Prescription Drug Payment Policy: Past, Present, and Future

Kathleen Gondek, Ph.D.

Prescription drug expenditures totaled more than $55 billion in 1990 and by the year 2000 are projected to rise above $125 billion (Burner, Waldo, and McKusick, 1992). They made up 7 percent of health care spending, yet an estimated 72 million Americans are without coverage for pharmaceuticals (Navarro, 1994). In 1988, 70 percent of retail prescriptions were paid out of pocket, with third parties paying 21 percent and Medicaid 9 percent (*The Pink Sheet*, 1994) Today, only about 50 percent of retail prescription expenditures are paid out-of-pocket.

The President's proposed health care reform (the Health Security Act) includes prescription drug coverage for all, including Medicare beneficiaries. The focus of this issue of the *Health Care Financing Review* is on prescription drug utilization, expenditures, and purchasing policies for both public and private payers. In addition, the experience of France, Germany, Sweden, and the United Kingdom illustrates an international perspective. Rather than simply elaborate the findings of each article, this article will focus on a brief review of the history of prescription drug coverage of public and private payers, referring to articles in this issue where relevant.

PUBLIC PAYERS

Federal assistance for State welfare programs was first provided under the Social Security Act of 1935. Early grants for these welfare programs involved Assistance for the Aged (Title I), Aid to Families with Dependent Children (Title IV-A), and Aid to the Blind (Title X); Aid to the Totally Disabled (Title XV) was added by amendment in 1950.

Medical assistance for persons 65 years of age or over was established by the Kerr-Mills amendments, to provide medical care for those who are not recipients of old age assistance but whose incomes are inadequate to meet costs of necessary medical care (Gardner, 1986). Drugs were provided by community pharmacies. Effective January 1, 1970, States were required to consolidate titles I, IV, X, and XV in order to be eligible for Federal cost sharing (although by April 1968, 40 States already had approved medical assistance programs).

Drug reimbursement as a component of medical services is not mandatory under Medicaid. In 1967, 31 States included some form of payment for drug services. Table 1 illustrates payment and coverage policies of the 31 State Medicaid drug programs in 1967 and of all States (except Arizona) and the District of Columbia in 1992. In 1992, all State Medicaid programs provided prescription drug benefits. Since 1982, the Arizona Health Care Cost-Containment System has provided all services on a capitated basis with prepaid health plans, health maintenance organizations, and other entities. The delivery of pharmacy services is the responsibility of each prepaid plan. The Omnibus Budget Reconciliation Act (OBRA) of 1990 drug rebate provision no longer allowed States to maintain formularies. Prior to this

The author is with the Office of Research and Demonstrations, Health Care Financing Administration (HCFA). The opinions expressed are those of the author and do not necessarily reflect the views or policy positions of HCFA.

legislation, 13 of 50 States and the District of Columbia had formularies, compared with 6 of 31 States in 1967. However, OBRA 1993 retracted that policy and again allowed States to have formularies, providing they meet the requirements of the law (Public Law 103-66, 1993). For example, a drug may be excluded only if the drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other drugs included in the formulary and there is a written explanation of the basis for the exclusion available to the public.

Table 1

Summary of Drug Cost-Containment Policies: 1967 and 1992

Feature	Number of States
1967	
No Formulary	24
No Dollar Limits	19
Dollar Limits	7
General Exclusions	7
100-200 Item Formulary	3
300-500 Item Formulary	3
900 Item Formulary	1
1992	
Copayment	27
Prescription Limit per Month	10
Refill Limit	26
Quantity Limit	40
Prior Authorization	34

NOTE: States may have more than one cost-containment policy.

SOURCES: U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs: *Current American and Foreign Programs.* Washington, DC., 1968; (Colligen, 1993).

Formularies, prior approval programs, generic substitution, copayments, spending limits, and audits to address fraud and over-utilization were cost-containment strategies utilized by Medicaid in the 1960s, and many continue today.

For fiscal year 1967, the total amount spent on drugs in Medicaid exceeded $182 million; in 1992, drug spending approached $6.8 billion (Colligen, 1993). California, which had the largest program, spent $36 million in 1967 and $824 million in 1992. Delaware, with the smallest expenditures, spent $112,000 in 1967 and was ranked 48th in 1992 with $9.8 million spent on drugs.

The reimbursement formulas used in the various State medical assistance programs in the 1960s included a markup applied to percentage of cost and a dispensing fee. Cost was provided by the *Red Book* or *Blue Book*, and the median price of several different manufacturers was used by some States. The dispensing fee ranged from $0.35 to $2.00; the percentage markup ranged from 33 ⅓ percent to retail list price. As addressed in the Adams, Kreling, and Gondek article, several States have varying dispensing fees. For this study, averages were obtained by the State or simulated. Payment for ingredient costs was estimated for a market basket of 80 drugs. Both dispensing fee and ingredient costs were utilized to determine whether Medicaid payment for pharmaceuticals is adequate. If a drug benefit for Medicare becomes part of health reform and all Americans have coverage for pharmaceuticals, will paying average costs still be viable?

Lamphere-Thorpe et al., in this issue, found that the cost of dispensing a prescription in North Carolina in 1991 was $5.37 and that large chains had higher dispensing costs than independents. The authors suggested a potential reimbursement policy based on pharmacy type. Caution is urged here, particularly because this and other studies have shown that the cost of dispensing is more closely related to prescription volume than store type. The study raises the question of what other factors may influence variation in dispensing costs.

The impact of cost-containment policies on utilization and expenditures was addressed in recent studies in the private sector (Smith, 1993), and in Medicaid (Soumerai et al., 1987). One conclusion

from these studies was that copayments reduced the number of prescriptions. The article by Buchanan and Smith in this issue illustrates, for acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus (HIV), the various cost-containment policies for prescription drugs across Medicaid programs today. To achieve the standardization of coverage across States for HIV, AIDS, and other terminal conditions, as suggested by the authors, diagnosis would have to be a required element of the prescription. However, confidentiality and privacy issues have arisen when diagnosis has been suggested as a necessary component for drug utilization review. Interestingly, in 1961 West Virginia required that diagnosis be written on all prescription forms. Auditors attempted to correlate drugs prescribed to the diagnosis outlined by the welfare medical program. While physicians today cite confidentiality issues, 98 percent of physicians participating in the program in the 1960s provided diagnosis on the prescription form. Could the suggested policy changes be implemented today while still safeguarding patient confidentiality?

MEDICARE

Under title XVIII of the Social Security Act, Medicare was implemented on July 1, 1966, to provide health insurance to individuals 65 years of age or over. Part A of Medicare covers inpatient hospital services and post-hospital care furnished by skilled nursing facilities (SNFs) and home health agencies—including prescription drugs given to hospital and SNF patients. Part B covers in-hospital and out-of-hospital physician care, outpatient hospital care, and certain other services, but generally not prescription drugs. Drugs that cannot be self-administered—generally injections—and are given as part of a physician's or hospital outpatient center's services, are covered under Part B.

One of the provisions of the Medicare drug benefit, under Clinton's proposed Health Security Act, is an advisory council on new breakthrough drugs that would examine the reasonableness of launch prices of new drugs. In 1993, there were 19 approved biotechnology drugs in the United States. The cost of these drugs is generally quite high; for example, Pulmozyme, for the treatment of cystic fibrosis, is approximately $10,000 per year.

The article by Griffiths et al. explores the coverage of recombinant human erythropoietin, a biotechnology drug covered by Medicare, used to treat anemia associated with end stage renal disease. This study gives us a glimpse into the future of the cost of covering new biotechnology-derived products for Medicare outpatients and the importance of determining their cost effectiveness. The article addresses several important questions, such as: What non-clinical factors affect the prescribing of erythropoietin? What is the impact of dose on patient outcomes? Is the treatment cost-effective? A missing component in the analysis is the utilization of other medications. We currently have no person-level data on Medicare beneficiaries' utilization of medications not reimbursed by HCFA. With a Medicare drug benefit, future access to all drug claims will facilitate comprehensive studies.

The study by Stuart and Coulson adds yet another dimension to previous work on health care utilization patterns prior to death. Lubitz and Riley (1993) stated that two important services were not included in their analysis—prescription drugs and nursing home care not qualifying for Medicare. Pennsylvania's Pharmaceutical Assistance Contract for the Elderly program, which provides prescription drugs to the elderly,

granted access to one of these variables for the Stuart and Coulson study. The analysis is the first to look at the impact of prescription drug utilization patterns prior to death. It would be interesting to examine this issue in a national sample. Prescription drug utilization may be confounded by the interrelationship between chronic conditions and cause of death, and needs to be further explored.

PRIVATE PAYERS

Commercial Insurers

Generally speaking, private insurers seem to follow the example of Medicaid prior to setting their own policies. In late 1967, Blue Shield announced a prepaid drug insurance program for groups in portions of New York, New Jersey, and Pennsylvania. Coverage to those areas and groups already having Blue Cross/Blue Shield hospital or medical plans was restricted to those under 65 years of age. Patients were covered only when they had their prescriptions filled at participating pharmacies.

The earliest examples of organized provision of pharmaceuticals were nonprofit union-operated pharmacies in health centers, funded in whole or in part by contributions of employers to union welfare funds. The first union to have this coverage was the International Ladies Garment Workers Union that began coverage in 1917.

Group Health Cooperative of Puget Sound was organized in Seattle, Washington, in 1947 to provide its members with a wide assortment of health services. The provision of prescription drugs was included from the start. Savings were achieved through direct purchasing of drugs in large quantities, using generic drugs wherever possible, requiring competitive bidding, and having a restrictive formulary.

The United Mine Workers of America Health and Retirement Fund of 1974 was the successor to the fund first created in 1950. The Gianfrancesco, Baines, and Richards article illustrates the insurance effect on prescription drug expenditures and utilization by comparing new and long-term Fund enrollees. New enrollees had an insurance effect for expenditures and utilization of 18 and 12 percent, respectively. The relevance of the insurance effect is important in calculating expenditures for the proposed Medicare drug benefit as seen in the Waldo article. What is the impact of insurance on high- and low-cost drugs and on different therapeutic classes? Can parallels be drawn from between the aging mine workers and the Medicare population?

INTERNATIONAL

The price of prescription drugs continues to be a concern of policymakers. Prescription drug policies in two countries, Canada and Germany, are described here. Canadian wholesale drug prices exceeded those in the United States for most therapeutic drug classes in 1967 (House of Commons, Canada, 1967). The 1964 Hall Commission in Canada made several recommendations to reduce drug expenditures (House of Commons, Canada, 1967). The recommendation that the Federal government contribute 50 percent of the cost of the drug benefit program in any Province was legislated for the Canadian Medicare program, which covers 90 to 95 percent of the population, and went into effect in 1968. The other recommendations did not become mandates. The Provinces maintain prescription drug programs that have varying prescription restrictions, much like Medicaid. Some Provinces utilize formularies, copayments, prior authorization, and/or coinsurance.

The General Accounting Office recently compared prices paid for prescription drugs in the United States and in Canada in 1991. The study concluded that wholesalers in the United States pay approximately 32 percent more for identical drugs than wholesalers in Canada (Comptroller General of the United States, 1992). The change from the United States paying less in 1967 to paying more for drugs in 1991 may be partially attributable to the dilution of the Canadian patent laws that encouraged the development of generic products under compulsory licensing, from 1967 to 1987, even if a patent for a trade product had not expired (Comptroller General of the United States, 1993a). Thereby, lower priced drugs became more readily available. The Patented Medicine Prices Review Board (PMPRB) was established in 1987 by the Canadian government because of concerns about reduced research and development of pharmaceuticals in Canada. The PMPRB reviews introductory prices of new drugs or price increases of drugs that are still under patent. It is believed that the board has contributed to price restraints in Canada.

The article by Katz describes the impact of German reunification on prescription drug utilization and expenditures. The study illustrates how quickly the former East Germany came to parity with the West in utilization and expenditures of prescription drugs. Will we see a parallel here in the United States with a Medicare drug benefit, including an increase in the utilization of more expensive products?

The article by Gross et al. provides an overview of drug policies in four countries: France, Germany, Sweden, and the United Kingdom. In order to appropriately assess the overall impact of these policies, the policies should be examined in the context of the individual country's health-care environment. To what degree do patient expectations and/or physician behavior impact on pharmaceutical spending? Is the drug therapy appropriate? The differences among countries in the proportion of drug spending relative to total health care spending raises questions. What contributes to this spending phenomenon? How have drug expenditures changed relative to overall health care expenditures?

In an effort to contain health care costs, Germany implemented a global budget for health care effective January 1, 1993. Drugs are one component of the budget. The global budget for drugs caps spending for 1993 at the 1991 level and requires that many drug prices be lowered 5 percent for 2 years (Comptroller General of the United States, 1993b). Beginning in 1994, physician associations and sickness funds will negotiate regional drug budgets. Both physicians and the pharmaceutical industry will be financially responsible for spending that goes beyond the capitated limit.

PROPOSED NATIONAL PLANS

As outlined in the Waldo article, the proposed Health Security Act expands Medicare benefits to include outpatient prescription drugs. The methods used by Waldo to estimate the cost of a Medicare drug benefit are somewhat different from those used by the Congressional Budget Office (U.S. Congressional Budget Office, 1994), particularly the assumptions of induced demand. However, the bottom line estimates are very close. There are several important questions the Waldo article addresses: How will the proposed drug benefit impact on drugs currently covered under Medicare or Medicaid? How do premiums and deductibles affect expenditures?

Unlike the Medicaid rebate program, the proposed Medicare rebate program does

not use best price, but rather suggests a weighted average manufacturers' price. The magnitude of the effect of the two different rebate programs to reduce drug expenditures remains to be seen. The Medicare rebates may have more of an impact on reducing discounts to volume purchasers than the Medicaid rebate law, because the Medicare outpatient drug market is roughly three times that of Medicaid. If the gap in pricing narrows, the rebate to both Medicare and Medicaid will become smaller.

In addition, there are several other proposed health reform plans. The American Health Security Act (McDermott-Wellstone) would replace the Medicare program with a single-payer program. Thus, beneficiaries would receive drugs under a universal program. Two other proposed plans would allow Medicare beneficiaries to enroll in a variety of health plans in which prescription drug coverage may or may not be available—the Health Equity and Access Act (Thomas-Chafee) and the Managed Competition Act (Cooper-Grandy). In other words, the drug benefit would not be mandated. How the drug cost estimates would change under other proposed legislation is unknown.

SUMMARY

The articles presented in this issue offer an array of policy-relevant studies in an area that has become increasingly important to both the public and third-party payers. Although it is believed that appropriate utilization of drugs can contribute to containing the growth of health care costs, the impact of appropriate prescribing, dispensing, and use of drugs associated with costs of hospitalizations and physician visits is generally unavailable. As new, ever-more-expensive drugs come to market, comprehensive studies of utilization, expenditures, prices, quality, and cost effectiveness will enhance the policy process.

REFERENCES

Burner, S.T., Waldo, D.R., and McKusick, D.R.: National Health Expenditures Projections Through 2030. *Health Care Financing Review* 14(1):1-29, December 1992.

Colligen, B.H. (ed.): *Pharmaceutical Benefits Under Medical Assistance Programs.* Reston, VA. National Pharmaceutical Council, 1993.

Comptroller General of the United States: *Prescription Drugs: Companies Typically Charge More in the United States Than in Canada.* GAO/HRD-92-110. Washington, DC. U.S. General Accounting Office, 1992.

Comptroller General of the United States: *Prescription Drugs: Canada's Drug Price Review Board.* GAO/HRD-93-51. Washington, DC. U.S. General Accounting Office, 1993a.

Comptroller General of the United States: *1993 German Health Reforms: New Cost Control Initiatives.* GAO/HRD-93-103. Washington, DC. U.S. General Accounting Office, 1993b.

Gardner, V.: *Structuring Drug Benefits.* Final report of the APHA Pharmacy Commission on Third Party Programs. Washington, DC. American Pharmaceutical Association, 1986.

House of Commons, Canada, Special Committee of the House of Commons on Drug Costs and Prices: *Second (Final) Report.* Ottowa. Queen's Printer and Controller of Stationery, 1967.

Lubitz, J.D., and Riley, G.F.: Trends in Medicare Payments in the Last Year of Life. *New England Journal of Medicine* 328(15)1092-1096, 1993.

Navarro, R.P. (ed.): *HMO Facts and Figures.* Ciba Pharmacy Benefit Report. 1994.

Pink Sheet, The: PCS Manages 21% of Retail Dispensed Prescriptions—Walsh America Data; Out-of-Pocket Scripts Dip Below 50% of Market, HMO Formulary Compliance Nears 90%. March 14, 1994.

Public Law 103-66, section 13602(d)(4)(A-E), *Omnibus Budget Reconciliation Act of 1993.* August 10, 1993.

Smith, D.G.: The Effects of Copayments and Generic Substitution on the Use and Costs of Prescription Drugs. *Inquiry* 30(2):189-198, Summer 1993.

Soumerai, S.B., Avorn, J., Ross-Degnan, D., and Gortmaker, S.: Payment Restrictions for Prescription Drugs Under Medicaid: Effects on Therapy, Cost and Equity. *New England Journal of Medicine* 317(9):550-556, 1987.

U.S. Congressional Budget Office: *An Analysis of the Administration's Health Proposal.* Washington. U.S. Government Printing Office, 1994.

Reprint Requests: Kathleen Gondek, Ph.D., Office of Research and Demonstrations, 2504 Oak Meadows Building, 6325 Security Boulevard, Baltimore, Maryland 21207.