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Outpatient Prescription Drugs: Acquisition and Reimbursement Policies Under Selected Federal Programs

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Summary

Varying reimbursement methods determine the payments for outpatient drugs supplied under different federal programs. The Veterans Health Care Act of 1992 limits the prices that drug manufacturers can charge the Department of Veterans Affairs (VA); several other government agencies, including the Department of Defense (DOD), are able to purchase pharmacy supplies through the VA supply system. The Medicaid program reimburses providers directly for covered pharmaceuticals, establishing upper payment limits on approved drugs and receiving rebates from manufacturers. The Medicare program provides limited coverage for outpatient drugs. For those drugs it covers, Medicare reimburses providers at the rate of 95% of the average wholesale price. This report discusses the reimbursement methods used to pay for outpatient prescription drugs by the VA, DOD, Medicaid, and Medicare. It will be updated as necessary.

Introduction

The federal government provides coverage for outpatient prescription drugs under several programs. The largest programs are administered by the Department of Veterans Affairs; the Department of Defense; Medicaid, the joint federal-state entitlement program that pays for medical services on behalf of certain groups of low-income persons; and Medicare, the nation's health insurance program for the elderly and certain disabled individuals. The Medicare program provides only limited outpatient drug coverage.

Department of Veterans Affairs (VA)

The VA maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves

approximately 3.65 million veterans. According to VA analysts, spending for pharmaceuticals will be approximately $1.8 billion in FY1999.

The Veterans Health Care Act of 1992 (VHCA, P.L. 102-585) established the Federal Ceiling Price Program, limiting the price manufacturers could charge for drugs purchased for the VA, the Department of Defense, the Public Health Service (including the Indian Health Service), and the Coast Guard. In order to receive reimbursement under the Medicaid program (as well as from the agencies listed above), manufacturers are required to provide covered drugs to the four protected agencies at a discount of at least 24% below the non-Federal Average Manufacturers Price (non-FAMP), minus any cash discounts, rebates, or similar reductions. The non-FAMP is calculated using the weighted average price paid by non-federal wholesalers over the previous 12 months. Thus, the Federal Ceiling Price (FCP) is calculated using the following formula:

(0.76 x non-FAMP) - additional discount = FCP

The FCP is the highest price that can be charged to the protected agencies for covered drugs, which are defined as all products that a drug company holds or markets under an original New Drug Application (NDA) as approved by the Food and Drug Administration, including certain single source and innovator multiple source drugs,[1] biological products, and insulin. This provision does not apply to generic drugs.

VHCA also required that, in order to be reimbursed under Medicaid, manufacturers of brand name drugs must make all their covered pharmaceutical products available on the Federal Supply Schedule (FSS), a listing of goods available for sale mainly to the federal government. All federal agencies (and a few other entities) may purchase pharmaceuticals from the FSS. In FY1996, the VA purchased $922 million in pharmaceuticals from the FSS.[2] The VA's National Acquisition Center (NAC) is the sole negotiator for the government with drug manufacturers in establishing the prices for the approximately 23,000 drugs listed on the FSS. The prices must be equal to or better than the best price charged to the manufacturer's most favorable comparable customer. Because the VA's NAC is not bound in its negotiations with manufacturers to the FCP limits, the Federal Ceiling Price and Federal Supply Schedule prices are not necessarily the same. In fact, many prices are more than 50% below the non-FAMP.[3] However, if the FSS price is higher than the FCP, the four protected agencies are not required to pay more than the FCP.[4]

Although most purchases are done through the FSS, the VA also negotiates contracts independent of the FFS. Through Blanket Purchase Agreements (established under FSS contracts) and other national contracts with manufacturers, the VA guarantees a volume

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[1] A multiple source drug is defined as one marketed or sold by two or more manufacturers or labelers; it can also be a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names, or both under a proprietary name and without such a name.

[2] U.S. General Accounting Office. *Effects of Opening the Pharmaceutical Schedule Are Uncertain*. GAO/T-HEHS-95-171, July 10, 1997. p. 1.

[3] Ibid, p. 4.

[4] Ibid.

purchase (either for their beneficiaries exclusively or for beneficiaries in additional federal programs) in exchange for discounts below the FSS prices.

In addition to these contracts for goods, the VA also awards a contract for distribution under the Pharmaceutical Prime Vendor Distribution Program. Under the current award, with very few exceptions, all drugs are distributed by one company. This contract included a *negative* 2.25% service fee for drugs distributed through facilities, and a negative 2.9% for VA's Consolidated Mail Outpatient Pharmacies.

Department of Defense (DOD)

DOD provides drugs to approximately eight million active duty personnel, retirees, and their families through three points of service: military treatment facility (MTF) outpatient pharmacies, TRICARE managed care contractor retail pharmacies, and the National Mail Order Pharmacy Program (NMOP). The pharmacy benefit is generally not available to Medicare-eligible retirees. As described above, DOD is covered by the Federal Ceiling Price Program established by VHCA.

Although some purchases of pharmaceuticals are made through the FSS, DOD negotiates independent contracts for the majority of their purchases. The pharmaceutical group of the Defense Supply Center in Philadelphia (DSCP) is the single entity which negotiates DOD's distribution and pricing agreements (DAPAs) with over 200 drug manufacturers. Their starting point for negotiations is the 24% discount on the non-FAMP which is required under VHCA. DOD estimates that DAPA negotiated prices for drugs are approximately 24% to 70% below the average wholesale price (AWP).[5] DSCP contracts directly with a wholesale prime vendor to store drugs and deliver requested pharmaceuticals directly to MTFs. In FY1997, MTF pharmacies dispensed approximately 55 million prescriptions at a cost of approximately $1 billion.[6]

The National Mail Order Pharmacy Program (NMOP) delivers up to 90-day supplies of drugs directly to beneficiaries at their homes for patients with long-term or chronic conditions. The DAPA prices, once only available to MTFs, are now used when purchasing drugs for the mail-order program.

Under TRICARE programs, insurers under contract with DOD provide prescription drug coverage to enrolled beneficiaries. In FY1997, the NMOP and TRICARE contractor retail pharmacy programs spent approximately $245 million for prescription drugs.[7]

Medicaid

Under Medicaid federal requirements, outpatient prescription drug coverage is an optional service. However, all 50 states and the District of Columbia provide some level

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[5] The average wholesale price (AWP) is the price reported by the *Red Book* or other national compendia.

[6] U.S. General Accounting Office. *Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness*. GAO/HEHS-98-176, June 1998. p.3.

[7] Ibid.

of coverage. Unlike the VA and DOD, the federal Medicaid program does not directly negotiate contracts to purchase drugs from manufacturers. Instead, in most cases, the federal government establishes price limits that are used by states for drug reimbursement. Manufacturers provide rebates to states based on their Medicaid sales in that state during specified time periods. According to the Health Care Financing Administration (HCFA), in FY1996, Medicaid served approximately 36.1 million beneficiaries and paid $10.7 billion in prescription drug benefits.

Payment for multiple source outpatient drugs is made subject to upper limits established by HCFA, plus a reasonable dispensing fee established by the state. Upper payment limits will be established only if (1) all formulations of the drug approved by the Food and Drug Administration (FDA) are evaluated as therapeutically equivalent, and (2) the drug is listed by at least three suppliers in current cost compendia of those drugs available for sale nationally. The upper payment level for these drugs is 150% of the published price (as listed in any of the published drug pricing compendia) for the least costly therapeutic equivalent, plus a reasonable dispensing fee.

Guidelines also exist for "other drugs." These are brand name drugs certified by a physician as medically necessary for a particular recipient, or a drug other than a multiple source drug for which a limit has been established. In these cases, Medicaid applies a payment level which is the *lower* of:

(1) the estimated acquisition cost plus a reasonable dispensing fee, or
(2) the provider's usual and customary charges to the general public.

Within federal limits, states can design their own prescription drug programs and attempt to limit their expenditures.

In addition to these price limits, states receive rebates from drug manufacturers under the Medicaid Drug Rebate Program established by the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508). Under this program, in order to be eligible for federal Medicaid matching funds, pharmaceutical manufacturers must enter into *national rebate agreements* (as opposed to the *pricing* agreements established by the VA and DoD) with the Secretary of Health and Human Services on behalf of the states (although the Secretary can authorize states to enter into contracts directly with manufacturers). The formula for calculating the multiple source drug rebate is:

a. the total number of units of each dosage form and strength paid for under the state plan in the rebate period, *multiplied by*
b. the greater of:

    (1) the difference between the average manufacturer price (AMP)[8] and the best price[9] ***or***
    (2) 15.1% of the AMP.

An additional rebate is given by the manufacturer for any price increase which is higher than the increase in the consumer price index (CPI).

Rebates for "other drugs" are determined by multiplying the total number of units of each dosage form and strength paid for under the state plan in the rebate period by 11% of the AMP.

Rebates are not required for Medicaid managed care plans.

Drugs are reimbursed in the following manner. Beneficiaries submit prescriptions to their pharmacy. The pharmacy submits a claim for reimbursement to the state Medicaid program. The claim indicates the manufacturer of the drug and the dosage dispensed. The state Medicaid office reimburses the pharmacist using the payment levels described above. Data accumulated by the state Medicaid office is submitted quarterly to each participating manufacturer holding a rebate agreement with Medicaid. The data include the total number of dosage units of each of the manufacturer's drugs that has been dispensed to Medicaid beneficiaries in that state during the quarter. This information is used to calculate the rebate (using the formula described above), which the manufacturer remits to the state.

Medicare

The Medicare program generally does not provide coverage for outpatient prescription drugs. For those that it does cover (see below), payments are made under Part B of the program. Like Medicaid, Medicare does not contract with manufacturers to acquire prescription drugs for its beneficiaries. Rather, it reimburses the providers of these drugs. According to HCFA, in FY1997, Medicare, which covered approximately 38 million beneficiaries, paid $2.75 billion for outpatient prescription drugs.

Medicare makes payments directly to physicians for drugs which cannot be *self-administered* and are "incident to" a physician's professional service. Coverage is generally limited to those drugs which are administered by injection.

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[8] The average manufacturer price is the average price paid to a manufacturer by retail pharmacies, or by wholesalers, for drugs distributed to the retail pharmacy class of trade.

[9] The best price is defined as the lowest price available from a manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity (excluding prices charged under VHCA, prices charged under the Federal Supply Schedules, prices used under state pharmaceutical assistance programs, and depot prices or single award prices of federal government agencies).

Despite the general limitation on coverage for outpatient drugs, the law specifically authorizes coverage for certain classes of drugs: those used in conjunction with home infusion or inhalation equipment, those used for the treatment of anemia in dialysis patients, immunosuppressive drugs for patients who have received organ transplants under Medicare, certain oral cancer and associated anti-nausea drugs, and certain immunizations. For these drugs, Medicare pays the physician or supplier (e.g., pharmacist) directly.

Drugs are identified using codes from HCFA's Common Procedure Coding System (HCPCS) that define the *type* of drug and a standard dosage amount where applicable. However, unlike the NDCs used under the federal ceiling price program, HCPCS do not identify specific drugs.

Medicare enters into contracts with local carriers and the four regional durable medical equipment carriers (DMERCs) to establish Medicare allowed amounts for covered drugs. There are no national limits set. The Balanced Budget Act of 1997 provided that the maximum allowable payment for outpatient prescription drugs is 95% of the average wholesale price (AWP). Carriers determine the AWP using such sources as the *Red Book* or other publications or databases used by the pharmaceutical industry. Prior to 1999, if a drug had both brand and generic sources available, reimbursement was based on 95% of the median AWP for generic sources. In some cases, however, a brand name product's AWP is lower than the median generic price. Therefore, in 1999, Medicare began calculating the AWP for multiple source drugs at the *lower* of the median generic AWP, or the lowest brand-name AWP.[10]

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[10] U.S. Department of Health and Human Services. Office of the Inspector General. *Comparing Drug Reimbursement: Medicare and the Department of Veterans Affairs*. November 1998. p. 1.