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# Explosion in the Medicine Chest

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*This overview ties together the various articles by relating them to the current debate on whether, and how, the Medicare program can add outpatient drugs as a covered benefit. The unifying theme for most of the articles is that they outline possible ways of administering a drug benefit and discuss policy issues that will arise, based on Health Care Financing Administration (HCFA) experiences or State government experiences in efforts to administer existing drug benefits in a cost-effective manner while attempting to ensure the best medical outcomes. The articles provide information about drug utilization among Medicare beneficiaries with and without insurance coverage, among Medicaid beneficiaries, and among subpopulations for whom drug therapies can be considered essential.*

## INTRODUCTION

This issue of the *Review* brings together a collection of articles on the topic of drug coverage in Medicaid and Medicare. Although, for the most part, the articles appear to be on rather narrow topics within the general subject, current events make each of the articles a timely contribution to discussions underway concerning political and economic issues relevant to the Medicare and Medicaid programs, relevant to private sector health care, and, in the end, relevant to economic and political concerns of the Nation as a whole. This overview takes a very, very long view of the issues, stepping back a few years in history to set the stage.

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## An Ancient Nexus

One can imagine a scene in ancient history sometime in the 5th Century B.C....As Hippocrates is putting the finishing touches on an Oath he is developing, his near-contemporary in history, Sun Tzu, in another corner of the globe, is busy writing the first known book on military strategy, *The Art of War*. Though true authorship in either case is uncertain, the connection between the “healing arts” and the “art” of war has continued throughout history, both in terms of coincidence of time lines, and, logically, because one “art” created a need for improvement in the other. It is also striking how much terminology is shared in common between the lexicon of the “healing arts” and what one would think of as the natural antithesis of these arts (or antagonist, to use a term shared in the lexicon of each), the “art” of war. To cite some examples, we speak of “battling” illness, “fighting off” colds, and “campaigns” to eradicate diseases. With regard to drugs, they have been referred to as an indispensable element of the “armamentarium” of modern medicine. In American history, in the 20th Century (A.D.), the two seemingly opposing endeavors, war and progress in medical science, have been companions over much of the course of our history.

As the 20th Century began, America had just concluded a war that changed the role of the Nation on the international scene, and added territorial possessions near (in the Caribbean) and far (the outer rim of the Pacific Ocean). On the medical “front,” it was in the immediate aftermath of the Spanish-American War that Walter Reed, in

the very first year of this century, confirmed Carlos Finlay's theory on the source of yellow fever—work that led to the eradication of the disease in Havana, Cuba. The contracting of yellow fever among American troops stationed in Havana was an impetus in the effort to control the disease.

A little later, America's late intervention in World War I was welcomed by the Allies. What may not have been so welcome was America's role in a catastrophe that reminded humanity of the devastation that disease can wreak, as more than 20 million people—almost three times the number of casualties in the war—died from the Spanish influenza pandemic of 1918-20. The flu virus was thought to have been carried to Europe by American troops entering combat in the last year of the war.

The "great wars" of the first half of this century both played a part in the revolutionary discovery of antibiotics. During World War I, Sir Alexander Fleming, as a member of the Royal Medical Corps, conducted bacteriological research. Although Fleming discovered penicillin in 1928, it took another war, and the efforts of two other individuals, to allow the full potential of antibiotics to be realized. In the same year that the Second World War began, Ernst Chain and Howard Florey began building upon Fleming's work, permitting antibiotics to be available to meet wartime needs. In the year the war ended, the three shared the Nobel Prize for medicine. Meanwhile, in America, it was also in the year that the Second World War began that Jonas Salk received his medical degree. In 1947, when what was the United States War Department became the Defense Department and the Cold War began in earnest, Salk began his polio research at the Virus Research Laboratory of the University of Pittsburgh. At the height of the Cold War, with the eradication of polio in this country, modern medicine demon-

strated that it could not only cure disease, it could also ward it off, as polio, smallpox, and other diseases were eradicated.

The year 1965 was a momentous year for health care in America, and, coincidentally, for the history of war in America. In March of 1965, America sent its first combat troops to Vietnam. In the same year, the Medicare and Medicaid programs were enacted, introducing two programs that expanded the role of government in providing access to medical care for large segments of the population. One of these public programs was a Federal-State medical assistance program that allowed coverage of outpatient prescription drugs from the outset, on an optional basis by the States (Gondek, 1994).<sup>1</sup> The other program, a social insurance program initially for retired workers and their dependents and survivors, did not cover drugs. Thirty years later, the decision to exclude drugs from Medicare is being re-examined, just as it has been a number of times over the past three decades.

### **The (More) Modern Age**

From all of the aforementioned, one might arrive at the lamentable conclusion that it takes a war to see advances in medicine and/or social policy, but that is not the case. The Nation's recent period of peace and prosperity has witnessed continued advances in medical knowledge and, most notably, breathtaking advances in the development and production of new drugs from new sources, such as genetically engineered drugs. However, the connection to the "art" of war still continues—at least at the level of shared lexicon. While the leaders of the Nation are now pondering the question of whether, and how, Medicare should cover drugs, recent news

<sup>1</sup> In 1967, 31 States offered Medicaid drug coverage, and by 1992, all State Medicaid programs covered drugs.

from the medical front highlights the explosion of new drugs available on the market, and the equally explosive growth in utilization and overall costs of pharmaceuticals. Thus, in *The New England Journal of Medicine*, there is talk of “explosive” increases in expenditures for drugs (Soumerai and Ross-Degnan, 1999); or a consultant comments on the situation among health maintenance organizations in California, “Nobody is comfortable with pharmacy. They all see it as *exploding*, as a major problem that is not controlled by anything that I have seen so far” (National Health Policy Forum, 1998).

This explosion in drug costs in the recent past reflects a number of factors, and it has drawn much attention partly because of the contrast with the recent success in containing overall medical costs. As Levit et al. (1998) explain the rise in costs: drugs are increasingly used as alternatives for other forms of treatment; third-party coverage of drugs has increased in the private sector (because of the spread of managed care, third-party payments went from 49 percent of costs in 1989 to 71 percent in 1997); the number of prescriptions dispensed has increased at higher than historical levels; new (higher-priced) drugs are being introduced at a more rapid rate, and are increasingly advertised on a direct-to-consumer basis, which appears to have increased demand; and, finally, prices have risen somewhat. The most recent data from IMS Health (1999) indicate that, for the 12 months ending February 1999, the trend of higher utilization continues as “the North American retail pharmacy sector, valued at \$79.8 billion, continues to grow at 11 percent, with the U.S. accounting for the majority of sales. The U.S. is being driven by a combination of strong product launches, sales and promotion investment, managed care, increases in branded drug prices and a rise in drug utilization.”

As another indicator of the dominant role of drugs and their rising costs, according to a Solomon-Smith-Barney analysis (Harris and Ripperger, 1999) among managed care plans—the prevalent form of health care in America, following what was termed the “managed care revolution”—pharmaceuticals as a share of costs in 1998 are approaching hospital costs, with “pharmaceutical expenditures now represent[ing] at least 15 percent of expenditures,” while hospital costs “now represent only 25 percent of total expenditures, down from roughly 40 percent only 5 years ago.” Soumerai and Ross-Degnan (1999) mention that a large health maintenance organization (HMO) in Massachusetts believes that if the trend in drug expenditures goes “unchecked, they are projected to overtake hospital expenditures (about 20 percent of costs) by the year 2002.”

This means two things for Medicare: coverage of drugs is very costly (which comes as no surprise), and to the extent that drugs do overtake other types of medical care in expenditures, and this difference reflects medical practice preferences and better outcomes through drug therapies, the gulf between the nature of coverage in the private sector (where a large majority of health plans cover drugs, as noted by Poisal et al. in this issue) and Medicaid, on the one hand, and Medicare, on the other, will only widen if the Medicare benefit continues to exclude drugs.

### **Covering Drugs in Medicare**

Perhaps it shows the genius of the English language or economy in the use of the available words of the English lexicon, or maybe it only shows a lack of imagination among speakers and writers looking for analogies and metaphors—after all, not everyone can be a Shakespeare—but, for

whatever reason, martial language is also to be found in the arena of sports, for example, and the arena of politics, where “campaigns” can lead to victory, or can result in crushing defeats. The battles that have occurred over the years on the question of whether drugs would be covered by Medicare are well known. Even in current discussions, people continue to recall the scene of then-chairman of the House Ways and Means Committee, Dan Rostenkowski, having his car attacked by Medicare beneficiaries venting their anger over the way in which drug coverage was financed in the Medicare Catastrophic Coverage Act of 1988. The Act, with its Medicare drug coverage provisions subsequently repealed, proved to be a Pyrrhic victory gained by proponents of extending drug coverage to the Medicare population.

When the Medicare program was first enacted, drugs “were largely ignored in Medicare,” as Stevens (1996) put it, at a time when drugs were “relatively inexpensive” and the issue of greater interest and concern was the “rapid development of hospital-based medicine.” However, it is also true that drugs as a possible benefit in Medicare were not completely ignored. Long (1994) notes that the original debate over Medicare did touch on the question of whether drugs should be covered, “but, because of concern about the cost, the result was merely a commission to study the issue in the late 1960s.” In 1967, President Johnson appointed the commission in question, the Task Force on Prescription Drugs, “specifically to study the inclusion of drugs under Medicare,” the opening salvo in the effort to add prescription drugs to the Medicare benefit package (Waldo, 1994).

It is difficult to disregard the importance of drugs for the elderly and disabled. A more recent commission, the National Bipartisan Commission on the Future of Medicare, could not ignore the question.

In the context of discussions of how to “modernize” Medicare and “rationalize” the cost and benefit structure of the program, there appeared to be consensus among the commissioners that outpatient drugs needed to be added to the Medicare benefit package. However, lack of consensus on how that would be done in a premium support system or otherwise, and how it would be financed, given the costs, were among the reasons that the Commission failed to achieve a “super majority” of 11 members supporting any recommendation to Congress, as required by the statute establishing the Commission (the Balanced Budget Act of 1997).

Adding drugs to the Medicare package would provide a new benefit to 39 million people whose drug expenditures in 1995 were \$22 billion, according to the Medicare Current Beneficiary Survey (MCBS) data in the article by Poisal, Murray, Chulis, and Cooper; or, as Cook puts it, there would be new coverage for the 13 percent of Americans who account for 36 percent of drug expenditures. No matter how you “slice” the numbers, aside from the cost issue, a change of this magnitude presents daunting issues in policy and administration, as well as concern about the effects on the marketplace from the presence of a new, major, public sector payer. As Long (1994) put it in the post—Medicare Catastrophic Coverage Act era, commenting on the effect on the marketplace and physician and beneficiary behavior, “No one knows the size of the potential supply effects of widespread additions to coverage.”

### **Aside From Money**

As difficult as the political and financing decisions are in answering the larger questions—should Medicare cover drugs?, how should the benefit be financed?—the ques-

tions of how a benefit might be administered, and what approach should be taken to payment and coverage policy, are equally difficult. Perhaps in reading Cook's article, it is best to assume that we have a can opener, as the economist assumed in the joke about the desert island and the engineer, attorney, architect, etc., who could not figure out how to open the cans containing their only supply of food. That is, assuming that the decision is made to cover drugs in Medicare, and a financing method is sorted out, Cook's contribution to this issue presents a discussion of the possible options for ensuring that a drug benefit is provided in a cost effective manner and at a fair price. She has quite a bit to say about Long's (1994) "potential supply effects" that may arise if Medicare were to cover drugs.

An intricate range of types of mechanisms are in use in the private sector and the public sector that are intended to contain drug costs. Discounts are available to large purchasers, generally in recognition of their volume purchasing or their ability to favor one product over another substitute product. Cook reviews private sector and government practices, including the use of pharmacy benefit managers, formularies, rebates, discounts, and mail order as ways of containing costs. In government practices, she provides a detailed examination of the effect on the marketplace of the Medicaid drug rebate, and the suitability of that model, or the Federal Supply Schedule (FSS) approach, for Medicare.

Cook analyzes the Medicaid rebate and discusses the interaction between Medicaid, as an extremely large segment of the drug purchasing market (12 percent of the market), and the private sector. She points out that, because the basis of the Medicaid rebate is not that it is able to shift consumption to a particular drug or set of drugs, but it is instead a mandated rebate, there are consequences for the marketplace—e.g., higher

launch prices for drugs, lower discounts for other purchasers, etc., though this market effect is compensated for somewhat by higher sales to an insured segment of the population that has very generous drug coverage through Medicaid. Cook reviews the history of the conflict between two sets of public purchasers, Medicaid, and users of the FSS. At one time, the FSS was used by Medicaid as the "best price" basis for payment, resulting in a rise in FSS prices for all payers because of the share of the market included within the scope of the FSS price. This is a history worth pondering today, given that there are pending legislative proposals to give all Medicare beneficiaries access to FSS prices when they purchase drugs.<sup>2</sup>

With regard to Medicare, Cook points out that if, for example, a pharmacy benefits manager (PBM) is used to administer a drug benefit for the traditional Medicare fee-for-service (FFS) program, the program should not expect the kinds of discounts that would be possible in a private sector network plan. Traditional Medicare would be more akin to a private sector indemnity plan in terms of the ability of the PBM to control the prescribing patterns of practitioners. Cook sees a modified rebate approach and mail order as more likely candidates for achieving cost savings in drug purchasing for the Medicare population.

### **Current Sources of Coverage**

Cook's article also mentions the disadvantageous position of many Medicare beneficiaries in terms of the costs they must now pay for drugs. Those covered by medigap are not "fully shelter[ed]...from the risk of high expenditures." Those with coverage in Medicare+Choice health plans may have limits that do not protect them from catastrophic levels of drug expendi-

<sup>2</sup>The Prescription Drug Fairness for Seniors Act of 1999 (S. 731, H.R. 664).

tures. And many beneficiaries, both those without any coverage and those with particular types of coverage (e.g., medigap<sup>3</sup>), are paying retail prices for drugs while other purchasers are obtaining substantial discounts. Even when using mail order, Cook notes, Medicare beneficiaries, as individual purchasers, may not be getting substantial discounts, even though many of the drugs they use are maintenance drugs that lend themselves to mail-order purchasing. Cook's observations illustrate the variation in type of coverage that exists among different populations.

The variation in type of coverage among Medicare beneficiaries is also highlighted in the contribution of Poisal, Murray, Chulis, and Cooper. The article provides valuable information about the depth and extent of drug coverage among Medicare beneficiaries. It is a companion piece to an earlier article by Davis et al. (1999), which was frequently cited during the deliberations of the National Bipartisan Commission on the Future of Medicare. The information of particular interest in the earlier article was the finding that, according to MCBS data for 1995, 65 percent of Medicare beneficiaries had some form of drug coverage. This information was seized on by some to argue that the need for drug coverage among this population was not as great as popularly believed.

The general issue of how to include drug coverage in a "modernized" Medicare benefit package was difficult for the National Bipartisan Commission on the Future of Medicare, and the issue of introducing a benefit that would crowd out private

sources of what appears to be extensive drug coverage among Medicare beneficiaries was particularly contentious. Some would argue that it makes sense to continue a situation of having Medicare beneficiaries relying on the many alternative sources of coverage they have, or at least somehow taking advantage of these sources to build on the available drug coverage and extend further coverage.

However, the Poisal et al. article provides a clarification of what the 65 percent figure represents. Included as coverage, for example, are a number of public programs, such as Medicaid, Medicare risk HMOs (to the extent that the drug coverage is financed by Medicare capitation payments), and other public sources of coverage such as the Department of Veterans Affairs, the Department of Defense, and State pharmacy benefit plans. In 1995, the two types of private sector insurance (employer-sponsored coverage, covering about 44 percent of beneficiaries with coverage, and individually purchased medigap plans) paid for 28 percent of all drug expenditures for Medicare beneficiaries, though 63 percent of beneficiaries had such coverage as their primary or secondary source of drug coverage.

The article shows that the presence of drug coverage varies significantly among subgroups of beneficiaries. Looking at income levels, the lowest rate of coverage is among people with yearly incomes of \$10,000-\$19,999—that is, generally the range of lower-income individuals not eligible for Medicaid. In this group, 60 percent had coverage, while there was a 70 percent rate of coverage among individuals with incomes of \$20,000 or more.

A measure of the depth of drug coverage among Medicare beneficiaries is the level of out-of-pocket expenditures different sub-

<sup>3</sup> Some medigap insurers offer their subscribers drug discounts (even those purchasing plans other than H, I and J, which have drug coverage). (Note, for example, a March 29, 1999, news release of Blue Cross and Blue Shield of Florida, available at the organization's website, [www.bcbsfl.com](http://www.bcbsfl.com). Blue Cross provides its subscribers with a 30 percent discount at participating retail pharmacies.)

groups incur. Poisal et al. highlight the skewed distribution of utilization that is familiar in health expenditures and reveals a great deal about the depth of drug coverage. They show that, even among beneficiaries with coverage, one-fourth had out-of-pocket expenses (beyond any premium payment) of \$284 in 1995. About 14 percent of the population had no expenditures for drugs, while another 14 percent had expenditures exceeding \$1,250 per year. Sixty-four percent of beneficiaries had out-of-pocket costs lower than the average of \$233 (not including any premium payments).

As one would expect, the sicker a person is, the more he or she spends on drugs. As noted in several of the articles included in this issue, individuals with insurance coverage have higher expenditures than those without insurance. However, with respect to drugs, Shih notes in this issue, and Soumerai and Ross-Degnan (1999) point out, that those without insurance may be foregoing necessary drugs.<sup>4</sup>

It is noteworthy that individuals with individually purchased supplemental insurance (medigap) as their primary source of coverage only had 46 percent of their cost of drugs paid through the policy. Given that among standardized medigap plans, the deductible, coinsurance and limit levels have not changed since the standardization required by the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), and given the rise in drug utilization and costs over the years since 1992, when the standardization was implemented, one can assume that the 46 percent figure is likely to be smaller today.

Poisal et al. also discuss methodological issues, such as the possibility of underreporting when surveys are used to determine health care expenditures, how drug

prices were determined in the MCBS, and why the current figures on drug coverage among Medicare beneficiaries are higher than previously thought.

### **Can Openers We Have**

Though there are many unknowns, how to go about administering a drug program is not entirely a tabula rasa for HCFA. The current political debate has everyone's attention focused on Medicare, but the Medicaid program has extensive experience in administration of a drug benefit. Medicare also covers some drugs, such as immunosuppressants and oral cancer medication. There are lessons to be learned—in a positive vein and in a cautionary vein, as Cook's article makes clear—from both the Medicaid program and from the Medicare program in how to administer a drug benefit.

There are two articles in this issue dealing with Medicare's coverage for the treatment of end-stage renal disease (ESRD). The ESRD program lends itself to analysis of a number of issues because of the kind of data being reported about ESRD beneficiaries, including information about health outcomes, through a conscious effort to collect relevant data on this population. Medicare's ESRD beneficiaries are a special population in many ways. The decision of Congress to extend Medicare coverage for people with ESRD, under special eligibility rules allowing more individuals to be covered, constituted a life line for this population. With respect to drug coverage, this is a unique population in that Medicare covers some particularly high-cost drugs that are essential for individuals with ESRD, Human Recombinant Erythropoietin (EPO) and immunosuppressive drugs.

The contribution of Greer, Milam, and Eggers is a story "from the trenches" (with apologies to the readers tired, by now, of

<sup>4</sup> Soumerai and Ross-Degnan cite a number of studies showing that "essential medications" were among the drugs that seniors did not purchase if they had no drug coverage.

allusions to that other lexicon) that shows how complicated payment policy in health care can be, and also illustrates the apparent interaction between payment policy and provider behavior. The authors review what happened with four different changes (one suspended) in the policy governing payment for EPO. Medicare covered EPO virtually from the date of its approval by the Food and Drug Administration, and the drug is made available to providers through a monopoly arrangement (a producer and distributor dealing, one might add, with a near-monopsony buyer, Medicare, which reimburses providers for the provision of the drug at a level nearing \$1 billion). To quote the article, “Balancing the sometimes conflicting goals of reimbursing providers and sellers of EPO fairly, but not excessively, and insuring patients receive quality EPO therapy has proven to be a complex task for all parties.”

Greer et al. found that there was a “synergism of good medical practice and good business practice” that resulted in a payment policy change having the opposite of its intended effect—program costs were increased. Payment for EPO changed from what was in most instances a fixed payment for a variable dosage, to a payment that varied by the level of dosage. At the same time, medical practice had already been moving in the direction of increasing the level of dosage because higher doses were found to be more effective. Under the initial EPO payment policy, the payment incentives were in the direction of lower doses (generating profits for the providers). Although in the initial period EPO therapy was increasingly used for more patients, there was no sustained trend of improved outcomes, as measured by hematocrit levels. Following the payment policy change in January 1991 to a dosage-based payment, the average dosage rose “so rapidly that the large drop

in Medicare payments in January 1991 was gone by April,” though, as Greer et al. state, this is not proof of causality.

Shih’s article uses the data sources available on individuals with ESRD (both those covered by Medicare and those not covered) to examine the effect of secondary insurance on utilization of drugs. She confirms the well-known phenomenon that insured individuals have higher levels of health care utilization than non-insured individuals, a point that Cook also notes in discussing what can be expected in the way of cost savings to Medicare from different discounting approaches (and consistent with MCBS data reported in Davis et al., that Medicare beneficiaries with no supplemental insurance of any kind had drug use rates that were 31 percent lower than the national average for all Medicare beneficiaries). Shih also found that the type of secondary coverage did not affect utilization levels.<sup>5</sup>

Shih’s work illustrates the important role that drugs play in treating the ESRD population. While the Medicare ESRD program has been crucial for people with ESRD, the structure of the Medicare benefit package has left ESRD beneficiaries exposed to the high costs of coinsurance and deductibles for covered services, as well as responsible for the cost of outpatient drugs used to treat comorbid conditions, which are common among this population.

In discussing the change in immunosuppression regimens over time, Shih’s article provides an example that is a microcosm of advances in drug therapies, and the associated increase in costs, as more effective, but more expensive, drugs become the preferred mode of treatment. While better outcomes may have been achieved, out-of-pocket costs rose for individuals with no other insurance.

<sup>5</sup> It is unclear whether all the secondary insurance categories Shih lists include drug coverage.



For this particular population, as Shih points out (and more generally for the entire Medicare population) the correlation between level of drugs prescribed and secondary insurance status can be a sign of:

- Over-use or over-prescribing of drugs among insured individuals (the moral hazard issue).
- The seeking out of secondary coverage by people who need drugs.
- Insufficient access to drugs among those without secondary insurance.

On the last point, Shih also discusses the interrelationship between payment policy and medical practice as illustrated by the composite rate for outpatient dialysis and the extent to which the cost of the provision of injectable drugs falls within the composite rate. She notes that her findings indicate that the composite rate, and the policy of covering EPO, are not sufficient to cover the medications needed by ESRD patients.

Shih found significant variation in prescription patterns across regions, a type of variation that is quite familiar in Medicare. Shih also highlights another example, a la Greer et al., of the interaction between a drug payment policy and the consequences of the policy. Transplant patients must continue to remain on immunosuppressants to avoid graft failure. As of 1986, Medicare covered immunosuppressants for 1 year after a transplant. As a result of a 1994 study highlighting the additional program costs resulting from graft failures, coverage of immunosuppressants was eventually extended to 3 years by 1998, even though the need to continue use of immunosuppressants does not end after 3 years. For individuals without other coverage, this payment policy can be detrimental, and it can have a cost effect in the Medicare program, in that eventual graft failure after the end of Medicare coverage (which also occurs 36 months after a successful transplant) may put the patient in

the position of being eligible again for Medicare coverage because of the need to return to maintenance dialysis.<sup>6</sup>

## **DUR in Medicaid**

Another paired set of articles are the two articles in this issue that report findings regarding drug utilization review (DUR) in Medicaid. DUR was mandated for Medicaid by OBRA 90, with the intent of improving outcomes and, directly, or indirectly through reduced use of other health care services, with the intent of containing escalating program expenditures. OBRA 1990 (which also contained the drug rebate provisions), required that there be demonstrations of innovative DUR approaches, such as on-line prospective DUR systems.

The article by Stuart, Briesacher, Ahern, Kidder, Zacker, Erwin, Gilden, and Fahlman provides descriptive data and information about DUR in various States. Commenting that many of the DUR systems in existence are proprietary and their owners do not provide either their DUR criteria or the results of their reviews, Stuart et al. have used an open architecture screening system in the public domain, developed by the Pennsylvania State University under a cooperative agreement with HCFA. They note that, to their knowledge, this is the first use of a uniform screener applied to Medicaid data across multiple States, and the first presentation of longitudinal DUR failure information for the States. They employ the screening mechanism to evaluate up to 8 years of Medicaid drug utilization data in four States to determine the extent of DUR failures (i.e., instances of drug prescribing or utilization that is inappropriate, because of

<sup>6</sup> Pending legislation, the Immunosuppressive Drugs Coverage Act of 1999, seeks to remove the time limit on coverage of immunosuppressants to provide for continued coverage beyond the end of Medicare eligibility.

drug interactions, incorrect dosage, early refill, etc.) for 61 specific drug use problems. The DUR criteria used constitute a “comprehensive and valid set” of screening criteria to detect “significant preventable problems,” developed by an expert clinical panel and periodically updated.

The principal finding of Stuart et al. is that there is extreme variation among the States, variation over time, and variation by Medicaid categories, in DUR failure rates, as well as variation by drug group and DUR criteria. Some of the failure rates they found may be viewed as alarmingly high (which the authors seek to explain) and others as remarkably low. There was also significant variation in drug utilization by beneficiaries in the different States examined, though there is a trend of rising drug use in all States in the period examined (1989-96 for three States, 1994-96 for Georgia, with data through the year before the year in which Baugh et al. found declining drug use [discussed later]). In what the authors call a “considerable achievement,” DUR failure rates for the elderly residing in the community declined precipitously in the three States for which they have 8 years of data. They view this as partly attributable to the attention that issues of aging and drug use have received in the scientific and popular press.

The research that Stuart et al. report on had its origin in the evaluation of the demonstrations of innovative DUR mandated by OBRA 1990. The contribution by Kidder and Bae analyzes the results of the evaluation of the Medicaid demonstrations of innovative DUR approaches. The evaluator contracted by HCFA examined State demonstrations of two methods of drug utilization review: Iowa’s online prospective DUR program, and Washington’s Project C.A.R.E., involving payment to pharmacists for cognitive services provided to patients.

The evaluator was also asked to examine the effectiveness of State programs of retrospective drug utilization review. As Kidder and Bae point out, by 1990, DUR was prevalent in the private sector, and today it is almost a given that any drug benefit program incorporates DUR functions.

The demonstrations were intended to determine whether particular practices can prevent prescribing problems and yield better outcomes—a plausible assumption about DUR, but one which, as Bae et al. have noted their article, had not been adequately evaluated. At the outset, Kidder and Bae also comment that, in spite of some studies indicating otherwise, prescribing problems are not as prevalent as many believe, a point also made by Stuart et al.

What Kidder and Bae conclude about the effectiveness of the interventions in the demonstration programs is that there was insufficient evidence that either prospective DUR or payment for cognitive services had a positive effect in reducing drug problems or reducing either drug expenditures or overall expenditures. With regard to cognitive services, the evaluation found that pharmacists are likely to view the provision of cognitive services as an “integral part of their function,” regardless of whether they receive payment. However, the limited examination of retrospective DUR that the evaluator was also asked to do showed that such interventions did produce significant results, and, though the authors are cautious about the findings, they point out that the findings on retrospective DUR are consistent with other studies.

Kidder and Bae also briefly discuss the cost of the programs evaluated before concluding that DUR is a permanent fixture, so to speak, but there can be further refinements to demonstrations; further research could determine whether existing DUR programs can be improved; certain tools might

be applied to improve DUR; and basic research can be undertaken on drug usage and adverse outcomes to feed into the DUR process. (They also mention that the movement to managed care in Medicaid now generally puts DUR issues under the control of the managed care plans.)

### **Declining Medicaid Utilization**

Amidst all the news of increasing use of drugs and availability of new drugs and new drug therapies, Baugh, Pine, and Blackwell have what they call a “counterintuitive and unexplained” finding that the percent of total Medicaid recipients who used at least one prescription drug declined, in all eligibility categories, between 1990 and 1997. Among the aged, for example, the decline was from 80.9 percent to 72 percent. This is quite noteworthy and seemingly constitutes the reversal of a trend, or a significant decline from a firmly established level. Other data seem to show that the level of utilization of drugs among the elderly, for example, has been quite consistent over the years, if measured by use of at least one prescription. In the MCBS data for 1992, 85.2 percent of beneficiaries residing in the community used at least one drug during the course of the year, with the rate among Medicaid-eligible Medicare beneficiaries being 86.7 percent (Laschober and Olin, 1996). In the 1995 MCBS data, the numbers were not significantly different: 86 percent of the total Medicare population used at least one drug, with 87 percent of the Medicaid population using at least one drug in the year (91 percent if the group includes only those who have Medicaid as their primary source of drug coverage). Long (1994) mentions that in 1991, 85 percent of Medicare beneficiaries used at least one drug in the year.

Baugh et al. also show that overall expenditures (not adjusted for inflation) among Medicaid beneficiaries in FFS have increased significantly in the period 1990-97, in spite of (and in some of the years, because of) legislative changes intended to control the growth in drug expenditures in Medicaid; that payment per recipient doubled in the time period they examined; and that prescription drugs account for 9.7 percent of total Medicaid expenditures in FFS, up from 6.8 percent in 1990. They comment on the effect of the growth in managed care in Medicaid. The HCFA reporting systems that form the basis of their findings do not contain any information on drug expenditures and utilization in Medicaid managed care plans. This makes the populations not comparable between the two end points, 1990 and 1997. Although they note that the managed care numbers are removed from both the denominator (beneficiaries) and numerator (expenditures, utilization) in these data, it is difficult to know how these data are affected by the relative distribution between the FFS program and managed care, in those States, for example, where Medicaid beneficiaries have a choice between managed care and FFS; and what effect, for example, mental health carve-outs may have on these numbers.

### **One Common Theme: Regional Variation**

It is frequently said of the States and their Medicaid programs that they are individual laboratories where innovations can be tested because the States are not required to conform to a rigid national standard. Baugh et al. point out the “noteworthy variations among the States.” In addition to the data on DUR failure rates, Stuart et al. discuss some of the differ-

ences among States in coverage requirements.<sup>7</sup> However, they, and Kidder and Bae, comment on the large regional variation in utilization and costs. Shih's regression analyses show that among the five most important explanatory variables in determining drug utilization levels, two are the location of the ESRD network.

There are many causes of regional variation in drug utilization across States. However, to the extent that the variation reflects differences in medical and prescribing practices, this raises a red flag for policymakers who would be considering how to structure a national-level benefit for the Medicare program. To date, very little attention has been paid to what geographic variation in drug utilization might mean for the Medicare program in terms of drug coverage itself, and what it would mean for overall expenditures in different geographic areas. What to make of regional variation in health care is a complicated policy conundrum which, to cite a recent example, posed great difficulties for the National Bipartisan Commission on the Future of Medicare as it tried to determine how to make appropriate geographic adjustments in the "premium support" system the Commission was considering.

### Permanence

At the end of the 20th Century, the Hippocratic Oath is still with us, the flu is still with us, and Sun Tzu's writings are enjoying a renaissance of popularity in the business community. The Medicare and Medicaid programs are still with us, though each program has undergone a number of changes over the last 30 years, some of which are the subject of articles in

<sup>7</sup> Refer to Buchanan and Smith (1994) for a list of Medicaid coverage categories and criteria for all States as of 1994.

this issue of the *Review*. Whether a significant change to the Medicare program is imminent remains to be seen. Greer et al. use a very apt phrase to describe the issue that they wrote about: "attempting to balance the best care of patients with fiscal reality." Although they use this phrase in the context of decisions made regarding coverage of a particular drug for a small, but costly, subpopulation of Medicare beneficiaries, the phrase that they use can serve to summarize the heart of the issue in the larger debate over drug coverage for Medicare beneficiaries: how to balance the best care of patients—the recognized crucial importance of drug therapies for the aged and disabled—with the fiscal reality faced by the Medicare program as the Nation attempts to deal with the retirement of the Baby Boom generation.

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