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Report for Congress

Medicare: Payments for Covered Prescription Drugs

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Medicare: Payments for Covered Prescription Drugs

Summary

Medicare does not cover most outpatient prescription drugs. However, a few categories of drugs, listed in the Medicare statute, are specifically paid for under the 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, and drugs (which are not self-administered) which are administered "incident to" a physician's professional service.

Payment for covered outpatient prescription drugs is made under Medicare Part B. The Balanced Budget Act of 1997 (BBA 97) specified that the amount payable would equal 95% of the *average wholesale price (AWP).* 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).

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

There is widespread agreement that the existing payment system needs to be reformed. Observers generally agree that Medicare payments should be brought more in line with market prices that providers actually pay to acquire the drugs. The key issue in designing a new drug payment system is what should serve as the basis for payment. Options include using actual sales price, estimated acquisition costs, actual acquisition cost, or a fee schedule. An alternative approach would use competitive bidding. Under a competitive bidding plan, contract entities such as pharmacy benefit managers, wholesalers, and distributors would bid on a confidential and competitive basis to supply some or all of Medicare-covered drugs. The reimbursement amount would be the average of bids. Physicians and pharmacy suppliers would conduct their own negotiations with any of the bidders selected. Medicare would pay the average price; physicians or suppliers could keep any difference between this price and the price negotiated with the contractor. The competitive bidding approach is reportedly under consideration by the House Ways and Means Committee.

It is likely that any AWP reform legislation would be included in a larger Medicare bill. The two House committees of jurisdiction (Ways and Means and Energy and Commerce) are currently developing a bill; it is expected that the House will consider the legislation early the summer of 2002. The Senate schedule is less clear. At this time it is difficult to predict what final form any legislation might take. This report will be updated when legislative action occurs.

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Introduction

Covered Drugs

Medicare does not cover most outpatient prescription drugs. 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 *cannot be self-administered*. 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:[1]

- *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 chronic renal failure who are on dialysis.
- *Oral Anti-Cancer Drugs*. Drugs taken orally during cancer chemotherapy providing 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.[3]

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[1] For a discussion of prescription drug coverage for Medicare beneficiaries, see: CRS Report RL30819, *Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues*, by Jennifer O'Sullivan.

[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) 3 years after a successful kidney transplant.

[3] Medicare also pays for an injectable osteoporosis drug approved for treatment of post-

(continued...)

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 General Accounting Office (GAO) reports that Medicare covers approximately 450 outpatient drugs under these categories. However, 35 drugs accounted for 82% of Medicare spending and 95% of claims in 1999. There are three major categories of Medicare spending: 1) drugs billed by physicians and typically provided in physicians offices (such as chemotherapy drugs); 2) drugs, billed by pharmacy suppliers, which are administered through durable medical equipment (DME), such as respiratory drugs given through a nebulizer; and 3) drugs, billed by pharmacy suppliers, which are patient administered (such as immunosuppressive drugs and some oral cancer drugs). Physician-supplied drugs account for the largest share of spending (over 75% in 1999) while pharmacy-supplied drugs account for the largest billing volume (more than 80% in 1999). Three specialties (hematology oncology, medical oncology, and urology) accounted for 80% of physician billings in 1999 while two inhalation therapy drugs (ipratropium bromide and albuterol) accounted for 88% of pharmacy billings.[4] The distribution of spending and billing patterns reflects the limited nature of Medicare's outpatient drug benefit.

Payment Rules

In General. Payment for covered outpatient prescription drugs is made under Medicare Part B. The Balanced Budget Act of 1997 (BBA 97) specified that the amount payable would equal 95% of the *average wholesale price (AWP)*. It did not, however, define AWP. 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). The Centers for Medicare and Medicaid Services (CMS,

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[3] (...continued)
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.

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

the agency that administers Medicare) reports that payments for covered drugs currently total about $5 billion a year (including beneficiary coinsurance).[5]

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.

Issues

Medicare payment is 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.

Prices

The prices Medicare pays for drugs are frequently 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 are 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 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 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.[6]

In March 2002, the OIG issued reports focusing on two nebulizer drugs, which, as noted above, account for the majority of pharmacy billings. The first report found

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[5] Centers for Medicare and Medicaid Services. *Reimbursement and Access to Prescription Drugs Under Medicare Part B.* Testimony by Thomas Scully before Senate Committee on Finance, March 14, 2002.

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

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.[7] 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.[8]

Many observers agree that Medicare pays more than other large purchasers for covered drugs. However, a number of these observers caution against using the VA's payments as a basis for Medicare payments. They note 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.

Implications for Physicians and Beneficiaries

The use of AWPs has come under increasing scrutiny in recent years. In the last year, hearings have been held in both the House and Senate on the issue. These hearings have highlighted the impact of inflated prices on beneficiaries as well as the Medicare program itself.

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

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

One practice was the subject of considerable concern. Some manufacturers are reportedly using inflated AWPs as a marketing device to increase market share. Physicians and suppliers do not pay the inflated AWP but they are 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 gets to keep. It is thought that some physicians and suppliers may choose the drug with the higher "spread." While the manufacturer does not receive a higher amount for each unit of the drug product, it does increase market share and thus overall drug company profits.[9]

Another concern is 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 results in a higher beneficiary copayment. In some cases the copayment amount may 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 recognize that Medicare payments for drug products are in excess of their actual acquisition costs. However, they claim that Medicare pays too little for the practice costs associated with administering the oncology drugs. They contend that they have been forced to use the higher drug payments to offset inadequate reimbursement for practice expenses. These oncologists contend that the calculation of their practice expenses under the physician fee schedule is flawed. They object to any changes in the AWP calculation until changes are made in the practice expense calculation. (See discussion below.)

Medicaid Implications

The use of an inflated AWP also has implications for Medicaid, the federal-state health insurance program for certain low-income persons. All states offer outpatient prescription drug coverage for at least some Medicaid beneficiaries and many offer it to all program recipients. Federal Medicaid regulations specify that total spending on a particular drug must fall below "upper payment limits." Within this limitation, states have considerable latitude in setting their payment formulas. Most use AWP less some percentage for most covered drugs. In addition, manufacturer rebates are required.[10]

The OIG recently completed an eight-state review of pharmacy acquisition costs for generic drugs reimbursed under Medicaid. The OIG compared invoice prices with the AWP for 1999. As a result of this review, it estimated that the actual

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[9] U.S. Department of Health and Human Services. Office of the Inspector General. Testimony by Janet Rehnquist before Senate Committee on Finance, March 14, 2002.

[10] For a discussion of Medicaid reimbursement for prescription drugs, see: CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*, by Jean Hearne.

generic acquisition cost was a national average of 65.93% below AWP. This represented a 55.31% increase over the 1994 estimate of a 42.45% discount. It further estimated that, if Medicaid payments had been based on the discounted percentages, the program could have saved as much as $470 million for the 200 generic drugs with the greatest amount of Medicaid reimbursement in 1999.[11]

The OIG also looked at reimbursement for pharmacy acquisition costs for brand name drugs in 1999. It estimated that nationally pharmacy acquisition costs were an average of 21.84% below AWP. This represented a 19.3% increase over the 18.30% average discount recorded in 1994. It further estimated that Medicaid could have saved as much as $1.08 billion if reimbursement had been based on the discounted amount.[12]

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 has been 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.[13]

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 provides average pricing information to most state Medicaid agencies.

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[11] U.S. Department of Health and Human Services. Office of the Inspector General. Testimony by Janet Rehnquist before Senate Committee on Finance, March 14, 2002.

[12] Ibid.

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

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 is currently used by a number of states in calculating Medicaid payments.[14]

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 additional 17 drugs related to chemotherapy and clotting factors, it instructed carriers not to use the DOJ data.[15] In light of pending congressional action, HCFA withdrew the authorization in November 2000.[16] Benefit Improvement and Protection Act of 2000, enacted December 21, 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 are 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.[17] A GAO report issued in October 2001, contained several recommendations relating to the

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[14] 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, September 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.

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

[16] HCFA, Program Memorandum Transmittal AB-00-115, November 17, 2000.

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

calculation of practice expenses for oncologists.[18] GAO has estimated that if the recommendations had been followed in 2001, payments to oncologists would have been $51 million higher.[19]

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 permits CMS to institute a revised payment policy after it has reviewed the GAO report. However, Tom Scully, Administrator of CMS has stated that he would rather work with Congress on developing an alternate payment methodology. However, if Congress does not act, CMS will develop its own approach.[20]

Options

There is widespread agreement that the existing payment system needs to be reformed. Observers generally agree that Medicare payments should be brought more in line with market prices that providers actually pay to acquire the drugs. These price determinations should reflect discounts. However, efforts to design an alternative system have been hampered by a number of factors.

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

A key issue in designing the new drug payment system is what should serve as the basis of payment. Underlying this central issue are 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

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

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

[20] Centers for Medicare and Medicaid Services. *Reimbursement and Access to Prescription Drugs Under Medicare Part B.* Testimony of Thomas Scully before Senate Committee on Finance, March 14, 2002.

would need to collect and verify. As noted, in the early 1990s the Administration chose not to use estimated acquisition prices because of the need to rely on detailed surveys. A number of approaches currently under consideration may also require both that manufacturers and/or physicians provide, or have available, more information than they do now and that CMS (through its contractors) obtain and verify such information.

A variety of options are under consideration. Some of the major modifications being considered include the following:[21]

- *Competitive Bidding System*. This approach is reportedly being considered by the House Ways and Means Committee. Contract entities such as pharmacy benefit managers, wholesalers, and distributors would bid on a confidential and competitive basis to supply some or all Part B covered items. The bid would include the dispensing fees. The reimbursement amount would be the average of bids, though CMS could exclude the high bids from the calculation. Providers would conduct their own negotiations with any of the bidders selected. CMS would pay the average price; physicians keep any difference between this price and the price negotiated with the contractor. Proponents of this approach argue that providers seeking good deals would drive market share to those entities securing the largest discounts from manufacturers.[22] GAO reports that preliminary results from a competitive bidding demonstration in Texas for nebulizer drugs shows no reported problems with access and a savings of about 26%. However, it also noted that competitive bidding might not be appropriate for all drugs, such as some chemotherapy drugs, which have few or no therapeutic equivalents.[23]

- *Average sales price*. Manufacturers would report an average sales price to CMS. This price would reflect manufacturer provided rebates, chargebacks and other discounts to purchasers. A letter outlining this approach was sent, in November 2001, to Thomas Scully, Administrator of CMS, by Congressmen Tauzin, Bilirakis, and Greenwood of the House Energy and Commerce Committee. They stated that this approach would provide a more accurate measure of providers true acquisition costs. A mechanism would need to be established both for reporting prices and verifying the pricing information.

- *Estimated acquisition costs based on average manufacturer price (AMP)*. AMPs are currently reported to CMS under the Medicaid drug rebate program. However, by law, the information is confidential and Medicare does not have

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[21] Several of these options were outlined in: U.S. Department of Health and Human Services, Office of Inspector General. Testimony of George Grob before Subcommittee on Health and Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, September 21, 2001.

[22] BNA's Health Care Daily Report. Competitive Bidding Model Is Heart of Ways and Means Part B Drug Proposal, April 12, 2002.

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

access to this information. The Inspector General's Office has noted that if this option were selected, an initial intensive effort should be made to validate the accuracy of the information.[24]

- *Actual acquisition costs*. The intention would be to pay the doctor or supplier what it cost them to obtain the drug. However, the only way to verify this information would be to obtain invoices, which would involve considerable paperwork and validation.

- *Fee schedule*. The FSS used by the Veteran's Administration could be used for Medicare. However, as noted earlier, the VA, unlike Medicare, purchases drugs for its healthcare system directly from manufacturers or wholesalers. Therefore, if this approach were used, the payment amount might be set at the FSS amount plus a certain percentage. It is not clear what the implications of this approach would be on the continued ability of the VA to negotiate comparatively low payment amounts for its own programs.

Prospects

While the Administration could make changes to the AWP mechanism administratively, it would prefer that the changes be made legislatively. It is likely that any AWP reform legislation would be included in a larger Medicare bill. The two House committees of jurisdiction (Committee on Ways and Means and Committee on Energy and Commerce) are currently developing a bill; it is expected that the House will consider the legislation in the summer of 2002. The Senate schedule is less clear. At this time it is difficult to predict what final form any legislation might take.

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[24] U.S. Department of Health and Human Services. Office of the Inspector General. Testimony of George Grob before Subcommittee on Health and Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, September 21, 2001.