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# UpDate

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## I. LEGISLATION

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### Savings For Medicaid Drug Spending

by Michael R. Pollard and John M. Coster

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Major changes in how the Medicaid program purchases prescription drugs could save \$3.4 billion in total Medicaid expenditures over five years—\$1.9 billion for the federal government and \$1.5 billion for the states.<sup>1</sup> These changes, set forth in the Omnibus Budget Reconciliation Act (OBRA) of 1990, will greatly reduce Medicaid's price for pharmaceuticals by requiring drug manufacturers to give discounts or rebates to Medicaid. The new law also established drug use review, physician and pharmacist education programs, and electronic claims submission systems that, once implemented, have the potential to profoundly change the way drugs are prescribed, dispensed, and taken.

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### Legislative History

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As of 1 January 1991, the federal government does not provide federal Medicaid matching funds (also known as federal financial participation, or FFP) to states for the drugs of a manufacturer that does not agree to provide each Medicaid program with a specific schedule of rebates for their prescription drug products.<sup>2</sup> With the Medicaid market representing 10–13 percent of the average pharmaceutical company's revenue, manufacturers have a major incentive to participate in Medicaid's rebate program.

**Political background.** The enactment of

these provisions was the culmination of an intense, sometimes bitter struggle between pharmaceutical manufacturers and selected minority groups on one side, and retail pharmacy groups, state Medicaid directors, the Bush administration, advocates for the poor and elderly, and the congressional sponsors of the legislation on the other. The underpinnings for these provisions were established during hearings on prescription drug prices held in 1989 by Sen. David Pryor (D-AR), chairman of the Senate Special Committee on Aging.

Senator Pryor and others in Congress realized that almost ten years of rapid escalation in drug prices had caused significant financial hardships for state Medicaid prescription drug programs.<sup>3</sup> To contain costs in their drug programs, states have imposed limits on beneficiaries' access to prescription drugs, instituted higher beneficiary cost-sharing provisions, and reduced pharmacy reimbursement. States were not able to address the primary cause of escalating program costs—steep increases in drug prices at the product level—because drug manufacturers would not negotiate lower prices with Medicaid programs.

Members of Congress questioned whether it was fair for Medicaid to be denied the significant discounts on drugs that manufacturers routinely offered to the Department of Veterans Affairs (VA) and other federal agencies, including the Department of Health and Human Services (HHS), for non-Medicaid populations, and other health care organizations, such as hospitals and health maintenance organizations (HMOs).<sup>4</sup> Also, many members of Congress felt it was poor public policy for Medicaid, the program serving the poor and many of the elderly, to be paying full retail prices for

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prescription drugs with tax dollars, when expansion of Medicaid benefits was being constrained by budgetary limits on federal and state spending for social programs.

**Previous efforts.** During the 101st Congress, Senator Pryor introduced two bills designed to lower Medicaid's drug prices. Enactment of either of these bills in their original form would have had an even more profound effect on pharmaceutical manufacturers and the pharmacy profession than the compromise provisions incorporated in OBRA 1990.

Senator Pryor's first bill, the Pharmaceutical Access and Prudent Purchasing Act of 1990 (S. 2605), would have required state Medicaid programs to form their own buying groups or join a federal Medicaid prescription drug buying group to emulate the highly successful pharmaceutical purchasing practices adopted by hospitals and group- and staff-model HMOs. The goal of this bill was to force pharmaceutical manufacturers to compete on price by bidding for a state Medicaid program's business in classes of similarly acting, therapeutically equivalent drug products.<sup>5</sup> Representatives of the pharmaceutical industry argued that such a program would be ill-advised because different chemical entities are not therapeutically interchangeable and that the program would place severe restrictions on the number of drugs that would be available to Medicaid patients. Supporters of the bill argued that drug companies were primarily concerned that other third-party payers would use the bargaining system established by S. 2605 to lower their own costs for drugs.

Pryor's second bill, the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1991 (S. 3029), was drafted in response to the drug discount plans developed by a few major pharmaceutical manufacturers in spring 1990. This version required manufacturers to offer Medicaid the prices that they were giving to their best customers, or their "best price."<sup>6</sup> To assure savings over time and to guard against steep future price increases by manufacturers, S. 3029 tied increases in best prices to the consumer price index (CPI).<sup>7</sup>

Although the Medicaid drug rebate plan

compromise reached by House and Senate negotiators in the final hours of the 101st Congress (Section 4401 of OBRA 1990, titled "Reimbursement for Prescribed Drugs") adds only about 190 lines to the Social Security Act, it has the potential to significantly reform the pharmaceutical marketplace and may shape not only how much the Medicaid program pays for prescription drugs in the next few years, but also how much other purchasers will pay. One of the immediate effects of the law is that manufacturers that previously offered discounts to large purchasers of outpatient prescription drugs (such as hospitals and HMOs) are withdrawing or modifying those discounts on the grounds that the Medicaid discounts have cut into their profit margins and thereby reduced their ability to extend deep discounts to other customers.<sup>8</sup> Senator Pryor and other sponsors of the legislation have forcefully stated that this is an unintended consequence of OBRA 1990 and that further action against the drug industry may be warranted.<sup>9</sup>

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## Key Provisions Of The New Law

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**Rebate requirements.** As of 8 March 1991, nearly all major brand-name and generic drug manufacturers signed agreements with the Health Care Financing Administration (HCFA), specified in OBRA 1990, to provide rebates according to the statutory formula.<sup>10</sup> As of 1 April 1991, federal matching funds were no longer available for the drugs of any manufacturer that had not signed such an agreement.

As a condition of this agreement, each state's Medicaid drug formulary (listing of approved drugs) must cover all of the manufacturer's products that are "covered outpatient drugs" and that are prescribed for a medically accepted indication, with certain exceptions. Rebates for single-source and innovator multiple-source drugs are keyed to two benchmarks: "average manufacturer price" and "best price."<sup>11</sup> Rebates for generic drugs are set at a flat percentage off the average manufacturer price, which is 10 percent for all quarters beginning after 31 December 1990 and ending before 1 January

1994, and 11 percent for all quarters beginning on or after 31 December 1993.

In its standard manufacturer rebate agreement, HCFA clarifies the nature of the average manufacturer price, which the statute defines. Direct sales to hospitals and HMOs, sales through the federal supply schedule (FSS), and sales to wholesalers where the drug is relabeled under the distributor's national drug code number are all excluded from average manufacturer price, consistent with congressional intent that the average manufacturer price only include sales to the retail class of trade. It does include cash discounts, free goods, and all price reductions other than the rebates provided for under this law (for example, manufacturers' offer of free goods if the purchaser buys a certain volume of product).<sup>12</sup>

Of major concern to the industry and the states has been the definition of "best price," which was loosely defined in the statute as "the lowest price available from the manufacturer to any wholesaler, retailer, non-profit entity, or governmental entity within the United States." This definition excludes "depot" (that is, centralized purchasing and distribution facilities) and single-award prices to any federal agency, but includes cash discounts, free goods, volume discounts, and rebate: other than those provided for in OBRA 1990. HCFA further clarifies "best price" by including capitated pricing structures (in which the purchaser pays a fixed amount for drugs regardless of the volume of drugs that are used) and FSS prices to any federal purchaser. The federal supply schedule lists some of the lowest prices for drugs in the United States. "Best price" is determined without regard for special packaging, labeling, or identifiers on the dosage form, product, or package. Congress also excluded "nominal prices" from the definition of "best price," primarily to protect the low prices on oral contraceptives traditionally received by federally funded family planning clinics. The definition of "nominal" is not clear in the statute, and the HCFA rebate agreement has defined it as any price that is lower than 10 percent of the average manufacturer price for the drug.

It is unclear whether or how the "best

price" concept will apply to rebates given by a manufacturer to a party that is not itself a purchaser from the manufacturer (for example, an HMO that receives a rebate directly from the manufacturer based on the volume of prescriptions filled by its members at community pharmacies). Arguably, this type of rebate would not be included in the "best price" calculation.

Rebate formula. The rebate formula is complicated and changes each year until 1994, when a permanent formula goes into effect. Under pressure from the pharmaceutical industry, Congress allowed for a phase-in period to give manufacturers time to adjust to the new law.

Two rebates apply to single-source and innovator multiple-source drugs. The basic rebate in 1991 is the greater of 12.5 percent of average manufacturer price, or the difference between average manufacturer price and the best price, as long as that difference does not exceed 25 percent of average manufacturer price. The additional rebate, which applies in 1991–1993, allows the states to recapture any increase in average manufacturer price that exceeds the rate of inflation. This rebate requires manufacturers to pay states the difference between the average manufacturer price for each dosage form and strength of a drug that was in effect 1 October 1990, increased by the CPI for all urban consumers, and the average manufacturer price currently in effect.

The basic rebate changes in 1992 by raising the limitation to 50 percent of average manufacturer price. It changes again in 1993, to the greater of 15 percent of average manufacturer price, or the full difference between average manufacturer price and best price. The basic rebate formula stays the same for 1994, but the additional rebate changes from a drug-by-drug comparison to a "weighted average manufacturer price" for all the manufacturer's single-source and innovator multiple-source drugs.

Given this rebate schedule, pharmaceutical manufacturers have powerful incentives to raise their best prices so that the spread between best price and average manufacturer price is as small as possible. This pricing strategy not only would yield a

smaller rebate paid by manufacturers to state Medicaid programs, it also would shift some of the costs of Medicaid rebates to customers who previously purchased their prescription drugs at or near the manufacturer's best price. Manufacturers also may seek downward adjustments in their average manufacturer price, such as providing free units of a product contingent on purchase volumes in place of cash rebates, as another means to diminish the difference between average manufacturer price and best price.<sup>13</sup>

Access and coverage. Congressional sponsors of Medicaid drug purchasing reform sought to restore some of the access to prescription drugs that had been lost as a result of state-imposed drug coverage restrictions. Significant progress was made in meeting this goal. In return for signing the rebate agreement, states are obligated to cover all of the prescription drug products of a manufacturer that signs the agreement. In addition, Medicaid must cover all the medically accepted indications for these covered drugs, as listed in the three national pharmaceutical compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeial Convention-Drug Information.

In a major victory for drug manufacturers, state Medicaid programs have to cover for six months any newly approved drug products not on the list of excludable drugs, thus giving manufacturers immediate entree into their target ambulatory markets. Historically, some state Medicaid programs have restricted access to new drugs unless they represented significant or moderate therapeutic advances over drugs that were already covered by the program.

To foster the appropriate use of prescription products and control the prescribing of drugs that are expensive or frequently abused or misused, OBRA 1990 allows states to subject any covered outpatient drug to prior authorization, except new drugs or biological products during the first six months after Food and Drug Administration (FDA) approval. Prior authorization requires a physician or pharmacist to obtain permission from the state Medicaid program before pre-

scribing or dispensing a product. If a state requires prior authorization as a condition of coverage or payment, the state must provide a response to the physician or pharmacist requester within twenty-four hours. In emergency situations, yet to be defined, at least a seventy-two-hour supply may be dispensed before approval is obtained.

The law also allows states to exclude from coverage or otherwise restrict certain drugs or classes of drugs that, over time, have been shown to be drugs of abuse or subject to frequent clinical misuse. The eleven classes of "excludable" drugs include drugs for anorexia or obesity, fertility, cosmetic purposes, hair growth, and smoking cessation; and over-the-counter drugs, barbiturates, and benzodiazepines. This list will be updated periodically by the HHS secretary when medical and clinical data demonstrate that the decision concerning coverage of a certain drug or class of drugs should be made at the state's discretion.

The prior authorization and drug exclusion provisions are controversial. Senator Pryor and Senate Special Committee on Aging staff have said on several occasions that the OBRA 1990 provisions do not preclude states from continuing to use formularies. Pharmaceutical manufacturers have interpreted these statements to mean that prior authorization will be the means by which states will discourage physicians from prescribing certain drugs. For those drugs that require prior approval, pharmaceutical manufacturers fear that physicians will decide that the therapeutic benefits of such drugs are not worth subjecting the patient to potential delay in obtaining their prescriptions and will simply prescribe drugs that are not subject to prior approval. Congressional sponsors of these provisions argue that many third-party prescription drug plans use some type of prior authorization, so why should Medicaid be different? Proponents of prior authorization believe that if a drug is really needed, physicians will go the extra step to get it for their patients.

Responding to significant pressure from pharmaceutical manufacturers to say something about prior authorization, HHS Secretary Louis W. Sullivan asked the states, in

a letter mailed to each governor the day after the final rebate agreements were sent to manufacturers, to refrain from implementing the OBRA 1993 Medicaid provisions "in a way that could inappropriately restrict access to prescription drugs."<sup>14</sup> The secretary is required to study the impact of the new prior authorization reforms on recipients' and providers' access to prescription medications and on costs, and to make recommendations to Congress about changes in these programs. Congress did not want any change in the states' ability to use prior authorization until the study could be completed.

**Pharmacy reimbursement.** Because states had made pharmacy reimbursement a primary focus of their Medicaid drug program cost containment efforts in the 1980s, Congress sought to limit the cuts in this area by seeking a freeze on state Medicaid pharmacy reimbursement levels. As enacted in OBRA 1990, the HHS secretary may not modify by regulation the formula used to determine Medicaid pharmacy reimbursement limits in effect 5 November 1990 (the date of enactment of OBRA) for four years (from 1 January 1991 to 31 December 1994). During that same period, any state in compliance with applicable federal regulations may not reduce the limits for covered outpatient drugs or the dispensing fees for those drugs. Subsequent to enactment of the moratorium, however, HCFA contended that as many as eight states may not have been in compliance at the time the OBRA 1990 provisions were enacted, and some states have indicated that they may not honor the OBRA 1990 prohibition. The moratorium language will probably require a technical amendment to make it conform to the Medicaid conference agreement.

While the moratorium precludes states from reducing reimbursement levels, it does not prohibit states from increasing them. However, given the tight fiscal constraints under which most states are operating, increases in pharmacy reimbursement are unlikely to occur.

**Drug use review.** The OBRA 1990 legislation includes a comprehensive drug use review program for Medicaid recipients, similar to that in the now-repealed Medi-

care Catastrophic Coverage Act of 1988. By 1 January 1993, states must provide for a drug use review program for covered outpatient drugs that assures that prescriptions are appropriate, medically necessary, and not likely to produce adverse medical results. Drug use review is multifaceted and consists of prospective and retrospective review and educational interventions.

Under current law, state Medicaid programs are required to identify patterns of fraud and abuse in their prescription drug programs, such as overprescribing and dispensing of controlled substances.<sup>15</sup> These efforts are part of the general Medicaid utilization review system known as surveillance utilization review.

Each state's drug use review program must provide for review of drug therapy before a prescription is filled or delivered to an individual (prospective) and after an individual has taken the drug for the required course (retrospective). Prospective review screens for potential problems due to therapeutic duplication, drug/disease contraindications, drug/drug interactions, incorrect drug dosage or duration of therapy, drug/allergy interactions, and clinical misuse of drugs.<sup>16</sup>

Each state Medicaid program must establish standards for counseling patients. The statute specifies that counseling by pharmacists must include the name and description of the medication, precautions for administration or use, common severe side effects, adverse effects, and potential drug interactions. Counseling may be conducted in person or via toll-free telephone, and pharmacists are not required to provide consultation when a Medicaid recipient or their caregiver refuses it. OBRA 1990's counseling guidelines are consistent with the standards adopted by the National Association of Boards of Pharmacy in 1990.<sup>17</sup>

While the counseling language was strongly supported by the American Pharmaceutical Association and the National Association of Retail Druggists, it was opposed by the National Association of Chain Drug Stores as being too proscriptive and unnecessarily placing additional liability on pharmacists. The practical effect of the new Medicaid counseling requirements is that

they may be incorporated into state pharmacy practice acts, making them applicable to all patients.

Drug use review will be organized and conducted by a review board to be established in each state. A drug use review board must comprise at least one-third, but no more than 51 percent, licensed and actively practicing physicians and at least one-third licensed and actively practicing pharmacists. The boards will conduct ongoing interventions for physicians and pharmacists targeted to therapy problems or individuals that are identified by retrospective drug use reviews. These programs will include written, oral, electronic, and face-to-face communications concerning suggested changes in prescribing or dispensing practices. Each board must submit an annual report to the state and may contract out its educational program function to educational institutions, state medical societies, state pharmacists' associations or societies, or other organizations specified by the state.

These educational programs are supposed to teach physicians and pharmacists how to identify and reduce fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. Drug use data will be assessed against predetermined standards based on the three medical compendia and the peer-reviewed medical literature. The law exempts drugs dispensed to residents of nursing homes, which are in compliance with the drug regimen review procedures mandated by OBRA 1987 and spelled out in 42 C.F.R. §483.60, from additional drug use review.

**Electronic claims management.** In an attempt to bring Medicaid pharmacy claims processing in line with the private sector, OBRA 1990 authorizes the HHS secretary to encourage states to establish a point-of-sale electronic claims management system to process claims for outpatient prescription drugs covered by Medicaid. These systems must be able to perform on-line, real-time eligibility verifications, claims data capture, and claims adjudication, and to facilitate payment to pharmacists. States that acquire such capability during fiscal years 1991 and 1992 are eligible for federal matching funds of up to 90 percent.

The leading prescription drug claims processors have adopted these technologies to reduce their paperwork burden and costs of administering large-scale outpatient prescription drug programs. As the percentage of pharmacy prescription drug transactions covered by third parties increases, the need for these systems in retail pharmacies becomes paramount. Because administrative costs can consume about half of a state's Medicaid drug program expenditures, most states are expected to apply for the enhanced matching funds.

**Demonstration projects and research studies.** The new law mandates two demonstration projects and six research studies. The first demonstration project will evaluate the efficiency and cost-effectiveness of providing specific information about a patient's drug history to a pharmacist to help fulfill the mandated counseling functions. HCFA must establish these demonstrations in ten states. The second demonstration is designed to determine whether it is cost-effective to reimburse pharmacists for providing clinical or "cognitive" services to Medicaid patients. The pharmacy profession lobbied hard for these demonstrations to prove that the practice of pharmacy involves more than simply dispensing medications and that pharmacists who intervene to avoid potential drug therapy problems may improve patient care and reduce costs.

Three of the research studies will be conducted by the comptroller general: (1) a study of the drug purchasing and billing practices of hospitals, "other institutional facilities," and managed care plans, which will also compare their ingredient costs to retail pharmacies; (2) annual reports to Congress on changes in prices charged by manufacturers; and (3) a study of methods to encourage Medicare providers to negotiate discounts with suppliers of prescription drugs. HCFA's Office of Research and Demonstrations will study the adequacy of current Medicaid reimbursement rates to pharmacists and how these rates affect Medicaid patients' access to drugs. The two remaining studies—one on prior approval procedures and the other on payment for vaccines—have not yet been assigned within HHS.

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## Implications For Generic Drug Manufacturers

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While manufacturers of brand-name drugs have to provide two rebates to the Medicaid program—a basic rebate and an inflation-adjustment rebate—manufacturers of generic drugs were not required to return either as high a percentage rebate to Medicaid as the brand-name companies or to provide an inflation-adjustment rebate. This was because Congress felt that competition among generic products had helped to keep generic drug prices low and that generic drug companies generally operated on smaller profit margins and could not afford to take a deeper cut. While generic drug manufacturers may not be pleased with having to give 10 percent rebates in 1991–1993 and 11 percent thereafter, several provisions in OBRA 1990 should bode well for the generic drug industry.<sup>18</sup>

First, the new Section 1927(e) added to Title XIX of the Social Security Act should enhance generic dispensing, because no payment may be made by a state for an innovator multiple-source drug dispensed after 1 July 1991 if, under applicable state law, a less expensive multiple-source drug could have been dispensed. This provision should encourage states to better enforce the Medicaid regulation that requires a generic drug to be dispensed unless the physician has indicated on the prescription, “brand medically necessary.” This new provision allows federal auditors to check actual prescriptions to determine if a generic could have been dispensed and to reduce federal matching dollars if it was not.

Second, Section 1927 (f)(2) instructs HCFA to establish a federal upper reimbursement limit for each multiple-source drug for which FDA has rated three or more products therapeutically and pharmaceutically equivalent (a so-called A rating), regardless of whether all such formulations of the drug have an “A” rating from FDA. Prior to OBRA 1990, HCFA could only establish federal upper limits if all formulations of the drug were “A”-rated. States may obtain lower prices for those multiple-source drugs for which no federal upper limit previously

existed, because some generic manufacturers price their products at or just below the federal limit to capture Medicaid prescriptions. Imposition of additional federal upper limits on multisource drugs before 1 January 1995, however, may violate the pharmacy reimbursement moratorium, since establishing such limits could have the practical effect of lowering pharmacy reimbursement.

On a related matter for generics, the law prohibits the federal government from paying for “B”-rated generics for Medicaid recipients. This was enacted in response to the recent scandal in which certain generic copies were not equivalent to their generic originators. This change will help to dispel claims that Medicaid recipients are receiving substandard or less than first-quality pharmaceutical products.

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## Impact On Other Pharmaceutical Purchasers

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Even before the ink was dry on the new Medicaid law, pharmaceutical sales representatives were telling customers who receive substantially reduced prices that their discounts might not be continued in light of the mandatory Medicaid rebates. Initially, few of the discounts negotiated with manufacturers by the VA, hospital systems, and HMOs were actually breached. As is the case with any industry with diverse pricing policies, some manufacturers reacted more quickly than others after enactment of OBRA 1990. The VA and others, such as the Department of Defense, predicted that manufacturers would wait until the war in the Persian Gulf ended to raise prices to federal purchasers, which most manufacturers did. The VA estimates that it will pay an additional \$150 million for prescription drugs this year due to the loss of its discounts.<sup>19</sup> The Army anticipates paying \$45 million more, and the Navy predicts a \$25 million increase in its drug expenditures.<sup>20</sup>

The specter of losing current discounts looms large not only for the federal government, but also for private purchasers who obtained substantial discounts from pharmaceutical manufacturers before enactment of OBRA 1990.<sup>21</sup> The loss of such discounts,

with the subsequent rise in overall health care costs, would be the opposite effect than what congressional sponsors envisioned.

While changes in manufacturer pricing are occurring, manufacturers do not need to reprice all their discounted products overnight to minimize the rebates they have to pay to state Medicaid programs. A manufacturer whose best prices are lower than 25 percent of the average manufacturer price will not have to extend any additional increments to state Medicaid programs in 1991. In 1992, however, the cap on Medicaid discounts moves to 50 percent of the average manufacturer price, so the pressure to raise best prices will intensify. The pressure becomes most intense in 1993, when there is no cap, and the rebate amount is the full difference between the average manufacturer price and the best price. The phase-in for the full Medicaid discount allows manufacturers time to gradually adjust their best prices up to a level closer to the average manufacturer price. The 15 percent minimum discount, which goes into effect in 1993, means that a manufacturer's best prices do not need to achieve parity with average manufacturer price to minimize the rebates due to the states.

If the phase-in of the OBRA 1990 Medicaid rebate provisions softens the law's impact on manufacturers in 1991 and 1992, why did some drug companies rescind their FSS discounts to the VA during the first few months of the rebate program?<sup>22</sup> The simple answer is that the prices offered to the VA are some of the lowest in the market, and Medicaid would also receive these prices if they were the "best price." Some critics of the pharmaceutical industry believe that this "cost shifting" may be part of a strategy by the drug manufacturers to force an outcry that would result in either the law's repeal or substantial modification.

Congressional sponsors of the 1990 Medicaid provisions have been informed about numerous changes in manufacturers' pricing that have decreased or eliminated the discounts previously obtained by large purchasers. Senator Pryor, in a scathing floor statement 6 March 1991, chided several pharmaceutical firms for steep increases in

their prices during the war in the Persian Gulf to the VA and the Defense Department.<sup>23</sup> He also wrote letters in January 1991 to HCFA and the VA indicating that it was not Congress's intention to jeopardize the discounts received by purchasers other than state Medicaid programs.<sup>24</sup> He asked both agencies to monitor and report back on manufacturers' pricing practices.

Sen. Jay Rockefeller (D-WV), who like Senator Pryor is a member of the Senate Finance Committee, also took the manufacturers to task for their actions against the VA in a floor statement in early March. Senator Rockefeller also wrote VA Secretary Edward J. Derwinski that he was "disappointed" and "offended" by the adverse pricing actions of drug companies against the VA. The letter was cosigned by Senators Bob Graham (D-FL), Dennis DeConcini (D-AZ), Daniel Akaka (D-HI), and James Jeffords (R-VT), all members of the Senate Veterans' Affairs Committee.

Pharmaceutical manufacturers demonstrated considerable ingenuity in the proposals they made to high-volume purchasers concerning continuation of their discounts soon after the Medicaid rebate provisions took effect. For example, one suggested to its high-volume customers that all of its single-source and innovator multiple-source products would be priced at higher levels and that prices for all of their multiple-source products would be reduced substantially, so that the net effect on the prices paid for the customer's entire "market basket" of prescription drugs would be the same as they were paying under their current contract. If the discounted prices paid by these customers were the manufacturer's best prices, a change such as that proposed would have allowed the manufacturer to raise its best prices and reduce the spread between average manufacturer prices and best prices.

Nothing in OBRA 1990 would prevent the pricing changes described above, because best prices are not indexed. Similarly, since manufacturers pay a flat percentage discount on noninnovator multiple-source products, it is in the manufacturer's best interest to reduce these prices as much as possible, given other market conditions.

Again, nothing in the 1990 law would prevent this. In those states where generic substitution is vigorously encouraged, lower prices for generics would be entirely consistent with the goal of saving consumers money on multiple-source drugs. Changes in pricing of this nature obviously would work only for those few manufacturers with a full product line of both single and noninnovator multiple-source drugs.

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## Policy Implications

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The full effects of the new law are yet to be seen. However, early responses from the pharmaceutical industry indicate that the Medicaid rebates have led manufacturers to rethink the discounts they provided to their high-volume customers and, in many cases, to revise or restructure those discounts.

Given the interest of many private payers in achieving health care cost savings by channeling patients to more structured managed care programs—where benefits may be richer but choices more limited—the effects of higher prescription drug prices because of leaner discounts could be a setback. Hospitals, HMOs, and managed care pharmacies have in the past obtained favorable discounts from many manufacturers because they can assure high volume and can manage drug use by influencing prescribing and dispensing. If manufacturers reduce or eliminate the savings these purchasers previously obtained, such purchasers will be forced to rely on means other than prudent buying to achieve savings in their drug costs, such as establishing more stringent formularies, adopting more pervasive prior authorization requirements, and increasing their reliance on therapeutic alternatives.

If pharmaceutical manufacturers attempt to use the Medicaid rebate program as the springboard for returning to a one-price policy, their financial returns may be short-lived. The electronic point-of-sale systems now available in pharmacies, combined with therapeutically based formularies and physician education programs to counter the efforts of pharmaceutical sales representatives, will limit the ability of manufacturers to hold the line on their prices to

sophisticated private purchasers. Similarly, as these purchasing and drug management capacities are developed in the Medicaid program, Medicaid also will be able to steer purchasers to those manufacturers who are still willing to offer high-quality pharmaceuticals at competitive prices.

Retail pharmacists would welcome the end of multi-tiered or so-called discriminatory pricing. Groups such as the American Pharmaceutical Association and the National Association of Retail Druggists have long argued that some manufacturers make up for the discounts they give to hospitals and HMOs by charging higher-than-necessary prices to retail pharmacies. While these groups would welcome a one-price policy, the return of this mode of pricing would not be welcome as a matter of public policy if manufacturers did not lower their retail prices while, at the same time, they raised their prices to all other purchasers who have negotiated substantial discounts.

The Medicaid provisions in OBRA 1990 reflect a strong feeling in Congress that government programs should be able to benefit from prudent purchasing practices. However, if this results in raising prescription drug prices for non-Medicaid populations served by the federal government as well as for those served by the managed care segment of the private market, Congress is unlikely to allow this situation to continue for long. Since the mid-1970s, national policy has encouraged the private sector to develop systems to better manage health care costs and use. It would be ironic, indeed, if OBRA 1990 removed the benefits achieved by managed care purchasers in their prescription drug programs.

The negative effects of the “best price” concept for managed care purchasers could be neutralized quite easily. One way would be to remove best price as the basis for the Medicaid rebates and substitute a flat percentage discount. This is the approach taken by the law toward manufacturers of generic drugs. Not all manufacturers within the brand-name drug industry would welcome this move, however, especially those that have not been deep discounters. In fact, for those companies with a one-price policy,

OBRA 1990 removed pressures in the market to provide discounts because it appears to force the deep discounters to reduce their discounts, and to bring their prices more in line with those of nondiscounters.

This was, of course, the central strategy behind Merck Sharp and Dohme's Equal Access to Medicines plan offered to the states in spring 1990. The Merck plan offered state Medicaid programs their best price for single-source drugs. Given that Merck is not a deep discounter, the rebates did not represent a substantial price concession for Merck. Similarly, other companies without deep discounts—such as Burroughs-Wellcome, Pfizer, and Miles Laboratories—followed suit in endorsing the Merck plan, while deep discounters, such as Upjohn and Schering, preferred a flat-rebate approach.

Another way to remedy the problem would be to index the best price for a covered outpatient drug to a date prior to the effective date of the legislation, such as 1 October 1990. This would lock manufacturers into the best prices they were giving prior to OBRA 1990 and would prevent them from ratcheting up those prices during a phase-in period. This approach was advocated by Senator Pryor in S. 3029, but it was criticized by both the industry and HCFA as tantamount to price controls on drugs.

Either of these legislative changes would remove pressures on manufacturers to raise best prices, although the second approach would probably still result in most manufacturers' paying higher rebates to Medicaid than the first approach, and might perpetuate some pressure for them to recapture a portion of their lower Medicaid revenues from the private sector via higher prices.

Whether OBRA 1990 will achieve the full extent of the federal savings projected by the Congressional Budget Office (CBO) for the Medicaid program is now in doubt, given the adverse impact on other federal programs of price increases announced by manufacturers who sell to federal agencies and federally subsidized health care programs other than Medicaid that serve the poor and uninsured. Whether pharmaceutical manufacturers will see the light and refrain from excessive price increases during

the phase-in period for the Medicaid rebates also remains to be seen. The one certainty of the new law is that Medicaid is now very much in the mainstream of pharmaceutical purchasing, and there is no going back to the days when Medicaid paid higher-than-necessary prices for prescription drugs.

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#### NOTES

1. The original federal target for savings from the Medicaid pharmaceutical rebates was \$1.6 billion, but the total was increased to \$1.9 billion during the House/Senate budget reconciliation conference to pay for expanded Medicaid benefits included in OBRA 1990 for the frail elderly and children's health care programs.
2. See Section 1927 of the Social Security Act or Section 4401 of OBRA 1990 (P.L. 101-508). If a state program covers nonprescription drugs, these are also subject to the mandatory rebate requirements.
3. U.S. Senate Special Committee on Aging, hearings on Skyrocketing Prescription Drug Prices, S. Hrg. 101-747 (Washington, D.C., 1990).
4. Sen. David Pryor, statement before the U.S. Senate Finance Subcommittee on Health for Families and the Uninsured, on Medicaid Prescription Drug Cost Containment Proposals. 17 September 1990.
5. S. 2605, the Pharmaceutical Access and Prudent Purchasing Act, was introduced 12 May 1990. This bill was criticized by representatives of the pharmaceutical industry for establishing a national formulary and encouraging "therapeutic" substitution of different drugs in the same therapeutic class by pharmacists without the knowledge and/or permission of the prescribing physician. Critics claimed that the bill would create "second-class" medicine for the poor. In June 1990, the president's Office of Management and Budget (OMB) offered a similar plan to S. 2605, except that it actually relied on therapeutic substitution of the preferred drug product (that is, switching of the drug product without the physician's knowledge, while S. 2605 relied on therapeutic interchange, where a switch of the drug product could only be made with the physician's consent.
6. S. 3029, the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act, was introduced 12 September 1990. A companion bill, H.R. 5569, was introduced in the House by Congressman Ron Wyden (D-OR) and Jim Cooper (D-TN). The indexing requirement for "best price" in this bill drew criticism from the pharmaceutical industry and HCFA Administrator Gail Wilensky for being price controls. This bill was drafted in response to the Equal Access to Medicines plan developed by Merck Sharp and Dohme.
7. CBO warned congressional staff that the long-term savings on prescription drugs were uncertain unless there was some safeguard in the bill against rapid

- increases in manufacturers' prices.
8. R. Pear, "Medicaid Is Denied Discounted Drugs Despite a New Law," *The New York Times*, 18 February 1991, 1.
  9. Sen. David Pryor, "Johnny Comes Marching Home to Increased Prescription Drug Prices," statement before the U.S. Senate, 6 March 1991.
  10. Christine Nye, director, Medicaid Bureau, Health Care Financing Administration, memorandum to state Medicaid directors, 8 March 1991.
  11. Single-source drugs are those that are still on patent and for which no generic competition exists. Innovator multiple-source drugs, also known as originator multisource drugs, are those whose patent has expired and for which generic competition now exists.
  12. Rozann Abato, deputy director, Medicaid Bureau, Health Care Financing Administration, letter to drug manufacturers, 14 February 1991. The agreement was also published in *Federal Register* 56, no. 35 (21 February 1991): 7049-7054.
  13. The rebate agreement between HHS and drug manufacturers states that in calculating their average manufacturer price, manufacturers should not include free goods, such as drug samples given away to physicians, but may include free goods if they are tied to purchase requirements. Some manufacturers ship free quantities of a product to certain customers instead of sending cash rebates for volume purchases. This practice is likely to increase as manufacturers seek to reduce the level of their average manufacturer price because the units of free goods shipped as rebates can be included in determining average manufacturer price, whereas free goods shipped as samples cannot.
  14. Louis W. Sullivan, HHS secretary, letter to governors, 15 February 1991. Sullivan took official notice of the claims by pharmaceutical manufacturers that prior authorization "might be misused unfairly to deny access to medically necessary drugs for Medicaid's beneficiaries." He warned that the department would "closely monitor" the implementation of prior authorization requirements to ensure that the intent of the law is carried out.
  15. See Center on Drugs and Public Policy, "Status of Drug Use Review in State Medical Assistance Programs" (Spring 1989).
  16. See Section 1927(g) of the Social Security Act.
  17. *National Association of Boards of Pharmacy Newsletter* 19, no. 10 (December 1990): 105-107.
  18. Dee Fensterer, president, Generic Pharmaceutical Industry Association, personal communication, 14 January 1991.
  19. Louise Rodriguez, Department of Veterans Affairs, personal communication, February 1991.
  20. Commander Lawrence Walters, U.S. Navy, personal communication, March 1991; and Colonel John Molino, U.S. Army, personal communication, March 1991.
  21. Pryor, statement before the U.S. Senate, 6 March 1991. Kaiser Permanente estimated that it will spend \$140 million more for prescription drugs in 1991 as a result of changes in manufacturers' prices subsequent to enactment of OBRA 1990. Peter Jennings, ABC "World News Tonight," 2 April 1991.
  22. The Upjohn Company suspended all of its discounts through the federal supply schedule 1 April 1991 but retained its discounts to the federal government through the depot system. Drugs supplied through the depot system are centrally purchased and distributed, and depot prices are not included in figuring a manufacturer's best price, whereas FSS prices are. See *Health News Daily*, 11 March 1991, 4-5. However, a significant percentage of VA purchasers for many products are made off the FSS; therefore, the elimination of these prices will have a substantial impact on total federal drug expenditures. Some companies, such as Syntex, did not quote FSS prices prior to enactment of OBRA 1990.
  23. Senator Pryor cited price increases—some of which were 200 to 800 percent higher than previous prices—for drugs manufactured by Upjohn, DuPont, Smith Kline Beecham, Novo Nordisk, and Eli Lilly as examples of excessive pricing behavior by pharmaceutical firms. He also reported that the VA projected that the price increases would cost the federal government \$150 million more than anticipated in 1991, which is twice the savings projected by CBO for Medicaid from the rebate program during its first year. *Congressional Record*, 6 March 1991, S.2711-S.2712.
  24. Sen. David Pryor, letters to Gail R. Wilensky, administrator, Health Care Financing Administration, and Edward J. Derwinski, secretary, Department of Veterans Affairs, 14 January 1991.