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Issues Related to Possible Coverage of Outpatient Prescription Drugs Under Medicare

Statement of
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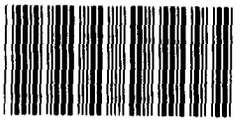
Before the
Subcommittee on Health
Committee on Ways and Means
House of Representatives



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Summary

Although Medicare currently does not cover outpatient prescription drugs that are self-administered, the Health Care Financing Administration has considerable experience with outpatient drug financing through its role as federal administrator of the Medicaid program. Thus, GAO does not see a lack of experience as a major hurdle to establishing a prescription drug program under Medicare.

Medicaid pays the lower of charges to the general public or the cost it estimates the pharmacy paid for drugs plus a dispensing fee. GAO would support this way of determining a reasonable price for drugs under Medicare.

However, Medicaid has had problems in estimating the cost of dispensed drugs. Historically, states have tended to use "average wholesale prices" as listed in several compendiums. HCFA and the HHS Inspector General have stated that these average wholesale prices exceed pharmacies' actual cost by an average of 15 to 18 percent.

As with any health financing benefit, there is potential for fraud and abuse under a Medicare prescription drug program. However, current law provides substantial penalties for fraud and abuse. GAO believes that the deterrent effect of the penalties already in law, combined with an adequate level of auditing/investigation, would permit fraud and abuse to be controlled.

GAO believes that the Congress should consider a number of other issues related to Medicare prescription drug coverage, including

-- whether Medicare or Medicaid would be primarily responsible for paying for drugs for individuals eligible for both programs;

-- how the allowable costs of prescriptions purchased before beneficiaries meet a drug deductible would be determined; and

-- whether pharmacies would have to accept assignment as a condition of participating in the program.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss issues related to the establishment of outpatient prescription drug coverage under Medicare. You asked that I discuss what we have learned in reviewing the prescription drug benefit under Medicaid and how those lessons could be applied to Medicare. You also asked that we specifically address fraud control and raise any issues that we believed the Subcommittee should consider in designing a Medicare drug benefit.

We believe that Medicaid's experience under its prescription drug program provides a good base of information for designing a program for Medicare. Medicaid has experienced some fraud and abuse in its drug program. Current Medicare law provides substantial penalties for fraud and abuse, and state pharmacy laws and Medicare law require record keeping that provides the evidence necessary to prosecute fraud and abuse. We believe that the deterrent effects built into the current law, combined with adequate review and audit of claims and enforcement action, should enable fraud and abuse to be controlled.

DOES HCFA HAVE EXPERIENCE WITH FINANCING OUTPATIENT DRUGS?

Because Medicare currently does not cover outpatient prescription drugs that can be self-administered, except for the recently enacted coverage of immunosuppressant drugs, the program has virtually no experience with financing outpatient drugs. However, many of the carriers that process other types of Medicare outpatient claims generally do have experience with paying for prescription drugs under their commercial lines of business. Moreover, the Health Care Financing Administration (HCFA), which administers Medicare, has had substantial experience with financing outpatient drugs through the Medicaid program. All but two of the states have elected to cover prescription drugs under Medicaid. HCFA has established guidelines and procedures for the states to use in administering

prescription drug programs and has helped states develop computerized management information systems to pay claims for drugs and manage the drug program.

Because of HCFA's and the carriers' experience with administering outpatient prescription drug programs, we do not see a lack of experience as being a major hurdle to establishing prescription drug coverage under part B of Medicare. Of course, HCFA and the carriers would need some time to institute the computer programs and other operational changes necessary to process claims.

HOW CAN REASONABLE PRICES FOR PRESCRIPTION DRUGS BE DETERMINED?

Our past work on the Medicaid prescription drug program has shown that determining a reasonable price for drugs can be difficult. Most states pay for drugs at the lower of charges to the general public or the pharmacists' cost of the drug plus a dispensing fee. The first limit--charges to the general public--is designed to assure that Medicaid does not pay more for a drug than someone walking into a drugstore would. The program also simplifies billing for the drugs because the pharmacy merely includes its usual charge for the drug on the Medicaid claim and does not have to maintain a special charge list for Medicaid. For these reasons, we would support the "charges to the general public" limit for any Medicare program that might be enacted.

We also believe that the second payment limit--cost of drug plus a dispensing fee--is a valid check on the reasonableness of pharmacy charges. However, problems can arise in determining the amount at which to set the limit. In effect, Medicaid tries to estimate what the pharmacist paid for the dispensed drugs, adds a dispensing fee to compensate the pharmacy for its costs (building, utilities, labor, etc.) and to pay it a reasonable

profit, and compares the resulting amount to the billed charges, paying the lower of charges or estimated costs plus profit.

States are supposed to set their dispensing fees based on surveys of pharmacy costs or similar data. Over the years pharmacies and their associations have complained that particular states' dispensing fees were unreasonably low. We have not assessed the validity of these complaints.

In 1986 Medicaid dispensing fees ranged from $2.00 to $5.12 per prescription. Thus, there is a wide variation in the levels used by the states. However, a well-designed survey of pharmacy costs should enable Medicare to set reasonable dispensing fees if a drug program is enacted.

Estimating the pharmacy's cost of the dispensed drug to preclude overcompensating the pharmacy is more difficult. Historically, many states have used average wholesale prices (AWPs) as listed in the Redbook or Bluebook--two compendiums of drugs listing prices by manufacturer, dosage form, and quantity--as the estimate of pharmacies' drug costs. But AWPs do not reflect many types of discounts and rebates available to pharmacies and, thus, tend to overstate pharmacies' drug costs. In the mid-1970's, the Department of Health and Human Services (HHS) estimated that AWPs overstated actual costs by 15 to 18 percent. A 1984 HHS Inspector General's report on the Medicaid drug program estimated that AWPs for the drugs in the sample exceeded actual costs by an average of about 16 percent.

Another problem related to pricing is that the Food and Drug Administration has determined that a number of manufacturers and suppliers sell therapeutically equivalent formulations of many

drugs.[1] In these cases, the main difference between the various "brands" of the drugs is price, and often the price varies widely. HCFA has taken action to attempt to assure that, in such cases, Medicaid does not pay the price of expensive brands of therapeutically equivalent drugs by establishing an upper limit on payments based on the cost of the lowest priced brand that is widely and consistently available. This limit is called the maximum allowable cost (MAC). But such limits have been established only for a small number of drugs, and none have been added to the MAC list since 1982. The process for adding drugs to the list and for updating MACs is cumbersome and time consuming, which at least partially explains the lack of use of the MAC program.

In the final analysis, the question of how much to pay for a drug comes down to the degree of assurance desired that the pharmacy is not overcompensated and that the program does not pay for expensive brand name drugs when therapeutically equivalent generics are available. The better the estimate of what the pharmacy pays for a drug, the more assurance the pharmacy is not overpaid. And the more incentives to dispense lower cost drugs, or only paying the price of lower cost drugs, the more assurance that high priced drugs are not paid for when equivalent, lower cost ones are available.

WHAT IS THE POTENTIAL FOR FRAUD AND ABUSE?

You asked us to address the potential for fraud and abuse under a Medicare outpatient drug program. As with any component

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[1]Often when a drug is introduced, the original manufacturer has a patent on it and sells it under a brand name. When the patent expires, other manufacturers or suppliers often sell the drug under its chemical name--called generic drugs--or under their own brand names--called branded generics. Generally speaking, generic drugs cost pharmacies less than brand name drugs.

of a health insurance program, there is potential for fraud and abuse. However, Medicare already contains provisions providing criminal and civil penalties for fraud and abuse, and the Congress is working on legislation to further strengthen these provisions.

Under Medicaid, the primary problems with fraud and abuse in the drug program have been

-- charging for brand name drugs when lower priced generic drugs were dispensed and

-- billing for services not rendered.

States normally require pharmacies to retain prescription forms and other records on drugs purchased and dispensed. If Medicare were to cover prescription drugs, current Medicare law would make such records available to the program. The current record requirements, combined with the severe penalties for defrauding or abusing Medicare, should act as strong deterrents to fraud and abuse. In addition, the record-keeping requirements make it relatively easy to investigate cases of suspected fraud. For these reasons, we believe that, with an adequate auditing/ investigative effort to give meaning to the deterrent built into law, fraud and abuse by pharmacies could be controlled.

OTHER ISSUES FOR CONSIDERATION

How Would Beneficiaries in Nursing Homes Be Affected?

Most nursing home patients are eligible for Medicare, and many of them are also covered by Medicaid. Drug costs for nursing home patients can be substantial. While relatively few nursing home patients have their nursing home "room and board" bills paid by part A of Medicare, those eligible for part B do

have covered services paid by Medicare and would be eligible for a part B drug program.

If Medicare assumes responsibility for drugs for its beneficiaries in nursing homes, Medicaid costs would go down and Medicare costs would go up, with a net effect that states would pay less for Medicaid and overall federal costs would be higher. This would result because most states pay Medicare premiums for Medicaid beneficiaries and the federal government shares in those state payments. The same circumstances could arise for dually eligible noninstitutionalized persons.

How Will Out-of-Pocket Costs Be Determined?

The allowable amount for drugs to be used to determine when beneficiaries meet whatever drug deductible applies should be specified in legislation. If the allowed amount is set at the amount Medicare would pay for the drugs, as is the case for other part B services, the beneficiary will not know when he or she has reached the deductible amount. This uncertainty would result because the beneficiary would normally pay the full amount charged but Medicare would recognize only the amount arrived at using its payment limitations. This could add a degree of confusion to the program and could result in more claims being submitted for processing.

On the other hand, if the actual amount paid by the beneficiary is considered the allowable amount for deductible purposes, it could somewhat lessen the incentive for beneficiaries to shop for a pharmacy with low prices.

How Will State Drug Substitution Laws Apply?

All states have laws relating to when a pharmacist can substitute an equivalent drug for the one prescribed. These laws

fall into two groups--those that require the prescriber to take a positive action to authorize substitution and those that require action to prohibit substitution.

Studies have shown that substitution is less likely to occur when the prescriber must explicitly authorize it. Under normal circumstances we see no justification for the government to pay for a more expensive drug when a therapeutically equivalent, lower price drug is available. If payment rates are set in light of the availability of substitutable drugs, pharmacists in some states could be forced to dispense a high cost drug because the prescriber did not authorize substitution but could be limited to a payment below the pharmacy's drug cost.

Should Assignment Be Mandatory or Optional?

This issue relates to the agreements pharmacies would enter to participate in a Medicare drug program. The basic questions are:

-- Will assignment be mandatory? That is, will pharmacies have to agree to accept Medicare's allowed amount as payment in full if they want to participate in the program?

-- If assignment is mandatory, what effect will that have on the number of pharmacies participating?

If accepting assignment is optional, a Medicare program would not assure beneficiaries that their drug costs would be limited to the program's deductible/coinsurance amounts because they would be liable for any differences between allowed amounts and actual charges. On the other hand, if assignment is mandatory, at least some pharmacies might choose not to participate.

There are indications that mandatory assignment would probably not greatly affect participation. As you know, assignment is mandatory under the Medicaid program, and states have been able to enlist most pharmacies to participate. There is also precedent in Medicare for mandatory assignment. Independent clinical laboratories must accept as a condition of participation Medicare's laboratory fee schedule amounts as payment in full, and the vast majority of laboratories participate. Finally, if a Medicare drug program is catastrophic in nature--that is, it has a relatively high deductible--pharmacies might not want to take the chance that beneficiaries would not use them for drugs purchased before the deductible is met because beneficiaries will probably look for participating pharmacies for all their drug needs.

What About Drugs Already Covered by Medicare?

Medicare currently covers one type of outpatient drug--immunosuppressant drugs, needed after organ transplants, for a maximum of 1 year after such an operation. If a Medicare drug program is enacted, the Congress should specify whether immunosuppressant drugs fall under the new program and, if so, whether the coverage for such drugs would be extended beyond the current 1-year limit.

This concludes my statement; I will be pleased to respond to questions.