aug. 20, 2003.

[16] Title 18 of the Social Security Act contains Medicare law.

Manufacturers are required to specify the unit (namely the lowest identifiable quantity) associated with each National Drug Code as part of the submission of data under Medicaid. For years after 2004, the Secretary can establish the unit for a manufacturer to report and the method for counting units.

In general, the manufacturer's ASP includes sales to all purchasers with certain exceptions including those exempted from Medicaid's "best price" determination and sales at nominal charges.

The determination of the manufacture's ASP takes into account volume discounts, prompt pay discounts, cash discounts, free goods contingent on any purchase requirements, chargebacks, and rebates (not including Medicaid rebates). The Secretary may include other price concessions, which may be based on the recommendations of the Inspector General, that result in a reduction in cost to the purchaser. The manufacturer will determine the ASP on a quarterly basis. The payment rates will be updated quarterly by the Secretary based upon the manufacturer's ASP determined for the most recent calendar quarter.

For an initial period, not to exceed a calendar quarter, in which the ASP is not sufficiently available, the Secretary may compute the amount payable based on the wholesale acquisition cost or the methodologies in effect on November 1, 2003.

Monitoring; Widely Available Market Price. The Inspector General is required to conduct studies, including surveys, to determine the widely available market price of drugs paid for under this provision. Based on these studies and other data, the Inspector General will compare the widely available market price with the ASP reported by the manufacturer as part of its Medicaid submission. The Inspector General will report to the Secretary if the ASP exceeds the widely available market price or average manufacturer price by a specified percentage. The specified percentage is 5% for 2005; in 2006 and future years, the percentage will be specified by the Secretary. In cases where the percentage is exceeded, the Secretary will adjust the payment amount for the next calendar quarter. The payment will equal the lesser of the widely available market price or 103% of the average manufacturer price.

The widely available market price is defined as the price that a prudent purchaser or supplier would pay for the drug or biological. In determining the price, the Inspector General is required to take into account discounts, rebates, and other price concessions routinely made available to such prudent physicians and suppliers. The manufacturer's average sales price is defined as the average price to all purchasers (except for certain exempt sales). The widely available market price and the ASP are different.

The law prohibits administrative or judicial review of: payment amounts; identification of units and package size; method to allocate rebates, chargebacks and other price concessions; the manufacturer's ASP when it is used for a determination of a payment amount; and the disclosure of the average manufacturer price when used for a payment adjustment.

Reports. The legislation calls for reports by the Secretary and the Inspector General.

Secretary's Report. The Secretary is to conduct a study and report to Congress by January 1, 2006, on sales to large volume purchasers such as pharmacy benefit managers and health maintenance organizations to determine if these prices do not reflect prices made available to prudent physicians. The report is to include recommendations on whether such prices should be excluded from the computation of a manufacturer's ASP for purpose of the New Section 1847A.

Inspector General's Report. The Inspector General is required to conduct a study on the ability of physician practices of various sizes (particularly large practices) in hematology, hematology/oncology, and medical oncology to obtain drugs and biologicals for the treatment of cancer patients at 106% of the ASP. As part of the study, the Secretary is required to conduct an audit of a representative sample of such practices to determine the adequacy of reimbursement. A report on the study is due to the Congress by October 1, 2005.

Competitive Acquisition Program. The new Section 1847B of the Social Security Act requires the Secretary to establish and implement a competitive acquisition program, beginning in 2006.

Program Design. Under the program, competitive acquisition areas will be established throughout the country for purposes of acquisition and payment for covered drugs and biologicals. Each year, each physician will be given the opportunity either to obtain drugs and biologicals through this program or alternatively to receive payment using the ASP methodology established under the new Section 1847A, discussed above. Physicians electing the competition program will make an annual selection of a contractor through which they will obtain the covered items. Claims for covered drugs and biologicals will be submitted by the contractor which will also be required to collect any beneficiary deductible and coinsurance. Medicare payments will only be made to the contractor and will be contingent upon the administration of the drugs and biologicals. The Secretary will provide for a process for recoupment where payment is made but the drugs or biologicals are not actually dispensed.

The Secretary is required to establish categories of competitively biddable drugs and biologicals. The Secretary is to phase-in categories beginning in 2006, in such manner as the Secretary determines appropriate. The Secretary can exclude drugs and biologicals from the competition program if the application to such drugs or biologicals is not likely to result in significant savings or would have an adverse effect on access.

Contracts. The Secretary will conduct a competition among entities for the acquisition of competitively biddable drugs and biologicals. For multiple source drugs, the Secretary will conduct the competition for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each competitively biddable category in each competitive acquisition area. The Secretary could not award a contract for a category unless the Secretary finds that it meets certain requirements. The entity has to have sufficient capacity to supply the drugs or biologicals in the area specified in the contract. The entity has to have arrangements in effect for the shipment, at least five days a week, of

competitively biddable drugs and biologicals and for their timely delivery (including for emergency situations).

The Secretary is to establish procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding shipments. The Secretary is also to specify standards for a grievance and appeals process for the resolution of disputes.

Contracts will be awarded for three years. The Secretary could limit the number of contractors to two in any category and area. The Secretary will select among qualified entities based on bid prices for drugs or biologicals within the category and area, bid prices for distribution, ability to ensure product integrity, customer service, past experience and other factors the Secretary may specify. The amount of the bid for any drug or biological is to be the same for all portions of an area. Bidders will be permitted, but not required, to submit bids for all areas of the United States. Bids will be confidential.

Contractor Requirements. A contractor will be required to disclose to the Secretary its reasonable acquisition costs. The contract will provide for price adjustments during the contract period to reflect significant increases or decreases in reasonable net acquisition costs.

All drugs and biologicals distributed by a contractor are to be acquired directly from a manufacturer or from a distributor that acquired the items directly from the manufacturer. Contractors are also required to comply with product safety safeguards determined appropriate by the Secretary. Contractors are required to comply with code of conduct and fraud and abuse rules.

Contractors may only supply covered drugs and biologicals directly to the physicians and not to beneficiaries, except where beneficiaries currently receive them in their homes or other non-physician office settings. The contractor could only deliver drugs and biologicals upon receipt of a prescription. Physicians will not be required to submit a prescription for each individual treatment, nor will a physician's flexibility be changed in terms of writing a prescription.

The Secretary is required to establish rules under which drugs or biologicals acquired through a contractor could be used to resupply inventories if physicians can demonstrate that the drugs or biologicals are required immediately, the physician could not have reasonably anticipated the immediate requirement, the contractor could not deliver them in a timely manner, and they were administered in an emergency situation.

Payments. Payments under the program are to be based on bids submitted and accepted. The Secretary is to determine a single amount for each competitively biddable drug or biological in the area. The Secretary is to establish special payment rules for new products for which a payment and billing code has not been established. If the Secretary excludes a drug or biological under the competition program, payment is to be made under the methodology established under the new Section 1847A.

There is no administrative or judicial review for the establishment of payment amounts, the awarding of contracts, the establishment of competitive acquisition areas, the phased-in implementation of the competition program, the selection of categories of competitively biddable drugs and biologicals, and the bidding structure and number of contractors.

Report. The Secretary is required to submit a report to Congress on the competitive acquisition program by July 1, 2008. The report is to include information on: savings; reductions in cost-sharing; access to competitively biddable drugs and biologicals; the range of choices of contractors available to physicians; the satisfaction of physicians and enrollees; and information comparing prices under the competitive acquisition program and those under the new Section 1847A.

Proposed Regulations. CMS issued proposed implementing regulations on March 4, 2005.[17] Under the proposed rule, physicians would be given the opportunity once a year to elect to participate in the program and select a vendor. The vendor would be the physician's sole source for the selected categories of Part B drugs. Under specified emergency conditions, the physician could obtain the drugs elsewhere. Payments to the physician for administering the drug would be the same as those made to physicians who purchased the drugs.

The proposed rule invited public comment on several issues. One issue is the drug categories to be included in the program. The preamble to the proposed regulations stated that the program could be phased-in starting with a large category such as all drugs administered in physicians' offices. Alternatively, the phase-in could start off more slowly with one or more categories of drugs such as oncology drugs. Comments were also sought on the designation of areas. Options range from a national area to regional areas or single state areas.

Special Provisions for Specific Drug Categories

Blood Clotting Factors. The Secretary, after reviewing a January 2003 GAO report on the issue, was required to provide for a separate payment for blood clotting factors. Such payment could take into account: the mixing (if appropriate) and delivery of factors to an individual, including special inventory and management and storage requirements; and ancillary supplies and patient training necessary for self-administration of such factors. The total amount of such payments in 2005, could not exceed the amount that would otherwise be made in the absence of the legislation. CMS established a furnishing fee of $0.14 per unit of clotting factor. The payment amount is to be increased each year, beginning in 2006, by the increase in the CPI for medical care.

Pharmacy Supplying Fee. The Secretary is required to pay a supplying fee (less the applicable deductible and coinsurance amounts) to licensed pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs and oral anti-nausea drugs

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[17] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B*, Proposed Rule, 70 *Federal Register* 10746, Mar. 4, 2005.

used as part of an anti-cancer chemotherapeutic regimen. CMS established a fee of $24 for 2005.

Radiopharmaceuticals. The payment methodology in effect prior to MMA is to continue for radiopharmaceuticals.

Inhalation Drugs. Medicare covers outpatient prescription drugs and biologicals that are necessary for the effective use of covered durable medical equipment. This includes drugs that must be put directly into the equipment such as respiratory drugs given through a nebulizer, specifically inhalation drugs. Section 305 of the law specified that such drugs and biologicals were to be paid at 85% of AWP (as of April 30, 2003) and under the ASP methodology established under new Section 1847A beginning in 2005. GAO was required to conduct a study on the adequacy of reimbursement for inhalation therapy and report to Congress by December 8, 2004, on the study. GAO issued its report in October 2004 which found a wide variation in dispensing costs. It recommended that CMS evaluate the costs of dispensing inhalation therapy drugs and modify the dispensing fee if warranted. CMS agreed with the recommendation.

Demonstration Project

Medicare Part B covers drugs furnished, incident to a physician's professional service, which generally cannot be self-administered. Also covered are oral cancer drugs provided they have the same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service.

Section 641 of MMA establishes a demonstration project for the coverage of drugs which are prescribed as replacements for drugs and biologicals which are generally not self-administered and covered oral cancer drugs. Effectively, this permits coverage of self-administered drugs and biologicals when they are replacements for currently covered items. The statement of the managers specified that:

> The managers intend that this provision of the demonstration will provide immediate Part B coverage for all immunomodulating drugs and biologicals used when treating multiple sclerosis. . . . [18]

The demonstration was to begin within 90 days of the enactment of MMA. (It actually began in September 2004; see discussion below.) It is slated to end December 31, 2005, the day before the new Medicare Part D drug benefit begins. Cost-sharing for these drugs are the same as that applicable under the new Part D benefit. The demonstration is limited to 50,000 patients and $500 million. A report on the project is due July 1,2006. The report is to include an evaluation of patient access, patient outcomes, and cost effectiveness (including an evaluation of cost

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[18] H.Rept. 108-391 *(Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Conference Report to Accompany H.R. 1),* Nov. 21, 2003, p. 698.

savings, if any, attributable to reduced physicians services and hospital outpatient services for drug administration).

Cost Estimates

Section 303(j) of MMA limited the application of Section 303 to the specialties of hematology, hematology/oncology and medical oncology. Section 304 of MMA specified that the provisions of Section 303 apply to other specialties. As noted in the conference report on the bill, this allowed CBO to provide one estimate for the impact of the provisions on oncologists and another estimate for the impact on other specialties. For oncologists the net impact of the revisions in the payment for drugs coupled with the increases in payments for the administration of drugs was a savings of $0.9 billion over the 2004-2008 period and $4.2 billion over the 2004-2013 period. For other specialties, the savings totaled $2.2 billion over the 2004-2008 period and $7.3 billion over the 2004-2013 period.

Section 303 of MMA did not apply to inhalation drugs and biologicals that are necessary for the effective use of covered durable medical equipment. As noted above, Section 305 specified the payment methodology changes that are applicable to such items. CBO estimated a savings of $1.3 billion over the 2004-2008 period and $4.2 billion over the 2004-2013 period.

The Section 641 demonstration project was estimated to cost $0.5 billion over the FY2004-FY2006 period.

Implementation

2004 Revisions

The President signed MMA into law on December 8, 2003. As noted, MMA specified that changes in the drug payment methodology could not be made in 2004, unless the Secretary concurrently made adjustments in physician practice expense calculations. On January 7, 2004, CMS issued interim final rule making changes in physician and drug payment methodologies as mandated by MMA.[19] The regulation superceded significant portions of the 2004 physician fee schedule regulation issued November 7, 2003.[20] It also effectively superseded the process outlined in the August 20, 2003 proposed regulation.

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[19] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004; Interim Final Rule," 69 *Federal Register* 1083, Jan. 7, 2004.

[20] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004; Final Rule," 68 *Federal Register* 63196, Nov. 7, 2003.

The revised fee schedule regulation included an increase of 1.5% in the conversion factor used to calculate payments for all services paid under the physician fee schedule. (In the absence of MMA, the update would have been a *negative* 4.5%). Also included were changes in the calculation of practice expenses associated with the administration of covered part B drugs.[21]

The January 2004 regulation also implemented the 2004 changes in drug payments. For most drugs, the 2004 payment is to equal 85% of the AWP. However, as required by MMA, certain drugs identified by GAO and OIG surveys, may be paid a lower percentage, but in no case less than 80% of the AWP. MMA identified certain other drug categories which are to be paid at a higher percentage.

The January regulation included an Appendix which identified each drug paid under Part B, the amount of payment for the drug, and the percentage this amount represents of the AWP. In some cases, there may be more than one payment amount for a drug. Payment equals 95% of the AWP if a drug is separately billed by an ESRD facility or infused through DME. The Appendix included in the January regulation contained a number of technical errors. Therefore, CMS issued a corrected Appendix on March 26, 2004.[22]

2004 Impact

The January regulations contained an analysis of the combined impact, on selected physician specialties, of the changes in physician payment rules and the AWP payment rules for 2004.[23] The analysis was done for physician specialties which derive a large portion of their Medicare revenues from covered Part B drugs. For example, for 2003, oncologists reportedly derived 77% of such revenues from drugs and 20% from the physician fee schedule (the remaining 3% was from miscellaneous items). For 2004, CMS estimated that revenues for drugs would decline 12% or abut $510 million; at the same time fee schedule payments would increase 47% or about $510 million. Therefore, CMS estimates relatively no net change in total payments to oncologists from 2003 to 2004 (**Table 1)**. Obviously the impact on individual physicians will vary based on the mix of drug and fee schedule services they provide.

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[21] For a discussion of physician payments, see CRS Report RL31199, *Medicare Payments to Physicians*, by Jennifer O'Sullivan.

[22] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. "Medicare Program; Changes to the Medicare Payment for Drugs for Calendar Year 2004; Correction of Interim Final Rule," 69 *Federal Register* 15703, Mar. 26, 2004.

[23] The Mar. 2004 technical corrections should have little impact on this analysis, according to a CMS official (telephone conversation, Apr. 2004).

Table 1. Combined Payment Impact of Drug and Physician Fee Schedule Payment Changes for Selected Specialities, 2004

Speciality	Percent of total Medicare revenues from drugs	Percent change in revenue, 2003-2004 from drugs	Percent of total Medicare revenues from fee schedule	Percent change in revenues, 2003-2004 from fee schedule	Combined percent change in Medicare revenues[a]
Hematology/ Oncology	77	-12	20	47	0
DME/Other medical supplier	42	-13	58	0	-6
Urology	43	-14	55	4	-4
Rheumatology	49	-11	47	6	-2
Obstetrics/ Gynecology	15	-13	84	4	1
Infectious disease	7	-12	92	5	4

Source: Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004; Interim Final Rule," 69 *Federal Register* 1109, Jan. 7, 2004.

a. Excludes impact of MMA geographic adjustments.

2005 Revisions

Average Sales Price Reporting. Beginning in 2005, Medicare payments to physicians for covered Part B drugs are based on the average sales price methodology. MMA required manufacturers to report ASP information (as part of their Medicaid submission) for calendar quarters beginning on or after January 1, 2004. (See MMA requirements above.) The initial quarterly submission was due April 30, 2004. Subsequent quarterly reports are due within 30 days of the close of the calendar quarter.

On April 6, 2004, CMS issued an interim final rule with comment period, which laid out the MMA requirements and provided a template manufacturers should use to report their ASP data.[24] On September16, 2004, CMS issued a modified final rule. In response to concerns that had been expressed by manufacturers, the modified final rule revised the estimation methodology for pricing concessions (such as rebates and chargebacks). Under the revised version, a rolling average is used; this should allow prices to be more stable from quarter to quarter.

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[24] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals; Interim Final Rule," 69 *Federal Register* 17935, Apr. 6, 2004.

Fee Schedule Revisions. On November 15, 2004, CMS issued a final rule making changes in physician and drug payment methodologies for 2005.[25] The regulation included an increase of 1.5% in the conversion factor used to calculate payments for all services under the physician fee schedule. Also included are new codes (and associated relative values) for drug administration services. Additionally, a one-year demonstration project, announced in early November, provides additional payments for oncologists in 2005.[26] The increase in drug administration services will be offset by a decrease in drug payments under the new ASP methodology.

The fee schedule regulation also implements the MMA requirement that payments for inhalation therapy drugs be based on the ASP. A dispensing fee is provided for supplying inhalation therapy. The 2005 dispensing fee is $57.

The rule also establishes payment amounts for supplying immunotherapy drugs to a transplant patient. The 2005 dispensing fee will be $50 for a new transplant patient and $24 for a transplant patient who has already been undergoing transplant therapy.

2005 Impact. The November regulations contained an analysis of the combined impact, on selected physician specialties, of the changes in physician payment rules and the implementation of the ASP methodology. As was the case for 2004, the analysis was done for physician specialities that derive a large portion of their Medicare revenues for covered Part B drugs. For example, for 2004, oncologists would reportedly derive 69% of such revenues from drugs and 28% from the physician fee schedule (the remaining 3% would be from miscellaneous items). For 2005, CMS estimated that revenues for drugs would decline about 13%, while fee schedule payments would increase 10% (including the impact of the one-year demonstration project).[27] Total revenues would drop 6% assuming no change in utilization. However, CMS assumed that the recent growth in the volume of drugs and fee schedule services would continue; as a result, CMS estimated total payments to oncologists would increase by 8%. Of course, these estimates were averages across all physicians; the impact on individual physicians will vary based on the volume and mix of services provided.

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[25] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Final Rule," 69 *Federal Register* 66235, Nov. 15, 2004.

[26] For a discussion of physician payments, see CRS Report RL31199, *Medicare Payments to Physicians*, by Jennifer O'Sullivan.

[27] ASP price data used for the estimates was from the second quarter of 2004. Third quarter data will be available soon; however, CMS does not expect substantial changes between the second and third quarter.

Table 2. Combined Payment Impact of Drug and Physician Fee Schedule Payment Changes for Selected Specialities, 2005

Speciality	Percent of total Medicare revenues from drugs	Percent change in revenue, 2004-2005 from drugs	Percent of total Medicare revenues from fee schedule	Percent change in revenues, 2004-2005 from fee schedule	Combined percent change in Medicare revenues, constant utilization	Combined percent change in Medicare revenues, with utilization growth
Hematology/ Oncology	69	-13	28	10	-6	8
Urology	35	-40	57	1	-14	-8
Rheumatology	44	-8	49	5	-1	16
Obstetrics/ Gynecology	13	-21	87	1	-2	5
Infectious disease	6	-25	94	0	-2	7

Source: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Revisions to Payment Policy Under the Physician Fee Schedule for Calendar Year 2005; Final Rule," 69 *Federal Register* 66235, Nov. 15, 2004.

Demonstration Project

As noted above, Section 641 provided for the establishment of a Medicare replacement drug demonstration project for coverage of certain self-administered drugs. A *Federal Register* notice dated June 29, 2004, announced the implementation of the program. CMS prepared a list of medical conditions and covered drugs. Beneficiaries wishing to participate in the program must have their physician certify that the individual has a medical condition for which coverage of the demonstration drug is allowed and either the physician has already written a prescription for the drug or intends to do so.

The program is limited to 50,000 people and $500 million. Initially, beneficiaries could submit applications between July 6, 2004-September 30, 2004. If more than 50,000 applied, participants would be selected at random. If less than 50,000 applied, applications could be submitted and accepted after September 30, 2004. Coverage would generally begin October 18, 2004, for applications submitted up to that date. The program ends December 31, 2005.

CMS has expanded the list of covered drugs several times. As of June 9, 2005, enrollment slots still remained.

Current Issues

Concerns of Oncologists

Payments. As noted earlier, payments to physicians for oncology drugs have constituted a large portion of Medicare outpatient drug spending. Many oncologists recognized that Medicare payments for drug products were in excess of their actual acquisition costs. However, they claimed that Medicare paid too little for the practice costs associated with administering the oncology drugs. They contended that they were forced to use the higher drug payments to offset inadequate reimbursement for practice expenses. They also stated that they would object to any changes in the AWP calculation unless changes were also made in the practice expense calculation.

As noted previously, MMA changed both the AWP and practice expense calculation, effective January 1, 2004. For the specialties of hematology, hematology/oncology and medical oncology, CBO estimated, at the time of enactment, that these changes would yield a cost of $0.1 billion in FY2004 and a savings (i.e., a reduction in payments) of $0.1 billion in FY2005, $0.9 billion over the FY2004-FY2008 period and $4.2 billion over the FY2004-FY2013 period. As noted above, CMS has estimated that these changes together with other physician payment changes (including the 1.5% increase in the fee schedule conversion factor) would on average, result in no change to payments to oncologists in CY2004.

MMA moved to a new payment methodology in CY2005. Payments are made at 106% of the ASP. Further, the transition adjustment add-on to practice expenses under the physician fee schedule is reduced from 32% in 2004 to 3% in 2005. As noted earlier, CMS estimated the combined fee schedule services and drug payment changes will result in a drop in total revenues of 6% for oncologists, assuming no change in utilization. However, CMS assumes that the recent growth in the volume of drugs and fee schedule services will continue; as a result, it estimates that payments to oncologists will increase by 8%.

On December 1, 2004, the Government Accountability Office (GAO) issued a report on Medicare Payments to Oncologists.[28] This report estimated that payments for drug administration services would be 130% higher in 2005 than they were in 2003, assuming no changes in utilization. Payments for drugs would decline over the period; however, it expected these payments to exceed acquisition costs by 22% in 2004 and 6% in 2005. It should be noted that the estimates for administration services did not include the impact of coding changes announced in the final fee schedule or the one-year demonstration project, both of which will further increase payments.

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[28] U.S. Government Accountability Office, *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Provider's Costs*, GAO-05-142R, Dec. 1, 2004.

Oncologists' Response. Since passage of MMA, oncologists have voiced concerns about reductions in payments.[29] They were particularly concerned about the potential for large reductions in 2005. In response, CMS took several actions which were designed to increase 2005 payments, including the coding changes and the demonstration project.

Despite the CMS changes and the findings of the GAO report, some oncologists continue to voice concerns. They suggest that some of the data used in the GAO report is flawed. More generally, they have stated that ASP information will be tilted toward what large purchasers are able to negotiate directly with manufactures, not what individual physicians or physician practices can obtain from wholesalers. Further, they note that wholesalers often include a markup in their pricing. As a result, they suggest that Medicare payments may be insufficient to cover their costs.

In its proposed rule issued August 5, 2004, CMS responded to these concerns. It stated its understanding that many physicians are part of purchasing groups which obtain discounts on drugs; it encouraged more physicians to consider participating in such arrangements. CMS further requested comments on the extent to which physicians can become members of buying groups and the effects of doing so. In the final regulation, CMS noted that the OIG is conducting a MMA-mandated study, due by October 1, 2005, on the ability of different size practices to obtain drugs at 106% of the average sales price. In addition, CMS itself is conducting another MMA-mandated study on sales of drugs to large volume purchasers.

CMS notes that it plans to continue to monitor any shifts or changes in utilization patterns. It should also be noted that MMA required MedPAC to review payment changes made by Section 303 of MMA with an emphasis on quality, beneficiary satisfaction, adequacy of reimbursement, and impact on physician practices. The study is due January 1, 2006.

Pharmacy Supplying Fee

MMA required the Secretary to pay a supplying fee to licensed pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs and oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. MMA did not specify that this must be a separately identifiable payment.

In the preamble to the January 7, 2004 fee schedule regulation, CMS stated that payment of this fee should be bundled into the 2004 payment amounts. CMS therefore, did not pay a separate amount in 2004. Some observers contended that the 2004 decision was contrary to the intent of the MMA requirement. As noted earlier, CMS's proposed rule for 2005 recommended a supplying fee of $10, a level below that recommended by some observers. The final rule raised the level to $24 for 2005.

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[29] Reportedly some oncologists suggested to their patients that they might no longer be able to provide their services in office settings, thereby forcing patients to return to hospitals. (Gardner Harris, "Among Cancer Doctors, a Medicare Revolt; New Payment System Spurs Talk of Return to Hospital Care and Old Drugs," *New York Times*, Mar. 11, 2004, p. C-1.)

Beneficiary Cost-Sharing

An issue of concern to policymakers was the inordinately high cost-sharing paid by some beneficiaries for covered drugs. Beneficiaries are required to pay 20% of Medicare's recognized payment amount. Inflated AWPs led to inflated beneficiary copayments. Some referred to this as the "cancer tax." Since drug payments are lowered under MMA, beneficiaries should see lower drug cost-sharing.

Relationship to New Part D Drug Benefit

MMA establishes very specific rules for payment of covered Part B drugs. The legislation takes a different approach with respect to the drugs covered under the new prescription drug benefit established under the new Medicare Part D program.

Under Part D, effective January 1, 2006, beneficiaries will voluntarily enroll with private prescription drug plans or Medicare Advantage organizations to obtain their drug benefits. These private plans will negotiate prices with drug manufacturers and pharmacies. MMA prohibits the Secretary from interfering with these negotiations. It also prohibits the Secretary from requiring a private plan to have a particular formulary. Further, the Secretary may not institute a price structure for the reimbursement of covered Part D drugs.

When Part D becomes effective in 2006, it will be important to distinguish those drugs paid under Part B and those paid under Part D, since drugs currently paid under Part B will continue to be paid under that part of the program. Both payment rules and beneficiary cost-sharing requirements will differ between the two programs.

Prospects

As of this writing, it is unclear whether the Congress will consider Medicare legislation this year. The most likely change would be an amendment to prevent a reduction in physician payments slated to go into effect in 2006. At the same time, the Congress might, if any problems have been identified, look at technical modifications to the ASP system or the new competition program.

Appendix A. Past Efforts to Address Medicare Payment Issues

Legislative and Administrative Activity

The question of what should be the appropriate payment amount for drugs covered under Medicare was a focus of discussion for a number of years. In 1991, the Health Care Financing Administration (HCFA, now CMS) issued regulations to pay for drugs based on the lower of the estimated acquisition cost or the AWP. Reliance on detailed surveys would have been needed to estimate acquisition costs. As a result, the Administration chose to rely on AWPs. In 1997, the President proposed legislation to pay on the basis of actual acquisition cost; physicians would report their actual costs to HCFA instead of relying on survey information. However, instead of this approach, Congress, under BBA 97, specified that payment be based on 95% of AWP rather than acquisition costs. Evidence continued to suggest that program payments were too high. In 1999 and 2000, the Administration recommended that payment should be based on 83% of AWP, an amount that would have reduced the pricing discrepancy. This recommendation was not adopted.[30]

Revised Pricing Information

In the late 1990s, an investigation by the Department of Justice (DOJ) and the National Association of Medicaid Fraud Control Units (NAMFCU) revealed that some manufacturers were reporting inflated AWPs for certain products. As a result, the DOJ and NAMFCU collected actual AWP data, from several wholesale drug catalogues, for approximately 400 drug codes (representing 51 drugs). In February 2000, NAMFCU reported that this information had been given to First DataBank, the company that provided average pricing information to most state Medicaid agencies. First DataBank agreed to use this data to calculate revised AWPs for the 51 drugs and to make this information available to state Medicaid programs. The information was used by a number of states in calculating Medicaid payments.[31]

HCFA also intended that the pricing information be made available and used by Medicare carriers (the entities that process Medicare claims). Particular concern was expressed by oncologists who continued to state that higher payments on the drug side were needed to offset inadequate payments for administration of the drugs. In September 2000, HCFA authorized contractors to use the prices obtained by the DOJ in determining prices for 32 drugs in the survey that were not chemotherapy or clotting factors. While informing carriers about the DOJ pricing data for an

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[30] Letter from Donna Shalala, Secretary of Health and Human Services, to Thomas Bliley, Chairman of the House Commerce Committee, May 31, 2000.

[31] U.S. Department of Health and Human Services, Office of the Inspector General, *Medicaid's Use of Revised Average Wholesale Prices*, OEI-03-01-00010, Sept. 2001. The report noted that of the 30 states using the revised prices, 24 believed there would be short term cost savings. However, some states questioned the long-term impact both because the utilization of the drugs with revised prices was low or utilization for these drugs would shift to other products.

additional 17 drugs related to chemotherapy and clotting factors, it instructed carriers not to use the DOJ data.[32] In light of pending congressional action, HCFA withdrew the authorization in November 2000.[33] BIPA 2000, prohibited the Secretary from implementing any payment reduction for drugs until GAO prepared, and the Secretary reviewed, a report on revised payment methodologies for drugs.

GAO Studies

The GAO issued the required report on September 21, 2001. The report again noted that physicians and pharmacy suppliers were generally able to obtain Medicare-covered drugs at prices significantly below Medicare current payments. For physician-billed drugs the average discount from the AWP ranged from 13%-34%. Even physicians who billed Medicare for low volumes of cancer drugs could also purchase drugs for considerably less than Medicare's payment. GAO also responded to the oncologists concern regarding perceived inadequate payments for the practice expense payments associated with the administration of chemotherapy drugs. The report noted that total payments to oncologists relative to their estimated practice expenses were close to the average for all specialties. GAO noted, however, that HCFA (now CMS) had deviated from the basic methodology for determining practice expense payments for certain services, including chemotherapy administration by nonphysicians in physicians offices. This reduced Medicare's practice expense payments for most chemotherapy administration services.[34] A GAO report issued in October 2001, contained several recommendations relating to the calculation of practice expenses for oncologists.[35] GAO has estimated that if the recommendations had been followed in 2001, payments to oncologists would have been $51 million higher.[36]

The GAO report on drugs also reviewed Medicare payments to pharmacy suppliers. It noted that widely available discounts in 2001 reflected average discounts from the AWP of 78% for ipratropium bromide and 85% for albuterol (the two inhalation therapy drugs accounting for the majority of Medicare payments to pharmacies.) In addition, Medicare pays a monthly dispensing fee to pharmacies for these and some other (but not all) pharmacy supplied drugs.

The GAO report, and subsequent testimony, recommended that CMS take steps to begin reimbursing providers for drugs and related services at levels reflecting provider's acquisition costs using information about actual market transaction prices. The BIPA provision permitted CMS to institute a revised payment policy after it

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[32] HCFA, Program Memorandum Transmittal AB-00-86 (and attachment), Sept. 8, 2000.

[33] HCFA, Program Memorandum Transmittal AB-00-115, Nov. 17, 2000.

[34] U.S. General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost,* GAO-01-1118, Sept. 2001.

[35] U.S. General Accounting Office, *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements,* GAO-02-53, Oct. 2001.

[36] U.S. General Accounting Office, *Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices,* Testimony of Laura Dummit, before U.S. Congress, Senate Committee on Finance, Subcommittee on Health, Mar. 14, 2002.

reviewed the GAO report. However, CMS indicated it would rather work with Congress on developing an alternate payment methodology.

Single Drug Pricer

Prior to 2003, the calculation of the AWP was made by each individual carrier. This led to considerable variation across the country. Beginning January 1, 2003, CMS used the single drug pricer (SDP) mechanism for each Medicare covered drug whose payment allowance was based on 95% of the AWP. Individual fiscal intermediaries and carriers no longer made the AWP determinations. Rather, they relied on the SDP files sent to them by CMS and processed claims on the basis of the price shown on the applicable file. The new policy did not apply to drugs billed to DMERCs (durable medical equipment regional carriers) because DMERC-paid drug allowances were already consistent nationally. The policy also did not apply to hospital outpatient drugs (except blood clotting factors) because the payment allowance for such drugs was determined by a different procedure.