

INTRODUCTION

Prescription drugs play an ever-increasing role in modern medicine. New medications are improving health outcomes and quality of life, replacing surgery and other invasive treatments, and quickening recovery for patients who receive these treatments. Drugs can reduce the need for bypass surgery, help prevent brain damage in stroke victims, lower cholesterol levels, or provide relief for chronic pain. Continued progress in biotechnology and genetic research promises still more innovative therapies in the coming years.

As important as prescription drugs are, not everyone has access to them. The newest drugs are often the most expensive, and millions of Americans have inadequate or no insurance coverage for drugs. The problems are especially acute for elderly and disabled Medicare beneficiaries. Many have chronic conditions for which drug treatments may be especially effective, such as osteoporosis, hypertension, diabetes, or depression. Medications for these conditions must be taken for extended periods, and beneficiaries with multiple problems may need several different drugs, many costing \$1,000 a year or more. And nearly all take some drug in a given year. Yet nearly a third of all Medicare beneficiaries, many with very limited incomes, have no financial protection for the costs of these drugs, if they can obtain them at all. Many more beneficiaries find themselves moving in and out of the protection provided by insurance.

Medicare has never included coverage of outpatient prescription drugs, with very limited exceptions such as cancer chemotherapy drugs, and anti-transplant rejection drugs. The exclusion of drugs was common in private health plans when Medicare was enacted in 1965. Since then drug coverage has become a standard feature of private insurance, and it has become clear that the omission of outpatient drug coverage represents a crucial gap in protection for the most vulnerable Medicare beneficiaries. Beneficiaries without drug coverage face heavy financial burdens, and many go without needed medications or purchase less than the amount prescribed. Even many beneficiaries who have coverage today are at risk of losing it, paying higher premiums, or receiving more limited benefits as the cost of prescription drugs continues to grow. The problem is not limited to Medicare beneficiaries: millions of other Americans are without drug coverage, and some insurers and employers are responding to spending increases by requiring health plan participants to pay a larger share of their own costs.

As part of a broader plan to modernize Medicare, President Clinton has proposed a new, voluntary Medicare drug benefit that would offer all beneficiaries access to

affordable, high-quality prescription drug coverage while maintaining the fiscal integrity of the program. In Congress, there has also been growing bipartisan interest in finding ways of extending drug coverage. At the same time, there has been increasing attention to the prices beneficiaries without coverage must pay for some needed medications. Congress is considering proposals that would give individual beneficiaries access to the discounts offered to group purchasers, or that would speed the availability of lower-cost substitutes for the newest and most expensive drugs.

As policymakers consider options to assure that every American can have access to innovative drug treatments, there is an urgent need for comprehensive and reliable information on drug coverage, drug spending, and drug prices. On October 25, 1999, the President directed the Secretary of Health and Human Services to study prescription drug costs and trends for Medicare beneficiaries. He asked that the study investigate:

price differences for the most commonly used drugs for people with and without coverage;

drug spending by people of various ages, as a percentage of income and of total health spending; and

trends in drug expenditures by people of different ages, as a percentage of income and of total health spending.

This report is the Department's response to that request. It represents the work of individuals and agencies throughout the Department, including the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE).

In Chapter 1, the report provides estimates of the extent of prescription drug coverage among both Medicare beneficiaries and the general population. Chapter 2 provides evidence of the consequences of lacking coverage, including reduced utilization and expenditures for drugs, higher financial burdens, and failure to obtain needed treatments. Chapter 3 examines drug prices, highlighting growing disparities between what is paid by employers and insurers and what is paid by individuals who must purchase drugs on their own. In addition, several issues relating to geographic variation in prescription drug coverage, utilization, and pricing – where results are not definitive – are discussed in Appendix C.

While this initial study is informative, the research conducted for this study has uncovered numerous areas in which further investigation and analysis could provide a better understanding of problems in prescription drug financing and possible solutions. In the future, the Department will be continuing the coordinated and intensive research effort that produced this report and will provide new insights and analyses as they become available. The conclusion of this report includes a discussion of ideas for future research.

In addition, the Department commissioned a literature review by Bruce Stuart and his colleagues at the Peter Lamy Center for Drug Therapy and Aging at the University of Maryland School of Pharmacy. The literature review is included as Appendix A of this report. This review assesses the current state of research on prescription drug costs and trends for Medicare beneficiaries with and without prescription coverage and examines the use of prescription drugs and drug pricing in other nations. The detailed literature search included a traditional index search of literature in the medical, social and behavioral sciences, health services research and public policy arenas; search for relevant statistical data in domestic and international documents; identification of relevant ongoing research efforts; and identification of relevant working papers and presentations at professional associations. The resulting review summarized the literature from the perspective of what is known and what needs to be known on the issues of prescription drug coverage, pricing, utilization, and spending.

MAIN DATA SOURCES FOR THIS REPORT

Analysis in this report is based chiefly on two household surveys conducted in 1996, the Medicare Current Beneficiary Survey (MCBS) and the Medical Expenditure Panel Survey (MEPS), and on data from pharmacy audits conducted by IMS Health. The following is a brief overview of these data sources. More detail on methodologies for MCBS and MEPS is provided in Appendix B.

MCBS and MEPS

For this report, coverage, utilization, and spending data for the Medicare population are drawn from MCBS. MCBS is a continuous, multipurpose survey of a representative sample of the Medicare population.¹ Work on the MCBS is done under the direction of HCFA's Office of Strategic Planning through its contractor, Westat, Inc. The 1996

¹ For a description of the MCBS, see G.S. Adler, Summer 1994, "A Profile of the Medicare Current Beneficiary Survey," *Health Care Financing Review*, 15(4): 153-163.

survey included approximately 16,000 beneficiaries either in or joining the continuing sample, plus an additional one-time over-sample of approximately 2,000 beneficiaries in areas with high Medicare risk HMO penetration. Each continuing sample person, or an appropriate proxy respondent, is interviewed three times a year over a four-year period, regardless of whether he or she resides in the community or in an institution. In 1996, the sample for the Cost and Use component used in this report totaled 11,884 individuals; after excluding people who were institutionalized for the entire year, the sample includes 10,869 beneficiaries. The analysis of trends also drew upon the MCBS for 1992 through 1995.

For this report, coverage, utilization, and spending data for the non-Medicare population, along with some prescription price data for the entire population, are drawn from MEPS. MEPS, co-sponsored by the Agency for Healthcare Research and Quality and the National Center for Health Statistics (NCHS), is conducted to provide nationally representative estimates of health care utilization, expenditures, sources of payment, and insurance coverage.² The MEPS has several components, of which two were used for this report: the Household Component (HC), a representative survey of the U.S. civilian noninstitutionalized population, and the Pharmacy Component (part of a broader Medical Provider Component), which contacts pharmacies reported by HC participants to supplement and validate information on prescription drug use and spending. The HC collects data through an overlapping panel design. In this design, data are collected through a preliminary contact followed by a series of six rounds of interviews over a two-and-a-half year period. Two calendar years of medical expenditures and utilization are collected from each household, along with information about insurance coverage. Data for 1996 are used in this report, based on a sample of 21,571 individuals.

The MCBS data used here include people who were in institutions only if they spent at least part of the year in the community. The MEPS HC is limited to noninstitutionalized people.³ This report therefore contains no information about drug coverage, utilization, or expenditures for the 1.6 million Americans, mostly elderly, who were living in nursing homes for the entire year of 1996, or for other people living in institutional settings such as long-term hospitals. Although facility residents are often heavy users of prescribed drugs, coverage and payment arrangements for these drugs are different from those for community residents. For example, drug costs may

² For a description of MEPS, see Cohen, J.W. et al, "The Medical Expenditure Panel Survey: A National Health Information Resource," *Inquiry*, 33 (Winter 1996/97), pp. 373-389.

³ A separate Nursing Home Component surveys facilities and residents.

be included in a nursing home bill, rather than charged separately by a retail pharmacy. As a result, collection of comparable information for the community and institutionalized populations is not possible.

Three features common to the two surveys should be considered in interpreting the results:

Both surveys found that some participants who failed to report having drug coverage actually had a prescription during the year for which payment was made by a third party. Payment source information might be supplied by the respondent in either MCBS or MEPS; in the case of MEPS, information could also be obtained through the pharmacy follow-back. In both surveys, the individual was deemed to have had drug coverage if self identified. In MCBS, however, there is an exception if a beneficiary reports drug coverage but has high out-of-pocket payments and no third party payments. In MEPS, the individual was also deemed to have drug coverage if identified in the pharmacy data.

When a person reported or was otherwise identified as having more than one source of drug coverage during a year, he or she was assigned to one source of coverage. In MEPS, people with multiple sources of coverage were assigned to the type of coverage they had for the longest time during the year. If they had multiple sources for the same length of time they were assigned according to the following hierarchy: private group insurance, private nongroup insurance, private “other” group insurance, Medicaid, and Medicare HMO. MCBS also has a hierarchy: Medicare risk HMO, Medicaid, employer-sponsored, individually purchased, and other public. In MCBS, unlike MEPS, beneficiaries are assigned to the first relevant category in this listing regardless of how many months they spent in which categories.

Both the MEPS and the MCBS analyses reported here treat individuals who reported coverage at any time during the year as covered. In fact, many people had drug coverage only for a part of the year. Data on duration of coverage for Medicare beneficiaries will be presented later in this report.

Further discussions of survey methodology can be found in Appendix B.

IMS Health

IMS Health conducts pharmacy audits to produce estimates of national sales of all pharmaceutical products sold through retail pharmacies. For each individual

prescription drug, the IMS data provide information on total units sold during a given period, the acquisition costs paid by pharmacies, and the retail prices paid by three categories of purchasers: those who paid cash (for whom no insurance payment was made at the point of sale), those for whom payment was made by Medicaid, and those for whom payment was made by a third-party insurer. (Note that these categories reflect the source of payment to the pharmacy itself. If someone paid cash for a drug and was later reimbursed by an insurer, as is common under indemnity insurance plans, the transaction falls into the cash category.)

Other Data Sources

In addition to these three basic surveys, this report draws on findings from two other community-based surveys. The first is the ongoing Consumer Expenditure Survey (CES) conducted by the Bureau of Labor Statistics, which collects information on household income and spending. The second is the 1997 National Health Interview Survey (NHIS) conducted by the NCHS at the Centers for Disease Control and Prevention.

Trend estimates for aggregate U.S. drug spending are derived from the National Health Expenditures Series developed by HCFA, which provides longitudinal information on aggregate spending by different payers for various categories of health services and supplies.

Finally, representatives of the Office of the Assistant Secretary for Planning and Evaluation and HCFA conducted a series of informal interviews with outside sources to collect background information for this report. These sources included representatives of drug manufacturers, pharmacy benefit managers, pharmacies, benefit consultants, consumer groups, and researchers familiar with the drug industry. They were asked for their insights on how the drug distribution system works, important trends in the industry, and any information that they could share about drug coverage, utilization, spending, and pricing.

Standard Errors and Statistical Significance Tests for Reported Results

Standard errors were produced for all of the survey-based results to ensure that the estimates derived from the surveys are robust – meaning that the reported estimates are not likely to be highly different from the values that would be produced if the entire population, rather than a sample, had been used to calculate the result. As a general rule, standard errors of greater than 30 percent of the reported result indicate that the estimate is unreliable. In these (relatively few) cases, the report will indicate that high standard errors preclude reporting the result.

Wherever possible, results noted in the text of this report have been subjected to statistical significance tests, to ensure that they are likely to be real, and not attributable to chance. The approach taken throughout this report is to indicate in a footnote only the few cases in which a result was not statistically significant. Thus, unless otherwise noted, results discussed in the text are statistically significant (at the 0.05 level, based on a two-tailed test).

The only results that were not subjected to significance tests were results based on the IMS data. The unique nature of the way IMS collects and reports its data does not allow for statistical testing of results from these audits. However, given the large sample sizes used by IMS (over 70 percent of US prescriptions filled at retail pharmacies), all results reported based on IMS data are highly likely to be statistically significant.

STRENGTHS AND LIMITATIONS OF THIS STUDY

There are a number of important strengths and limitations of this study. In general, the main strengths of this work are the variety and diversity of data sources used in the analysis to create a more comprehensive picture than would have been otherwise possible. Specifically:

The study took advantage of a comprehensive array of public data sources including newly available data on prescription drugs from the MEPS, detailed data on the Medicare population from the MCBS, and data from the NHIS, CES, and the National Health Expenditure Series.

The study also made use of an important private sector data base on pharmaceutical prices from IMS Health. These data not only offer an enormous sample size (nearly 70 percent of prescriptions from retail pharmacies), but they are a data source accepted and widely used by industry, and have been in existence for a relatively long time.

Taken together, the public and private data sources represent the most recent data available to address the main analysis questions.

We also undertook a comprehensive literature review and conducted informal conversations with a wide range of industry experts to inform our analysis and to help explain the intricacies of the pharmaceutical marketplace.

As with all studies of this kind, there are limitations to the data and our analysis that are important for the reader to understand. Many of the key weaknesses stem from the short time frame in which the study was completed, which prevented more in-depth analysis on some topics, or inherent limitations of the data that are available to analyze prescription drugs. Specifically:

The sample sizes for MEPS and MCBS are too small to do some subgroup analyses and to go beyond the simple two and three variable cross-tabs we present. In addition, both sample sizes are too small for any meaningful drug-by-drug analysis. Our use of IMS data alleviates these concerns for the analysis of drug prices.

Although the 1996 MEPS and MCBS data represent the most recent data files available, given the dynamic nature of the pharmaceutical market, it will be important to continue to examine these issues as more information becomes available.

Individually, each of the main data sets is not fully representative (e.g. nursing home patients are not included in this analysis, MCBS only includes information on Medicare recipients, and IMS data used in the study only cover retail pharmacies). Taken together, however, the data sources cover the range of populations more effectively than most previous studies.

Lack of rebate information, which manufacturers consider to be highly sensitive, is a ubiquitous problem in analyzing drug prices. Given the highly competitive nature of this market, it is unlikely that there will ever be a comprehensive data source on rebates.

This short-term study presents descriptive results using only univariate analysis with two and three variable cross-tabs. Descriptive analysis of this type cannot explain why covered individuals use more drugs or whether use of drugs leads to better outcomes. We plan to undertake future analysis that will use multivariate techniques to delve further into the data presented here, although such analysis is likely to push the limits of available data.

A problem common to all surveys that sample individuals is their reliance on self-reported data. Self-reported data may not be accurate due to recall problems. Both MEPS and MCBS, however, use multiple rounds of interviewing of the same respondents each year in an effort to mitigate recall problems. In addition, MEPS uses a pharmacy follow-back survey to validate

information reported by respondents, and the IMS data are derived directly from the retail pharmacy.

The conclusion of this report includes a discussion of ideas for future research that were generated during the course of developing this report. The strong foundations that this report lays should allow us to delve further into these topics in future analysis.