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Medicare: Payments for Covered Part B Prescription Drugs

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Jennifer O'Sullivan
Specialist in Social Legislation
Domestic Social Policy Division

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Summary

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173) added a new voluntary prescription drug benefit under a new Medicare Part D, effective January 1, 2006. Most categories of outpatient drugs used by Medicare beneficiaries are covered under the new Part D. However, there are certain categories of outpatient drugs, listed in the Medicare statute, that have traditionally been paid for under Medicare Part B. These drugs continue to be paid under Part B. 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) that are administered "incident to" a physician's professional service, and drugs necessary for the effective use of covered durable medical equipment.

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). Beginning in 1998, the amount payable was set at 95% of the average wholesale price (AWP); this limit was intended to place some control 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.

MMA revised the way the program pays for Part B drugs. Beginning in 2005, payments for these drugs are based on an average sales price (ASP) payment methodology, which sets payments at the weighted average ASP plus 6%; 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 can be provided through a newly established competitive acquisition program (CAP). In addition, MMA increased the payments for physician practice expenses associated with the administration of covered drugs.

Some observers have expressed the concern that payments under the ASP methodology may not fully cover physicians' costs of acquiring the drugs. However, several recent reports suggest that physicians can obtain the majority of Part B drugs for less than the Medicare payment amount.

The startup date of the CAP program was delayed from January 1, 2006, to July 1, 2006. Observers have noted that despite the fact that the law requires at least two vendors for each competition area, only one vendor is participating during the initial phase. This vendor is serving the entire country. A number of observers have also questioned how many physicians will elect to sign up for the program and meet its requirements. As of this writing, data is not available on the number of physicians who have signed up. Therefore, it is too early to gauge the potential impact. This report will be updated as events warrant.

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Introduction

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173) added a new voluntary prescription drug benefit under a new Medicare Part D, effective January 1, 2006. Most categories of outpatient drugs used by Medicare beneficiaries are covered under the new Part D. However, there are certain categories of outpatient drugs, listed in the Medicare statute, that have traditionally been paid for under Medicare Part B. They continue to be paid under Part B.

MMA revised the way the program pays for Part B drugs. Beginning in 2005, payments for these 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 can be provided through a newly established competitive acquisition program (CAP).

Part B Drugs

Covered Drugs

Medicare Part A (the Hospital Insurance program) and Medicare Part B (the Supplementary Insurance program) cover prescription drugs under certain circumstances. Medicare Part A covers drugs provided in connection with an inpatient stay in a hospital or skilled nursing facility. Medicare's payment to the facility for the inpatient stay covers these costs. Medicare Part B covers drugs provided in connection with outpatient hospital services. In general, the costs for these drugs are packaged with the payment rate for the primary procedure or treatment; in certain cases the drugs are paid for separately.

Medicare Part B also covers the following categories of drugs:

- *Drugs Furnished Incident to Physicians' Services*. This category includes drugs or biologicals that *are not usually self-administered by the patient* and are administered "incident to" a physician's

service.[1] 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.

- *Immunosuppressive Drugs*. Drugs used in immunosuppressive therapy (such as cyclosporin) following discharge from a hospital for a *Medicare-covered* organ transplant.[2]
- *Erythropoietin (EPO).* EPO for the treatment of anemia for persons with end-stage renal disease (ESRD) who are on dialysis. Coverage is available regardless of whether the drug is administered by the patient or the patient's caregiver.
- *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. Oral anti-emetic drugs administered with a particular chemotherapy treatment must be initiated within two hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time.
- *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.
- *Antigens*. A reasonable supply of antigens that have been prepared for a particular patient if the antigens are prepared by a physician, and the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen. Antigens must be administered in accordance with the plan of treatment and by a doctor or by a properly instructed person (who could be the patient) under the supervision of the doctor.
- *Intravenous immunoglobulin (IVIG).* IVIG is an approved pooled plasma derivative for the treatment of primary immune deficiency disease. It is covered when the patient has a diagnosed primary immune deficiency disease, it is administered in the home of the patient, and the physician determines that administration of the derivative in the patient's home is medically appropriate. Items or

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[1] Medicare has always covered prescription drugs that cannot be self-administered. In 2000, Congress 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" is defined as more than 50% of the time for all Medicare beneficiaries using the drug.

[2] 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.

services related to the administration of the derivative are not covered.

The program also pays for supplies that are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals that must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment (e.g., tumor chemotherapy agents used with an infusion pump or heparin used with a home dialysis system).

Medicare also covers the following immunizations:

- *Pneumococcal pneumonia vaccine*. The vaccine and its administration. For coverage purposes, Medicare does not require that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.
- *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.

Most categories of outpatient prescription drugs not covered under Medicare Part B may be covered under the new Medicare Part D program, provided the beneficiary is enrolled in that program.

Spending for Part B Drugs

MMA changes to the calculation of payments for Part B drugs have apparently stemmed the rapid increase in payments under this category. The Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS) reported that expenditures for Part B drugs totaled more than $9 billion in 2005. It noted that while the program covered more than 500 drug procedure codes, the majority of spending was concentrated on a relatively small subset of codes.[3]

Previously, the Medicare Payment Advisory Commission (MedPAC) estimated that Medicare spent approximately $10.34 billion in 2003 on Part B drugs (a 22% increase over 2002). These numbers did not include drugs provided through outpatient departments of hospitals or to end stage renal disease patients in dialysis facilities. In 2003, an estimated $2.8 billion was billed by freestanding dialysis facilities.

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[3] HHS, Office of the Inspector General, *A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005*, OEI-03-05-00430, June 2006.

MedPAC reported that Medicare Part B paid for approximately 450 drugs. However, the top 10 drugs accounted for 56% of the spending in 2003. New drugs were replacing older ones. Of the top 10 drugs, four were approved by the Food and Drug Administration in 1996 or later. Additionally, spending on injectables too new to have received their own payment codes accounted for 4% of Part B drug spending. Further, 13 of the top 20 drugs treated cancer or the side effects associated with chemotherapy.[4]

Part B Payment Rules

As is the case for most other Part B services, Medicare pays 80% of the recognized amount for covered drugs, while the beneficiary is liable for the remaining 20% (known as coinsurance). No balance billing above the recognized amount is permitted.

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 control 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.

MMA revised the way Part B pays for covered drugs. 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 can be provided through a newly established competitive acquisition program (CAP). 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 CAP.

MMA specified that 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.

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[4] Medicare Payment Advisory Commission, *A Data Book: Healthcare Spending and the Medicare Program*, June 2005.

ASP Methodology

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

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 determines the ASP on a quarterly basis. The payment rates are 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.

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.

Implementing regulations for the ASP reporting requirements were issued on April 6, 2004,[5] and revised on September 16, 2004.[6] The physician fee schedule

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[5] HHS, CMS, *Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price for Medicare Part B Drugs and Biologicals*, Interim Final Rule with Comment Period, 69 *Federal Register* 17935, Apr. 6, 2004.

[6] HHS, CMS, *Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price for Medicare Part B Drugs and Biologicals*, Final Rule, 69 *Federal Register* 55763, Sept. 16, 2004.

regulations for 2005[7] and 2006[8] included modifications to the sections relating to payment calculations.

On June 21, 2006, the Centers for Medicare and Medicaid Services (CMS, the agency that administers Medicare) announced the payment amounts for the third quarter of calendar 2006 (which were based on information from the first quarter of 2006). It reported that payment amounts across all drugs and across the top physician administered drugs increased on average (weighted by Medicare expenditures) by slightly over 0.5%. It further noted that preliminary 2005 data for the top physician-administered drugs suggests that overall utilization of these drugs appears to have increased compared with 2004 levels. For 28 out of the top 50 drugs in terms of volume, the payment amounts changed 2% or less, and for 24 of these drugs the change was about 1%. Overall, the payment amounts for 30 of the top 50 drugs increased, while three remained the same. CMS reported that for those drugs with a decrease, competitive forces (such as multiple manufacturers, alternative therapies, new products, recent generic entrants, or market shifts to lower priced products) were a factor.[9]

ASP Calculation

Manufacturers are required to report ASP data to CMS for Part B drugs and biologicals. Reports are due not later than 30 days after the last day of each calendar quarter. Manufacturers report data by 11-digit national drug codes (NDCs) which indicate the manufacturer, product dosage form, and package size of the drug. Manufacturers submit the number of units sold and the ASP for those units.

CMS converts the ASP for each NDC into the average sales price per billing unit (the Health Care Common Procedure Coding System code (HCPCS code)). More than one NDC may meet the definition of a particular HCPCS code. The ASP per billing unit and the number of units sold for each NDC assigned to the HCPCS code are used to calculate a weighted ASP for the code. CMS weights the ASP per billing unit equally for each NDC regardless of package size.

Inspector General Review

MMA included language specifying how to calculate a volume-weighted ASP based on information reported by manufacturers. The reporting unit was the lowest identifiable quantity of the drug (e.g., one milliliter, one tablet). However, the MMA allowed the Secretary, beginning in 2004, to use a different reporting unit. The

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[7] HHS, CMS, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005*; Final Rule, 69 *Federal Register* 66236, Part III, Nov. 15, 2004.

[8] HHS, CMS, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B*; Final Rule, 70 *Federal Register* 70116, Part II, Nov. 21, 2005.

[9] [http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp].

Secretary used his discretion and changed to the amount of the drug represented by the NDC. The amount of the drug represented by one NDC may differ from the amount represented by another NDC.

Recently, the Office of the Inspector General (OIG) of the Department of Health and Human Services issued a report which stated that the method used by CMS is incorrect because it did not use billing units consistently throughout the equation. It stated that although CMS uses billing units to standardize ASPs across NDCs for each HCPCS code, it does not similarly standardize sales volume across NDCs. It further suggested that as a result, CMS reimbursement for the first quarter of 2005 was higher than it should have been for 46% of HCPCS codes, lower than it should have been for 13% of the codes, and no different for the remaining 41%.[10]

CMS responded to the OIG report by stating that it is continuing to look at refinements to the ASP methodology, but has no immediate plans to make changes. CMS further states that prices appear to be stabilizing and beneficiaries' access to care has been maintained during the transition to generally lower drug prices.[11]

Monitoring Widely Available Market Price

The OIG is required to conduct studies, including surveys, to determine the widely available market price of drugs paid for under the ASP provision. Based on these studies and other data, the IG is to compare the widely available market price with the ASP reported by the manufacturer as part of its Medicaid submission. The IG is to report to the Secretary if the ASP exceeds the widely available market price or average manufacturer price (AMP) by a specified percentage. MMA set the percentage at 5% for 2005 and specified that the percentage was to be specified by the Secretary in subsequent years. The Secretary set the percentage at 5% for 2006.

In cases where the percentage is exceeded, the Secretary is to adjust the payment amount for the next calendar quarter. The payment is to equal the lesser of the widely available market price or 103% of the AMP. 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 ASP 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 OIG issued a report on ASPs and AMPs in April 2006.[12] It reviewed volume-weighted ASPs for the first quarter of 2005, which CMS calculated based on

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[10] HHS, Office of the Inspector General, *Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs*, Report OEI-03-05-00310, Feb. 2006.

[11] HHS, OIG, Report OEI-03-05-00310, Appendix E.

[12] HHS, Office of the Inspector General, *Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices*. OEI-03-04-00430, Apr. 2006.

data submitted by manufacturers for the third quarter of 2004. The OIG again stated that the way CMS makes the volume-weighted ASP calculation is incorrect and supported its own alternative approach. It further stated that comparisons between ASPs and AMPs yield different results depending on the method used to calculate volume-weighted ASPs and volume-weighted AMPs. Specifically, this has an impact on whether or not certain drugs meet the 5% threshold. CMS noted that the OIG review was conducted during the initial implementation phase of the ASP methodology. It contended that much of the estimated savings identified in the report did not persist in subsequent quarters and payment limits for many codes have been revised. Again, as it did in response to the February 2006 OIG report cited above, CMS was not proposing to make any immediate changes to its calculations.

The OIG issued a report in June 2006 comparing ASPs and widely available market prices. It analyzed the purchase prices for nine procedure codes for oncology drugs.[13] For five of the nine codes, the volume-weighted ASP (calculated using the CMS methodology) exceeded the widely available market price by at least 5% for the fourth quarter of 2005. For these codes the difference ranged from 17% to 185%. The OIG estimated that Medicare expenditures could be reduced by as much as $67 million in 2006 if the reimbursement codes were lowered to the widely available market price for these codes. It further noted that the estimates did not take into account price discounts which may be offered. The CMS response stated that the report did not note the downward trend in drug prices occurring after the fourth quarter of 2005. However, the OIG stated that widely available market prices for four out of the five procedure codes still exceeded the 5% threshold.

Other Issues Related to ASP

Several additional issues have been raised in connection with the ASP payment methodology.

Concerns of Oncologists. As noted earlier, payments to physicians for oncology drugs have constituted a large portion of Medicare outpatient drug spending. Prior to passage of MMA, drug payments were tied to the AWP. 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, MMA revised the payment methodology for drugs. At the same time, it increased the payments for physician practice expenses associated with the administration of covered drugs.

Following passage of MMA, many oncologists voiced concerns about reductions in drug payments. In response, CMS took several actions which were designed to increase 2005 and 2006 payments. For 2005, there was a demonstration

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[13] HHS, Office of the Inspector General, *A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005,* OEI-03-05-00430, June 2006.

project focusing on three areas of concern for cancer patients: pain, nausea and vomiting, and fatigue. Any practitioner could elect to participate in the demonstration project; those that did were required to provide information describing a chemotherapy patient's status with respect to these three areas. Participating oncologists received $130 per patient per day. In 2006, CMS established a new one-year demonstration focusing on treatment provided to beneficiaries for any of 13 cancers listed as a primary diagnosis. Physicians who report on three measures (focus of service, current disease state, and whether management adheres to clinical guidelines) qualify for an additional $23 in addition to the payment for the service.[14]

Despite the CMS changes, some oncologists continue to voice concerns. They have suggested that ASP information is 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.

Several recent reports suggest that Medicare payments are generally adequate. The OIG issued a report in September 2005 which reviewed Medicare payments to physician practices for the treatment of cancer patients during the first quarter of 2005. It found that physician practices in the specialties of hematology, hematology/oncology, and medical oncology could generally purchase drugs for the treatment of cancer patients at less than the MMA-established reimbursement rates. The OIG based its conclusion on a statistical estimate of average prices paid by physician practices for 39 payment codes that constituted more than 94% of total Medicare allowed amounts for drugs associated for these specialties in 2004. It also based its conclusion on an estimate of the percentage of months that the practices were able to purchase drugs at less than the reimbursement amount. The report noted that regardless of size, physicians could generally purchase most (but not all) drugs within the 39 payment codes at less than the reimbursement amount. However, large practices were able to purchase drugs at greater discounts for more payment codes than smaller practices.[15] A subsequent June 2006 OIG report (discussed above) found that for five of nine codes for oncology drugs, the volume-weighted ASP exceeded the widely available market price by at least 5% for the fourth quarter of 2005.

MedPAC issued a report in January 2006 based on site visits as well as an analysis of carrier claims for the first six months of 2005. It found that Medicare paid less for chemotherapy drugs in 2005 than in 2004, although the volume of drugs provided to beneficiaries increased. As in previous years, physicians tended to substitute newer, more expensive drugs for older products. Although the use of chemotherapy services varied by geographic region, MedPAC found no indication of access problems in any region. While larger practices were able to purchase

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[14] HHS, CMS, *2006 Oncology Demonstration Program: Improved Quality of Care for Cancer Patients Through More Effective Payments and Evidence-Based Care*, Fact Sheet, Nov. 2, 2005.

[15] HHS, OIG, *Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients*, Report to Congress, A-06-05-00024, Sept. 2005.

chemotherapy drugs at lower prices than smaller practices, all could buy most drugs at prices below the Medicare rate, though profit margins were generally low. The report further noted that all physician practices considered the 2005 payment changes significant. Many oncologists responded by cutting costs and increasing efficiency (particularly with respect to drug purchasing activities) finding new sources of revenue (such as imaging) or selecting more profitable patients. Many oncologists also cited the 2005 quality of life demonstration project for ensuring their continued participation in Medicare. However, payments under the demonstration made it difficult for MedPAC to evaluate the effects of the payment changes.[16]

When CMS issued its 2006 third quarter payment amounts in June 2006, it stated that it would continue to support groups representing Part B drug purchasers, especially small and rural purchasers, to help them identify the most favorable drug prices possible.[17]

Intraveneous Immune Globulin (IVIG). A number of observers have expressed concerns about beneficiary access to IVIG drugs which are used to treat patients with cancer or immune disorders. In response, CMS (as part of the physician fee schedule regulations for 2006) established a temporary add-on payment to cover the additional preadministration-related services required to locate and acquire adequate IVIG and prepare for its infusion during a period of market instability. CMS determined that the pricing was adequate and that there was no overall product shortage. However, it noted that with increasing demand and manufacturer allocations of many formulations, physician staff had to expend extra resources on locating and obtaining the products and scheduling infusions. For 2006 only, physician practices are permitted to bill the add-on code. CMS anticipated that working with stakeholders and ongoing market corrections would help to ensure that the marketplace stabilizes over the year.[18]

On June 21, 2006, CMS announced the payment amounts for Part B drugs for the third quarter of 2006; the amount increased 11.9% for lyophilized intravenous immune globulin services (IVIG) (powdered form) and 3.5% for liquid IVIG. At the same time CMS noted that it and other agencies within HHS are continuing to work with stakeholders to better understand the present situation and to assess potential actions that will help to ensure an adequate supply of IVIG and patients receiving appropriate and high quality care. It indicated it would continue to monitor IVIG marketplace developments and beneficiary access to care.[19] Many stakeholders continue to push for reforms to address both payment amounts and access issues; several have suggested making the add-on payment permanent.

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[16] Medicare Payment Advisory Commission, *Effects of Medicare Changes on Oncology Services, Report to the Congress*, Jan. 2006.

[17] [http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp].

[18] HHS, CMS, *CMS Announces Payment Update and Policy Changes for Medicare Physician Fee Schedule*, Press Release, Nov. 2, 2005.

[19] [http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp#TopOfPage.].

Supplying and Dispensing Fees

Under certain circumstances the program will pay a supplying or dispensing fee. MMA required the Secretary to pay a supplying fee (less the applicable deductible and coinsurance amounts) to pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs and oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. For 2006, CMS established a fee of $24 for the first prescription in a 30-day period ($50 for immunosuppressives furnished during the first 30-day period following a covered organ transplant) and $16 for each subsequent prescription during such period.

The program covers 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, i.e., inhalation drugs. For 2006, CMS established a dispensing fee of $57 for a 30-day prescription for the first time the beneficiary uses inhalation drugs and $33 for other months. In addition, the program will pay a 90-day dispensing fee of $66.

Competitive Acquisition Program

MMA Provisions

MMA required the Secretary to implement a competitive acquisition program (CAP) beginning in 2006. The intent of the program was to enable physicians to acquire certain drugs from an approved CAP vendor thereby enabling them to reduce the time they spend buying and billing for drugs. At the same time, it was expected that competition among vendors would reduce prices thereby reducing Medicare costs.

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

The Secretary was required to establish categories of competitively biddable drugs and biologicals. The Secretary was to phase-in categories beginning in 2006, in such manner as the Secretary determined appropriate. The Secretary could exclude drugs and biologicals from the competition program if the application to such drugs

or biologicals was not likely to result in significant savings or would have an adverse effect on access.

Contracts. The Secretary was to conduct a competition among entities for the acquisition of competitively biddable drugs and biologicals. For multiple source drugs, the Secretary would 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 found that it met certain requirements. The entity had to have sufficient capacity to supply the drugs or biologicals in the area specified in the contract. The entity had 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 was required to establish procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding shipments. The Secretary was also to specify standards for a grievance and appeals process for the resolution of disputes.

Contracts would be awarded for three years. The Secretary could limit the number of contractors to two in any category and area. The Secretary would 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 specified by the Secretary. The amount of the bid for any drug or biological was to be the same for all portions of an area. Bidders would be permitted, but not required, to submit bids for all areas of the United States. Bids would be confidential.

Contractor Requirements. A contractor would be required to disclose to the Secretary its reasonable acquisition costs. The contract would 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 would be acquired directly from a manufacturer or from a distributor that acquired the items directly from the manufacturer. Contractors would be required to comply with product safety safeguards determined appropriate by the Secretary. They would also be required to comply with code of conduct and fraud and abuse rules.

Contractors could 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 would not be required to submit a prescription for each individual treatment, nor would a physician's flexibility be changed in terms of writing a prescription.

The Secretary was required to establish rules under which drugs or biologicals acquired through a contractor could be used to resupply inventories if physicians could demonstrate that the drugs or biologicals were 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 were to be based on bids submitted and accepted. The Secretary was to determine a single amount for each competitively biddable drug or biological in the area. The Secretary was to establish special payment rules for new products for which a payment and billing code had not been established. If the Secretary excluded a drug or biological under the competition program, payment would be made under the ASP methodology.

There would be 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. MMA required the Secretary to submit a report to Congress on the competitive acquisition program by July 1, 2008. The report would 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 ASP system.

Implementation

Implementation of the CAP program has been somewhat slower than originally anticipated.

Program Development. CMS issued proposed rules on March 4, 2005[20] and an interim final rule with comment period on July 6, 2005.[21] At that time, it was expected that the bidding by potential vendors would begin July 6, 2005 and close August 5, 2005.[22] However, effective August 3, 2005, CMS suspended bidding due to concerns raised by various stakeholders. One issue was the fact that CMS indicated that CAP prices would be used in the calculation of ASP prices (under the ASP methodology discussed above). Another concern was that under the rule, vendors would be reimbursed only for the portion of drugs administered by the physician, not for the entire amount shipped. In some cases, not all of a drug in a vial is used, but must be disposed of under state pharmacy laws.

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[20] HHS, CMS, *Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B*; Proposed Rule, 70 *Federal Register* 10746, Mar. 4, 2005.

[21] HHS, CMS, *Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B*; Interim Rule, 70 *Federal Register* 39022, July 6, 2005.

[22] HHS, CMS, *CMS Offers New Option for Physicians Who Administer Drugs in Their Offices*, Press Release, June 27, 2005.

On September 6, 2006, CMS issued an interim final rule[23] stating that the election period would begin in the spring of 2006 with the program beginning on or around July 1, 2006. It stated that this would allow more time for refining CAP operations, additional testing of the claims processing system, and further educational activities.

In November 2005, CMS announced refinements to the CAP program; most were included in the final physician fee schedule issued November 21, 2005.[24] This regulation established processes for vendors to furnish additional drugs and newly approved drugs under the CAP. It also provided for more consistency between CAP policy and Part B drug policy on unused drugs. Specifically, CMS will consider the unused portion remaining in a single use vial to have been administered provided: (1) the CAP physician has made good faith efforts to minimize the unused portion of the drug in scheduling patients and ordering and administering the drug; and (2) the CAP vendor made good faith efforts in how it supplied the drug. Corrections to the November 2005 regulation were published February 24, 2006.[25]

A separate notice also issued on November 21, 2005,[26] specified that vendor purchases made under the CAP program would not be taken into account for purposes of calculating the ASP for drugs paid under the ASP methodology.

Key Regulation Features. Under the final rule, physicians are given the opportunity once a year to elect to participate in the program and select a vendor. The vendor is to 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 are to be the same as those made to physicians who purchase the drugs.

Vendors wishing to participate are required to submit bids, with winning bidders selected based on bid price. Successful vendors are awarded a three-year contract and are required to meet certain standards. They must have sufficient means to acquire and deliver competitively biddable drugs within the contract area. They must have arrangements in effect for shipping at least five days each week for the

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[23] HHS, CMS, *Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B*; Interim Final Rule, Interpretation and Correction, 70 *Federal Register* 39022, July 6, 2005.

[24] HHS, CMS, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B*; Final Rule, 70 *Federal Register* 70116, Part II, Nov. 21, 2005.

[25] HHS, CMS, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B*; Correcting Amendment, 71 *Federal Register* 9458, Feb. 24, 2006.

[26] HHS, CMS. *Medicare Program; Exclusion of Vendor Purchases Made under the Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B for the Purpose of Calculating the Average Sales price (ASP)*, Interim final Rule with Comment Period, 70 *Federal Register* 70478, Nov. 21, 2005.

competitively biddable drugs and means to ship in emergency situations. They must meet standards relating to quality, service, financial performance and solvency. They must also have a grievance and appeals process for dispute resolution.[27]

CAP vendors are required to submit bids on at least one drug in each HCPCS code in each drug category (such as drugs "incident to" physicians' services). CMS has stated that it does not contemplate creation of a formulary-like process. It expects that the program would provide an incentive for vendors to include a broad selection of drugs within individual codes, since physicians are unlikely to select vendors who offer unduly restrictive choices within codes.

Payments under the program are based on submitted bids with a single payment amount established for each CAP drug in the competitive acquisition area, updated from the bid period to the payment year. The payment amount for a drug category cannot exceed the weighted amount determined under the ASP methodology for that drug category. Payments are generally updated annually.

CAP vendors are required to collect the deductible and coinsurance from the beneficiary. However, this cannot be done until the vendor has received Medicare payment for the drug (unless the CAP vendor has entered into an agreement with the physician to collect, in its behalf, the deductible and coinsurance at the time the drug is administered). Further, if the beneficiary has supplemental insurance, the CAP vendor must wait until payment from the supplementary insurer has been received to determine if the beneficiary owes any additional amount.

Physicians participating in the program must agree to a number of conditions; they are required to: (1) share information with the CAP vendor to facilitate the collection of deductibles and coinsurance; (2) file drug administration claims within 14 days of administering the drug; (3) pursue appeals, on a timely and appropriate basis for CAP claims that are denied for medical necessity issues; (4) accept assignment for CAP drug administration claims; (5) notify the CAP vendor when a CAP drug is not administered; (6) agree to comply with emergency drug replacement rules; (7) agree to the requirements of the "furnish as written" (FAW) provision (under which FAW may be used to furnish a patient with a therapy not provided by the CAP vendor, provided appropriate medical necessity documentation is submitted); (8) maintain an inventory for each CAP drug obtained; and (9) provide a copy of the CMS CAP Beneficiary Fact Sheet during the patient's first visit following the physician's participation in CAP.[28]

When members in a group practice bill Medicare using the group's physician identification number (PIN) or National Provider Identifier (NPI), they must commit as a group to participate in CAP. A physician wishing to participate apart from the group must not have reassigned his or her benefits to the group and must be billing using his or her own PIN or NPI.

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[27] [http://www.cms.hhs.gov/CompetitiveAcquisforBios/03_infovendors.asp#TopOfPage.].

[28] [http://www.cms.hhs.gov/CompetitiveAcquisforBios/02_infophys.asp#TopOfPage.].

2006 Program. For 2006, there is a single national distribution area which includes all 50 states, the District of Columbia, and the territories. The 2006 program applies to the single drug category consisting of drugs commonly provided "incident to" a physician's service. CMS states that this drug category, which includes over 180 drugs, represents 85% of Medicare drug spending for injectable drugs. Drug administration claims will continue to be paid by the Medicare Part B carrier, while CAP vendors will be required to submit the drug claims to the designated carrier which is Noridian Administrative Services.

On April 21, 2006, CMS announced that BioScrip had been selected as the single vendor for the initial phase of the CAP program.[29] Physicians wishing to participate must file an election form. On May 5, 2006, CMS announced that the physician election period would run from May 8 through June 2, 2006; program participation would begin July 1, 2006. On May 31, 2006, CMS announced an extension to the election period. Physicians who had completed their forms by June 2, 2006 would still begin their CAP participation on July 1, 2006. Physicians who completed their forms during the extension period, which ran from June 3 through June 30, 2006 would begin participation in the CAP on August 1, 2006.

As of this writing, it is not clear what portion of Part B drug claims will be paid under the CAP program. Observers have noted that despite the fact that the law requires at least two vendors for each competition area, only one vendor is participating during the initial phase. This vendor is serving the entire country. A number of observers have also questioned how many physicians will elect to sign up for the program and meet its requirements. As of this writing, data is not available on the number of physicians who have signed up for the program. Therefore, it is too early to gauge the potential impact.

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[29] HHS, CMS, *New Competitive Acquisition Program for Drugs Administered in a Physician's Office Selects Vendor*, Press Release, Apr. 21, 2006.