Medicaid Drug Formularies

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Executive Summary

Medicaid spending is projected to exceed $276 billion in 2003. It will be larger than Medicare. Some experts predict that without significant reform it will bankrupt the states by 2020.

Spending on prescription drugs is neither the largest nor the fastest growing category of Medicaid spending. In Colorado, Medicaid spends much more on hospital services, personal health care, nursing homes, and physician services than on prescription drugs.

Because prescription drugs reduce other health care expenses, controlling Medicaid prescription drug expenditures by arbitrarily limiting physicians' freedom to prescribe risks increasing Medicaid spending in other categories.

- Using "clot-busters" to treat strokes saves about 4 times the drug price by reducing other health care costs. According to one estimate, using atypical antipsychotics to treat schizophrenia cost about $4,500 a year and saved about $73,000 a year in institutional treatment costs."

- A 1993 paper examining formulary restrictions in 47 Medicaid programs found that "a restricted formulary may reduce prescription drug expenditures by approximately 13 percent, on average. Because of service substitution, however, such a policy does not translate into reductions in total program expenditures. Savings in the drug budget appear to be completely offset by increased expenditures elsewhere in the system."

- A 1996 survey of 200 physicians in the Tennessee Medicaid managed care program found that two-thirds of those forced to change their patients' prescriptions reported serious adverse consequences including death, strokes, and adverse drug interactions. In British Columbia, 27% of physicians surveyed reported admitting patients to hospitals as a result of problems created by government mandated prescription drug substitutions.

- Medicaid populations have a higher proportion of people with fragile health. People in poor health often need the reduced side effects common to newer, more expensive drugs.

The evidence suggests that drug utilization controls typically increase overall spending. The Michigan and Florida formulary programs lack any mechanisms for tracking their effects on overall spending or patient care.

- In 1992, the Health Care Financing Administration ran demonstration drug utilization review programs in Washington State and Iowa. The programs had no "measurable effects in reducing the frequency of drug problems or on utilization of and expenditures for prescription drugs and other medical services."

- According to the Kaiser Commission on Medicaid and the Uninsured, neither the Florida nor the Michigan Medicaid formulary programs include any mechanism to track the overall costs and benefits or their drug formulary programs.

- An independent evaluation of the Florida program found that drugs with the highest denial rates were agents that "are often appropriate for use by patients with multiple illnesses, and persons who are medically complex and at high risk from adverse effects of drug therapy or inadequate treatment of their disease.

Formulary laws politicize medical care and promote unequal treatment by exempting politically powerful patient groups, primarily those with severe mental illness or AIDS, from their strictures. The poor, and debilitated, those who are ill-equipped to protest treatment, are the most likely to suffer.

- Michigan formulary advocates promised to forbid prior authorization for branded products with no generic competition. In 2001, the legislature scrapped that protection. Florida formulary advocates eased passage by exempting patients in nursing homes. After passage the nursing home exemption was eliminated.

- Relative to private plans, Michigan restricts patient access to drugs for cardiac conditions, depression, and diabetes. In Florida in 2001, only generic equivalents, all rated BX by the FDA, were allowed for thyroid replacement agents. BX means that there is inadequate clinical data to establish the highest level of brand-generic equivalency.

- In Florida, physicians reported that Medicaid patients denied drugs went without medicine until the situation was resolved. Multiple trips to the pharmacy were particularly difficult for recently discharged hospital patients and elderly patients with chronic conditions.

Medicaid Drug Formularies: Do They Perform as Advertised

By Linda Gorman, Senior Fellow

Introduction

Over the last four decades, state and federal officials have continuously expanded the scope of state Medicaid programs and consistently underestimated the associated costs. Medicaid began in 1966 with an expenditure of less than $1 billion. By 1971, annual spending was $6.5 billion, more than twice the projected figure. In 2001, total expenditures were $228 billion, not including spending on children's health insurance. Long-term care, primarily for the elderly, consumes almost half of current Medicaid budgets. With the baby boomers beginning to retire in 2009, some experts predict that without fundamental changes in the program's structure, a quadrupling of long-term care costs will bankrupt state governments by 2020.[1] At present, Medicaid is second only to education in most state budgets. In FY 2001, Colorado reported spending $1.1 billion on its share of the Medicaid program. This amount was matched by the federal government for a total of approximately $2.25 billion.[2]

Whether labeled preferred drug lists, formularies, brand name drug restrictions, or "therapeutic consultation services," prescription drug price and quantity controls are the latest fad in the continuing struggle to control Medicaid expenditures. Like the construction moratoriums and certificates of need that were the fashion in the 1970s, and the mandatory managed care, block grants, and capitated care that were the rage of the 1990s, centralized control of prescription drug purchases substitutes the dictates of bureaucrats for the informed decisions of those intimately familiar with the problem at hand.

Ceding control over patient care decisions to the equivalent of prescription drug boards may be dangerous both for patients and for state budgets. Treatment decisions for those who are seriously ill typically require that informed experts on the person's situation exercise their judgment to find the best compromise between competing goals. Like every other human institution, government has

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[1] Richard Teske. April 2002. *Abolishing the Medicaid Ghetto: Putting Patients First.* 'American Legislative Exchange Council, Washington, DC, p. 3.

[2] United States Department of Health and Human Services, Medicaid /SCHIP Budget and Expenditure Information System. *Net Reported Medicaid and SCHIP Expenditures, FFY 2001*. http://cms.hhs.gov/medicaid/mbes/sttotal.pdf. Accessed March 1, 2003.

limits. Rules that require a change in order to save money may work just fine on mentally alert patients in otherwise good health. They may end up adding to costs when applied to elderly patients with failing memories.

Medicaid Prescription Drug Spending in Perspective

Over the last ten years, many states have presided over continuous expansions in their Medicaid programs despite falling quality and skyrocketing budgets. Medicaid provides medical care assistance to four distinct populations:

- the impoverished elderly, many of whom are in nursing homes,
- people who are eligible due to disability,
- children who meet eligibility requirements, and
- some adults, primarily pregnant women near or below the poverty level.

When considering the growth of prescription drug spending, it is important to keep in mind that the rapid growth of prepaid medical plans for Medicaid clients in the early 1990s obscures the true amount of spending on prescription drugs. When states pay the managed care plans a flat annual fee for each Medicaid client enrolled, prescription drugs consumed by that person are paid for by the managed care plan and are not counted in Medicaid spending on prescription drugs.

Because managed care enrollment makes sense only for relatively healthy Medicaid beneficiaries, the population responsible for reported spending on Medicaid prescription drugs includes a disproportionate fraction of elderly, blind, and disabled people, a group likely to benefit disproportionately from the fewer side effects and greater efficacy of many of the newer, more expensive, prescription drugs. In 1990, prescription drug payments for the elderly, blind, and disabled accounted for 76 percent of the $4.4 billion spent on Medicaid prescription drugs. By 1997 those groups accounted for 82 percent of the roughly $12 billion spent.[3]

For the United States as a whole, payments for prescription drugs grew rapidly in the 1990s with an annual rate of increase of 11.1 percent from 1990 to 1997. At the same time, the fraction of out-of-pocket drug expenditures shrank dramatically. In 1988, 60 percent of all drug expenditures were paid for out-of-pocket, private health insurance paid for 24 percent, and public program picked up the remaining 16 percent. By 2000, out-of-pocket expenditures were just 32 percent of total prescription drug expenditures. Private health insurance paid for 46 percent of the total and public expenditures had risen to 22 percent.[4]

[3] David K. Baugh, Penelope L. Pine, and Steven Blackwell. Spring 1999. "Trends in Medicaid Prescription Drug Utilization and Payments, 1990-97," *Health Care Financing Review,* p. 79-105.

[4] Office of the Actuary, National Health Statistics Group, Centers for Medicare and Medicaid Services. June 2002.

Matthew, please create some bar graphs to accompany the above paragraph

Although pronouncements from public officials might lead one to think otherwise, spending on prescription drugs is neither the largest nor the fastest growing category of health spending. Using data from the 1996 Medical Expenditure Panel Survey, Columbia University professor Frank Lichtenberg calculated that for the United States as a whole, inpatient hospital stays accounted for 41.5 percent of expenditures, office-based visits were 20.2 percent of expenditures, and prescription medicines were 13.9 percent of expenditures. Outpatient visits, dental visits, emergency room visits and other medical expenditures made up 10.2, 7.8, 3.3, and 3.0 percent of expenditures.[5]

Components of Colorado Medicaid Spending

As the attached chart shows, the federal government estimates that Medicaid spent $560 million on hospital stays in Colorado in 1998, almost three times as much as the $131 million spent on prescription drugs and other nondurable medical supplies. Payments for hospital stays grew at an annual rate of 14.3 percent from 1980 to 1998. The annual rate of growth of prescription drug costs was just slightly higher at 14.7 percent. Payments for other personal health care, which includes payments provided through home and community-based waivers in the Medicaid program, grew much faster than either hospital stays or prescription drugs. By 1998 they had reached $266 million, posting an annual growth rate of 26.1 percent between 1980 and 1998. At $290 million, spending on nursing homes was second only to spending on hospitals though it was growing more slowly at an average annual rate of 7.4 percent between 1980 and 1998. Nationally, Medicaid pays for almost half of all nursing home care. Personal health care expenditures grew about 12 percent between 1980 and 1998. They were $1,505 million in 1998.

As one would expect, the severely ill account for a large share of Medicaid spending on prescription drugs. In FY 1998, the Centers for Medicare and Medicaid report that 40.6 million people used the Medicaid program. About 10.5 million of them, 26 percent, were elderly, blind, or disabled.[6] In 1997, about 21 million people received at least one prescription through Medicaid, and 36 percent of them were elderly, blind, or disabled. Between 1990 and 1997, Medicaid prescription drug payments for the blind and disabled grew 6.6 percent per year. Payments for the aged grew 1.4 percent, payments for children, 3.3 percent, and payments for adults declined by 0.6 percent.[7]

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[5] Frank R. Lichtenberg. September/October 2001. "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs,* p. 243.

[6] U.S. Department of Health and Human Services, Health Care Financing Administration. September 2000. *A Profile of Medicaid, Chartbook 2000.* p. 13.

[7] David K. Baugh, Penelope L. Pine, and Steven Blackwell. Spring 1999. "Trends in Medicaid Prescription Drug Utilization and Payments, 1990-97," *Health Care Financing Review,* p. 96.

As would be expected in a program originally designed to help the needy, Colorado's Medicaid case mix includes a disproportionate number of people in frail health. In 1995, the Urban Institute calculated that Colorado Medicaid had:

- 39,900 elderly people enrolled at an average cost of $8,493 each,
- 59,900 blind and disabled people enrolled at an average cost of $7,461 each,
- 92,600 thousand adults enrolled at an average cost of $1,814 each, and
- 176,500 thousand children enrolled at an average cost of $1,247 each.[8]

The difference in per capita costs for the various populations served under Medicaid can be significant. The table below reproduces the rough, unofficial, estimates of costs for various Medicaid populations that were used to forecast FY 04-05 state share of Medicaid expenditures by the Colorado Department of Health Care Policy and Financing in November 2002.[9] It shows that though the elderly, and the needy disabled and blind, account for more than half of all expenditures, they constitute less than 25 percent of the Medicaid population.

Medical Considerations

Because Medicaid populations tend to have a higher proportion of people with fragile health, political attempts to arbitrarily cap prescription drug spending run the risk of increasing other health care costs. Though new drugs are often more expensive than older ones, they also reduce costs by improving patient quality of life and reducing the side effects that can be deadly to those with fragile health. The H2 antagonists that were introduced in the late 1970s, for example, reduced the costs of surgery for gastrointestinal ulcers, and the risk of dying from them, by more than half. Using "clot-busters" in treating strokes saved about 4 times the drug price by reducing other health care costs. According to economist John Calfee, atypical antipsychotics for treating schizophrenia that cost about $4,500 a year "avoided about $73,000 a year in institutional treatment costs."[10]

Defenders of closed formularies often argue that offering a variety of drugs in each therapeutic class wastes money, because all therapeutic substitutes are essentially the same. This is not true. Dosing, packaging, and different metabolic pathways may make a particular compounds in a therapeutic class suitable for one person but not for another with the same condition.

There is also no absolute guarantee that any particular generic drug will be a therapeutic substitute for the brand name product that it imitates. In the United

[8] Susan Wallin, Marilyn Moon, Len Nichols, Stephen Norton, Barbara A Ormond, Jean Hanson, and Laurie Pounder. November 1998. *Health Policy for Low-Income People in Colorado.* New Federalism: Highlights from State Reports, The Urban Institute, Washington, DC, p. 4.

[9] Department of Health Care Policy and Finance, State of Colorado. November 1, 2002. Assumptions and Calculations, Executive Budget Request FY 03-04, p. K-76.

[10] John E. Calfee. 2000. *Prices, Markets, and the Pharmaceutical Revolution*. The AEI Press, Washington, DC. p. 10.

States, bioequivalency is determined by statistical trials that compare a generic drug with its branded counterpart in a small group of generally healthy volunteers. Results are compared for the drug's absorption over time, its maximum concentration in the body, and the time it takes to attain maximum concentration. Products considered interchangeable can depart from the brand-name version by up to 25%. Given the statistical constraints, the Food and Drug Administration estimates that "A generic product that truly differs by –20%/+25% or more from the innovator product with respect to one or more pharmacokinetic parameters would actually have less than a 5% chance of being approved."[11]

Statistical studies measure population differences, not variations in individual metabolisms. Small differences in bioavailability become important when the difference between a therapeutic and a toxic dose is small, when a particular drug has a narrow therapeutic range, or when the inability to tolerate a substitute may have serious consequences.

A 1994 Veteran's Administration study found that serum levels of phenytoin, an antiepileptic drug, were 22-31 percent lower when patients were on a generic phenytoin than when the same patients were given the brand-name product Dilantin.[12] A survey of 130 experts on cardiac arrhythmias found that a switch to generic antiarrhythmic drugs caused serious problems in over sixty cases.[13] At present, the therapeutic categories judged most likely to be sensitive to generic substitution are cardiovascular drugs, psychotropic agents like the atypical antipsychotics, and anticonvulsants. Other potentially sensitive categories include low-dose oral contraceptives, bronchodilating agents, oral diuretics, and oral anticoagulants. The debilitated or elderly with abnormal gastrointestinal, renal, or hepatic function are most likely to be at risk.[14]

In addition to harming patients, adjustment problems can wipe out the savings expected when patients are switched to cheaper drugs within a particular therapeutic category. Omeprazole and lansoprazole, first generation proton pump inhibitors marketed under the brand names Prilosec and Prevacid, are commonly used to treat cases in which there is too much acid in the stomach. Initial evaluations of the pharmacology of the drugs found them similar in structure and mechanism although they were metabolized by different routes. As of July 2000, however, the average wholesale cost of a 30-day supply of a

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[11] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management:*Approved Drug Products With Therapeutic Equivalence Evaluations.* Washington, DC, US Government Printing Office, 19th Edition, 1999. Cited in James D. Henderson and Richard H. Esham. January 2001. "Generic Substitution: Issues for Problematic Drugs," *Southern Medical Journal,* **94**, 1, pp. 20. Online edition as of November 5, 2002.

[12] D.H. Rosenbaum, A.J. Rowan, L. Tuchman, and J.A. French. 1994. "Comparative bioavailability of a generic phenytoin and Dilantin," E*pilepsia*, May/Jun, 35(3) 656-60.

[13] J.A. Reiffel, P.R. Kowey. 2000. "Generic antiarrhythmics are not therapeutically equivalent for the treatment of tachyarrhythmias," *Am J Cardiol*, 85(9), 1151-3.

[14] J.L. Colaizzi and D.T. Lowenthal. 1986. "Critical Therapeutic Categories: A Contraindication to Generic Substitution?" *Clin Ther*, 8(4), 370-9.

standard dosage was $116.41 for lansoprazole and $124.17 for omeprazole.[15] To save money, many managed care organizations "encouraged" a switch to lansoprazole under their therapeutic interchange programs. Unfortunately, patients previously stabilized on omeprazole experienced more severe symptoms when switched to lansoprazole.[16] Some patients did not respond to lansoprazole and others could not tolerate its side effects. According to researchers at one Veterans Administration hospital, the predicted 12 percent savings from the therapeutic interchange were "quickly offset" by the associated failure rate of 28 percent.[17]

A 1996 survey of 200 physicians participating in Tennessee's TennCare Medicaid managed care program found that two-thirds of the physicians who were forced to switch their patients' prescriptions reported serious adverse consequences including death, strokes, and adverse drug interactions.[18] In Canada, The Fraser Institute reported on the success of British Columbia's drug control system and concluded,

> In British Columbia, 27 percent of physicians reported that they had to admit patients to the emergency room or hospital as a result of the switching of medicines mandated by the operation of the government reference price system. Confusion or uncertainty by cardiovascular or hypertension patients due to mandated medicine switching was reported by 68 percent of doctors while 60 percent observed a worsening or accelerating symptoms. British Columbia doctors for other types of patients reported similar problems with the result being an increase of patients who stop taking their medications and increased emergency room admissions. This patient confusion and uncertainly generated by government's price control system is a clear implication that the system operates for the convenience of government, not the well being of patients.[19]

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[15] M. Michael Wolfe, MD. *Overview and Comparison of the Proton Pump Inhibitors for the Treatment of Acid-Related Disorders,* UpToDate, an online clinical reference, http://www.uptodate.com/html/AGA_topics/jan_01/text/10094a1.htm as of 21 February 2001.

[16] W.W. Nelson, L.C. Vermeulen, E.A. Guerkink, D.A. Ehlert, and M. Geichelderfer. Sep. 11, 2000. "Clinical and humanistic outcomes in patients with gastroesophageal reflux disease converted from omeprazole to lansoprazole," *Arch Intern Med*, 160(16), 2491-6.

[17] P.B. Amidon, R. Jankovich, C.A. Stoukides, and A.F. Kaul. May, 2000. "Proton pump inhibitor therapy: preliminary results of a therapeutic interchange program," *Am J Manag Care*, 6(5), 593-601.

[18] Yankelovich Partners, Inc. 1996. *Effects of prescription drug access restrictions on medical practice and patient outcomes: A survey among physicians enrolled in TennCare.*

[19] *Canadian Health Care—A System in Collapse*. January 27, 1999. The Fraser Institute, Vancouver,British Columbia. As posted on the web at http://www.fraserinstitute.ca/publications/backgrounders/20000127/index.html as of January 15, 2001.

Because government formulary systems have cost as their central concern, legislative management of drug prescribing decisions routinely compromises patient health by limiting access to new discoveries. In Canada, the Patented Medicines Price Review Board controls drug approvals. Concerned with cost above all, Canadian officials simply refuse to approve new drugs that are priced higher than the most effective drug currently in use. This policy is followed no matter how effective the new drug is. Between 1994 and 1998 the Board considered 400 drugs. It approved only 24.[20] Although the glacial approval process results in lower prices for some drugs, Canadians wait years for access to new drugs that are routinely available in the United States.

Patients who do not do well on the drug the Board chooses but who might do better on one of the other compounds in a particular class are simply out of luck. Even patients stabilized on a particular medication may have problems. Canadian provinces change their formularies when drug prices change, forcing patients to change as well. In one survey, 27% of doctors in British Columbia reported admitting patients to hospitals as a result of problems created by government mandated prescription drug substitutions.[21]

In the United States, the Veterans Administration formulary is famous for its lack of choice. As of 2002, the Veterans Administration carried only 7 of the drugs that were the 20 most popular drugs for elderly Medicare recipients in 1996.[22] In 2000, patients with pancreatic cancer were required to "fail first" on other drugs before being given access to Gemzar, the newest drug for that disease. Whether fail first is an ethical option given that treatment with 5-FU, the only other alternative, has been described as "palliative" with "dismal outcomes" remains an open question.

The Florida prescription drug list covered 83 of the most commonly prescribed brand-name drugs in 2001, but the list did not include any of the popular thyroid replacement agents Synthroid, Levoxyl, or Levothryod. All of the generic equivalents that were included were rated "BX" by the FDA. BX means that there is inadequate clinical data to establish the highest level of brand-generic equivalency.[23] The Kaiser Foundation's analysis of the Michigan preferred drug list showed that it was considerably more restrictive than private plans for drugs used to treat cardiac conditions, depression, and diabetes.

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[20] William McArthur. May 19, 2000. *Prescription Drug Costs: Has Canada Found the Answer?* National Center for Policy Analysis Brief Analysis No. 323. Accessed on the web at http://www.ncpa.org/ba/ba323/ba323.html on February 2, 2003.

[21] William McArthur. January 21, 2000. "Memo to Al Gore: Canadian Medicine Isn't Cheap or Effective," *The Wall Street Journal, p. A19.*

[22] Naomi Lopez Bauman. March 2002. *Playing Doctor in Tallahassee: How Lawmakers' Efforts to Save Money May Threaten Quality Care for Mentally Ill Medicaid Patients.* Policy Report #37, James Madison Institute, Tallahassee, Florida.

[23] Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 18.

In spite all of the evidence showing that patients do better when their physicians have access to a wide variety of drugs, legislation to resurrect state formularies appeared in a number of states in 2001-2002. The Oregon Health Plan Drug Formulary, signed into law in 2001, is typical. As is the case in Washington State's Therapeutic Consultation Service program, it specifically exempts drugs used to treat cancer, mental illness, and AIDS.[24] The fact that these exemptions are allowed at all shows that those in charge of government health care are perfectly aware that limiting drug choices can compromise patient care.

The Political Landscape

In general, arbitrary controls on pharmaceutical spending entail relatively small political risk. Those most severely harmed are likely to be dead, and in any case the seriously ill represent a fairly small fraction of the voting population. Now that formulary laws have begun to specifically exempt diseases that affect patients with well organized lobbying groups, the people most likely to be harmed by the arbitrary drug denials common to Medicaid drug lists are often poor, debilitated, and ill-equipped to protest poor treatment.

Shareholders in pharmaceutical companies, another group likely to be harmed by state attempts to control drug prices, are invisible. The companies themselves are large, and earn earning billions of dollars in revenue each year from sick people who need their products. As those people also have no idea how much molecular biochemists, drug production factories, and regulatory compliance cost, they are easy targets for irresponsible demagogues who think they can benefit by whipping up hatred for "Big Pharma."

Like all price controls, drug price controls have no immediately discernable impact. This means that the officials responsible for them can take immediate credit for saving taxpayer money even if the drug restrictions they promote end up increasing other health care costs. As Frank Litchenberg has pointed out, the cost increases caused by prescription drug restrictions generally get lost amid the general cost increases in other health care budget categories. "Drug costs (and changes in drug costs) are visible to the naked eye," but "identification of drug benefits requires careful analysis of good data." This means that "people making drug policy decisions need to consider the full range of effects, not just the costs, of newer drugs.[25]

Events in Washington State illustrate how the political game is played. In a January 2002 media release announcing the Therapeutic Consultation Service, the Washington State Department of Social and Health Services claimed that prescription drug costs are today's "#1 medical assistance cost driver" and

[24] Mary Bellotti. July 13, 2001. "Governor expands health care plan," *PortlandTribune.com* as of September 24, 2002. http://www.portlandtrubune.com/archview.cgi?id=5028.

[25] Frank R. Lichtenberg. September/October 2001. "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs,* p. 250.

predicted that Washington's 2001-2003 drug spending would be "nearly $1 billion."[26] Nationally, the annual growth rate of Medicaid spending on prescription drugs and nondurable medical equipment was 14.2 percent between 1980 and 1998. In Washington State it was 17 percent, with total spending of $310 million in 1998.

Predicting spending growth to $1 billion in 2003 from a base of $310 million in 1998 means that the state expects its prescription drug costs to triple in five years. Though officials may try to blame the increase on manufacturer price increases, the facts do not support them. Annual percentage increases in the Bureau of Labor Statistics price indices for prescription drugs and medical supplies were 3.7 percent in 1998, 5.7 percent in 1999, 4.4 percent in 2000, and 6.0 percent in 2001. Using these figures, a base amount of $310 million at the beginning of 1998 would have grown to about $376 million by the end of 2001. Even if Washington State prescription drug expenditures were growing at the 1980 to 1998 trend rate of 17 percent per year, $310 million would grow to just $680 million in 5 years.

The same press release discusses the advent of the Therapeutic Consultation Service, a medication management system in Atlanta hired to monitor prescriptions written under the Washington State Medicaid drug benefit program. The program is biased against brand name drugs, typically newer, more expensive, and more effective compounds. It requires prior approval for medications not on its preferred drug list, places arbitrary limits on the number of brand name prescriptions an individual can fill each month, and operates under a "fail-first" philosophy that prevents patients from accessing more expensive therapies before the cheaper ones have failed them.

Although Washington officials claimed that physicians retain ultimate control over prescribing decisions, this has not been the case in Florida, the first state to implement the program. There, pharmacists and pharmacy technicians in Atlanta must provide prior approval before a prescription that fails to meet program specifications is filled. Denial of physicians' requests for exemption is not uncommon.

Washington State officials also claimed that "the implementation of a similar program by the Florida Medicaid system last year—where drug increases were held to zero growth—has shown that the review and intervention techniques involved in TCS can be remarkably successful in controlling the prescription drug expenses [*sic*]." In contrast, the January 2002 report on the program issued by Florida's Agency for Health Care Administration said that Florida's Medicaid

[26]Department of Social and Health Services, Washington State. January 2002. "DSHS and the Therapeutic Consultation Service." Online edition, February 2, 2003, http://www.dshs.wa.gov/mediareleases/word/factsheet0102.doc.

prescribed drug funding experienced a 10.3 percent growth in FY 2000-2001 and was projecting an increase of 13.9 percent for FY 2001-2002.[27]

The Evaluation Flim-Flam

One way to avoid acknowledging the ill effects of a favorite plan is simply not to look for them. Though the Florida Agency for Health Care Administration January 2002 annual report on the prescription drug control program explicitly states on page 2 that "Initial results as the Preferred Drug List was phased into the claims edit system show reductions in projected costs, achieved while maintaining quality of care and encouraging prescribers' control over their patients' therapies," the section on the clinical evaluation of the medical effects of bureaucratic second guessing on page 17 reveals that the agency has no way of knowing whether this is true because it has only begun to discuss the parameters of an independent evaluation with researchers at the University of Florida.[28]

According to the report by the Kaiser Commission on Medicaid and the Uninsured, evaluation is not a part of the Florida prescription drug control program. "Florida has not announced plans to evaluate the specific impact of the preferred drug list on the quality of care delivered to Medicaid beneficiaries," it noted in its report, and "input from beneficiaries was noticeably absent from the legislative process."[29]

It is clear that knowledgeable people do not share the official enthusiasm for the Florida formulary. The Formulary Study Panel that Florida convened in 1999 recommended against adopting a preferred drug list. The most knowledgeable and politically powerful patient groups, notably those afflicted with HIV/AIDS and serious mental health problems, marshaled successful lobbying efforts to exclude "their" drugs from the control program.

The first independent evaluation of the Florida program was conducted by researchers at the University of Florida's Center for Medicaid Issues and suggests that opponents' doubts were well founded. A preliminary analysis of the program found that the drugs with the highest denial rates were agents that "are often appropriate for use by patients with multiple illnesses, and persons who are medically complex and at high risk from adverse effects of drug therapy or inadequate treatment of their disease."[30] Substantial numbers of physicians reported that their Medicaid patients were not getting the brand name medication

[27]State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 2.

[28] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 17.

[29] Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 23

[30] Mary Kay Owens, Earlene Lipowski, and Renee Dubault. June 2001. *Florida Medicaid Prescribed Drug Program: Four Brand Prescription Limit Policy—Final Report, Phase 1.* Florida Center for Medicaid Issues, College of Health Professions, University of Florida, p. 9.

that they needed, and that denials had resulted in negative clinical outcomes. Physicians reported that patients denied their drugs went without medicine until the situation was resolved, and that multiple trips to the pharmacy posed a particular burden for recently discharged hospital patients and elderly patients with chronic conditions.

According to a Kaiser Commission report on Michigan's program, when Michigan officials created their state prescription drug list they simply assumed, without evidence, that the projected savings would materialize. "Confronted by the growing budget deficit...[they] sought savings from Medicaid—particularly the pharmacy program." The savings goal was set at $42.8 million. The legislature was so sure that the savings would materialize that it subtracted the same amount from the year's Medicaid appropriation.[31] Just months after the program began, the state agency in charge reported savings of about $800,000 a week, almost exactly what was necessary to achieve the goal set by the legislature. Such statements are common in centrally planned enterprises in which people know they must satisfy the plan. The authors of the Kaiser Commission report note that further details about the exact sources of these savings, and what the state is doing with them, have not been forthcoming.

Problems for Patients

Florida's handling of early prescription refills provides an example of how rigid bureaucratic orders can make life difficult for people locked into government monopolies. In Florida, the state considers early refills of maintenance prescriptions "a privilege." When it found that some pharmacy providers had automated 25-day refill policies for maintenance drugs and dispensed 7 months of supply in a six-month calendar period, it banned the practice as waste and abuse. Patients were directed to make other arrangements to cope with the "hurricane disasters and recipient travel plans" that Florida officials list as "the most common reasons for early refills."[32]

In a small number of cases patients sought emergency care when they could not get their prescription filled. In July 2001, the *Orlando Sentinel* reported that a death might have been associated with the program. Close associates of a dead Medicaid patient said that he took seven brand-name medications per month, and often skipped doses while waiting for approval of his physicians' prior authorization request.[33]

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[31] Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson and Rejeev Ramchild. January 2003. *Case Study: Michigan's Medicaid Prescription Drug Benefit.* Kaiser Commission on Medicaid and the Uninsured report no. 4083, Kaiser Family Foundation, Washington, DC. p. 11-12.

[32] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 33.

[33] Groller, G. "New Medicaid Drug Policy Stirs Up Fears," *Orlando Sentinel*, July 1, 2001. Cited in Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 29.

Also of concern, particularly at a time when low physician reimbursements are making many doctors and health plans unwilling to treat Medicaid patients at all, is the fact that physicians felt that the program was time consuming, made coordinating care more difficult, and created "just one more set of hurdles and hassles associated with Medicaid."[34] This raises physician costs and makes them less likely to participate in Medicaid. And, as the Kaiser Commission's case study on Michigan's Medicaid Prescription Drug Benefit program makes clear, these problems are by no means unique to Florida.[35]

Given the existing evidence, it not possible to determine how Florida's program affects patient health. It is also impossible to determine whether any savings on the prescription drugs are erased by increases in administrative costs and payments for acute care. It is also unlikely that this situation will be immediately corrected as generally accepted theoretical performance measures for prescription drug management programs do not yet exist.[36]

Past Formulary Failures

People commonly defend the Florida Medicaid prescription drug control program with the comment that "if it wasn't a good idea, the Blues wouldn't have been doing it for the past twenty years."[37] The implicit assumption that Medicaid drug restrictions are the same as those in the private insurance market suggests a fundamental lack of understanding.

Private sector plans have been dismantling strict formularies in favor of co-pay arrangements that encourage patients to evaluate their need for a particular drug in terms of its additional costs. Unlike the state Medicaid prescription drug control programs, most commercial insurance plans do not deny their customers access to the drugs that they want. They may charge higher co-pays, but people who think that the drug warrants the extra expense are free to purchase them. Patients faced with a thoroughly recalcitrant health insurer can find another one or, in extreme cases, sue for redress.

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[34] Mary Kay Owens, Earlene Lipowski, and Renee Dubault. June 2001. *Florida Medicaid Prescribed Drug Program: Four Brand Prescription Limit Policy—Final Report, Phase 1.* Florida Center for Medicaid Issues, College of Health Professions, University of Florida, p. 13.

[35] Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson and Rejeev Ramchild. January 2003. *Case Study: Michigan's Medicaid Prescription Drug Benefit.* Kaiser Commission on Medicaid and the Uninsured report no. 4083, Kaiser Family Foundation, Washington, DC.

[36] In fact, no comprehensive set of performance measures for drug managment programs have yet been developed. See Anita J. Chawla, Marjorie R. Hatzmann, and Stacey R. Long. Spring 2001. "Developing Performance Measures for Prescription Drug Management," *Health Care Financing Review,* **22**, 3, pp. 71-84.

[37] Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 19.

Medicaid patients have no such recourse. The program assumes that they are too poor to pay even nominal amounts for co-pays, there is no tiered system, and patients have no way to register their preferences. Many Medicaid patients lack the financial resources to simply buy the drugs that they need on the open market.

Existing evidence on the effect of formularies suggests that the restrictions may add expense. Numerous attempts to use formularies to control private sector prescription drug spending have failed. In 1999, the National Pharmaceutical Council reviewed the research on restrictive formularies. In general, the results suggested formularies increase costs because overruling physician prescribing decisions increases the utilization of other forms of health care.[38]
A 1993 study by W. J. Moore and R. J. Newman looked at formulary restrictions in 47 Medicaid programs. They concluded that

> . . . a restricted formulary may reduce prescription drug expenditures by approximately 13 percent, on average. Because of service substitution, however, such a policy does not translate into reductions in total program expenditures. **Savings in the drug budget appear to be completely offset by increased expenditures elsewhere in the system**.[39]

In addition to increasing costs by withholding treatment, restrictive formularies are expensive to administer. Sudovar and Rein compared California's rule-bound Medicaid prescription policies with the less restrictive ones in Texas in 1978. They concluded that California could have saved $14 million by switching to the Texas system and that $5 million of the savings would have come from reduced administrative overhead.[40]

This estimate does not include the pain and suffering imposed by long waits for more effective medicines. Grabowski *et al.* looked at the experience of nine states with Medicaid formularies between 1979 and 1985. They found that during the first four years a drug was on the market, Medicaid patients had access to new drugs less than 40 percent of the time. This was true for all drugs, even those highly ranked for therapeutic importance.[41]

When New Hampshire officials sought to control Medicaid costs by limiting prescriptions to three per person per month, schizophrenia patients made more visits to community mental health centers and hospitals. Soumerai *et al.*

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[38] Richard A. Levy and Douglas Cocks. 1999. *Component Management Fails to Save Health Care System Costs.* National Pharmaceutical Council, Washington, D.C.

[39] W.J. Moore and R. J. Newman. 1993. "Drug Formulary Restrictions as a Cost-Containment Policy in Medicaid Programs," *Journal of Law and Economics,* 36, 71-97.

[40] S. Sudovar and S.D. Rein. 1978. "Managing Medicaid Drug Expenditures," *Journal Health Human Resource Administration*, 1:200-230.

[41] H.G. Grabowski, S.O. Schweitzer, S.R. Shiota. 1992. "The Effect of Medicaid Formularies on the Availability of New Drugs," *Pharmacoeconomics,* Suppl 1, 32-40.

estimated that the additional service cost was 17 times higher than the reduction in drug costs.[42]

In 1992, the Health Care Financing Administration awarded two cooperative agreements for demonstration of prospective drug utilization review programs for Medicaid patients in Washington State and Iowa. The assumption was that utilization review could lower errors in prescribing, spot harmful drug interactions, and reduce costs by substituting less expensive drugs for more expensive ones, claims similar to those made for the Therapeutic Consultation Service. In general, the results provided no evidence of "any measurable effects in reducing the frequency of drug problems or on utilization of and expenditures for prescription drugs and other medical services."[43]

How Formulary Programs Treat Patients

Long before the Florida and Michigan Medicaid prescription drug control programs were begun, state legislatures had developed a variety of techniques to control prescription drug spending. These included formularies, prescription limits, generic substitution requirements, prior approval systems, and refill limits. Before 1990, many state Medicaid programs maintained closed formularies. States maintained lists of the drugs that they would pay for, and exceptions were few and far between. Their reaction to the introduction of the atypical antipsychotics, relatively new compounds that were expensive but far cheaper than hospitalizing schizophrenics, was one of simple denial. Once the states with formularies had made it perfectly clear that they were willing to put budgetary concerns above the improvement in patient welfare, the resulting public furor drove Congress to outlawed restrictive formularies for Medicaid in the Omnibus Budget Reconciliation Act of 1990.

Many of the 1990 limitations were repealed in the Omnibus Budget Reconciliation Act of 1993. Under the 1993 revision, passed near the peak of enthusiasm for managed care, one way to legally maintain a closed formulary was to include all FDA approved drugs in the formulary and require prior approval before they could be dispensed. The regulations governing prior approval criteria simply stated that states had to respond to requests for prior approval within 24 hours and pay for a 72-hour emergency supply of the drug under review.

As late as 1999, Kentucky was still automatically entering every drug approved by the FDA on its prior approval list. In the case of olanzapine (Zyprexa), use was restricted by a "fail first" requirement for almost two years after the drug was made available. "Fail first" requires that patients get sick on cheaper drugs before

[42]S.B. Soumerai, R.J. McLaughlin, D. Ross-Degnan, C.S. Casteris, and P. Bollini. September 1994. "Effects of a Limit on Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services By Patients with Schizophrenia," *New Engl J. Med,* 331(10), 650-5.

[43] David Kidder and Jay Bae. Spring 1999. "Evaluation Results From Prospective Drug Utilization Review: Medicaid Demonstrations," *Health Care Financing Review,* p. 115.

they are allowed access to more expensive ones. For schizophrenics, therapeutic failure was defined as a "break," a bout with uncontrolled psychosis. Current research suggests that uncontrolled psychotic breaks are associated with a poorer chance of long term recovery. Any health care system that requires a therapeutic break before prescribing a drug that is known to be more effective, and to produce fewer irreversible side effects, is cutting costs by prolonging patient suffering. According to a 1999 report for the Kentucky Legislative Research Commission, "In the case of schizophrenia, the side effects, and the personal, medical, and social costs [of therapeutic failure] can be very substantial. In such cases of therapeutic failure, medication delayed is tantamount to medication denied."[44]

Michigan and Florida provide other examples of government fecklessness in its duty to protect patients. The original Michigan Pharmaceutical Product List (MPPL) promised to forbid prior authorization for branded products that had no generic competition. But there is no way to make a legislature honor past promises. In 2001, the Michigan legislature scrapped that protection and recreated the MPPL as a program based on prior authorization and supplemental rebates. In Florida, advocates for the program eased its passage by initially exempting patients in nursing homes. That exemption was legislated out of existence shortly after the measure passed.

In constraining physicians' drug choices with statewide formularies, monthly prescription limits, or required therapeutic substitutions, government officials implicitly substitute the judgment of a bureaucracy for that of a physician. But physicians have the most information about individual cases, so it is no wonder that bureaucrats trying to substitute for them end up making costly mistakes. The problem, as researchers from the Managed Care Outcomes Project so delicately put it, is that even in small-scale experiments in HMOs

> A causal relationship between stricter HMO cost-containment practices and increased resource use also is supported by previous studies reporting shifts to more-expensive resources when restrictions are placed on the availability of drugs in Medicaid programs. These shifts are not inconsistent with prevailing economic theory based on findings that greater choice enhances consumer satisfaction and economic efficiency. Likewise, systems theory predicts that often unforeseen effects are found when complex systems (such as the healthcare system) are perturbed.[45]

[44] Joseph Fiala and Sheila Mason Burton. May 1999. *Kentucky Medicaid Drug File and Prior Authorization System,* Research Report No. 281, Program Review & Investigations Committee, Legislative Research Commission, State of Kentucky, Frankfort, Kentucky. As published on the web at http://www.lrc.state.ky.us/lrcpubs/rr281.pdf as of March 5, 2001.

[45] Susan D. Horn, Phoebe D. Sharkey *et al.* March 1996. "Intended and Unintended Condequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," *The American Journal of Managed Care*, II(3), p. 262.

Formulary Programs Legitimize Corrupt Practices

Supplemental rebates are the centerpieces of both the Michigan and Florida Medicaid drug restriction program. Supplemental rebates are cash payments from drug manufacturers that purchase the privilege of selling their products to state Medicaid drug programs. According to the Kaiser Commission Michigan case study, "Drugs not selected as "best in class," or whose manufacturers would not offer supplemental rebates to the states, were excluded from the MPPL [the drug control list] and subject to prior authorization."[46]

Florida statute allows the Agency for Health Care Administration to "negotiate supplemental rebates from manufacturers of at least 25% of average manufacture price" (AMP).[47] "For a brand-name product to be considered by the [Pharmaceutical and Therapeutics Committee] for inclusion on the [Preferred Drug List], the manufacturer must offer a minimum 25% of the AMP rebate."[48] In Florida, manufacturers can choose to run disease management programs "in lieu of cash rebates." Why officials think that citizens will benefit when a drug manufacturer's attention is shifted from finding new cures to disease management programs remains a mystery.

Ironically, both programs fine the producers who fund the research and development that lead to new medicines and favor the producers of copycat generics. Money, not patient outcomes, drives the process, a situation that that health expert Merrill Matthews has labeled "Prescription Drug Payola."[49]

In other contexts, payments to state officials in exchange for using a specific product or hiring a specific contractor are called kickbacks. Kickbacks are against the law because they put manufacturers who price their products fairly at a disadvantage and they create asymmetric incentives that promote irresponsibility with the public purse. In the Medicaid case, they encourage state and federal officials to ignore the fact that Medicaid expenditures are out of control because the Medicaid program itself is a dysfunctional 40-year-old program in need of drastic reform.

The irresponsibility engendered when state officials are allowed to extort money from the stockholders of legal businesses who refuse to make special deals with the state was most recently illustrated by the way in which state officials manipulated public opinion to attack tobacco companies. When state officials

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[46] [46] Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson and Rejeev Ramchild. January 2003. *Case Study: Michigan's Medicaid Prescription Drug Benefit.* Kaiser Commission on Medicaid and the Uninsured report no. 4083, Kaiser Family Foundation, Washington, DC. p. 11.

[47] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 10.

[48] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 12.

[49] Merrill Matthews, Jr. April 19, 2002. *Prescription Drug Payola Scam Breaks Wide Open.* Independence Institute Issue Backgrounder #2002-E, Golden, Colorado.

were pursuing the companies, they sought public approval by claiming that the money merely made up for the health costs that smoking imposed on taxpayers. In fact, of course, smokers were already more than paying such costs via state tobacco taxes. Once state officials received huge sums of money from tobacco companies in exchange for dropping the lawsuits against the businesses, they diverted the money to programs designed to increase their professional stature or their ability to attract votes.

Successful state attempts to loot the assets of cigarette companies merely increased the price of legal cigarettes and created a whole new industry devoted to cigarette smuggling. In health care, the stakes are much bigger. As William Orzechowski and Robert C. Walker point out in a paper written for the National Taxpayer's Union,[50] *price control schemes like those in Florida and Michigan are little more than state officials' attempts to avoid paying their fair share of drug research and development. If they succeed, Medicaid patients will be denied access to new therapies, state health care spending will climb, and drug research and development will be retarded. As the most effective way to control health care costs is to find cures for cancer, arthritis, diabetes and all of the other ills that afflict us, the official enthusiasm for prescription drug formulary lists demonstrates yet again that government monopolies in health care are a sure prescription for poor results.* ✍

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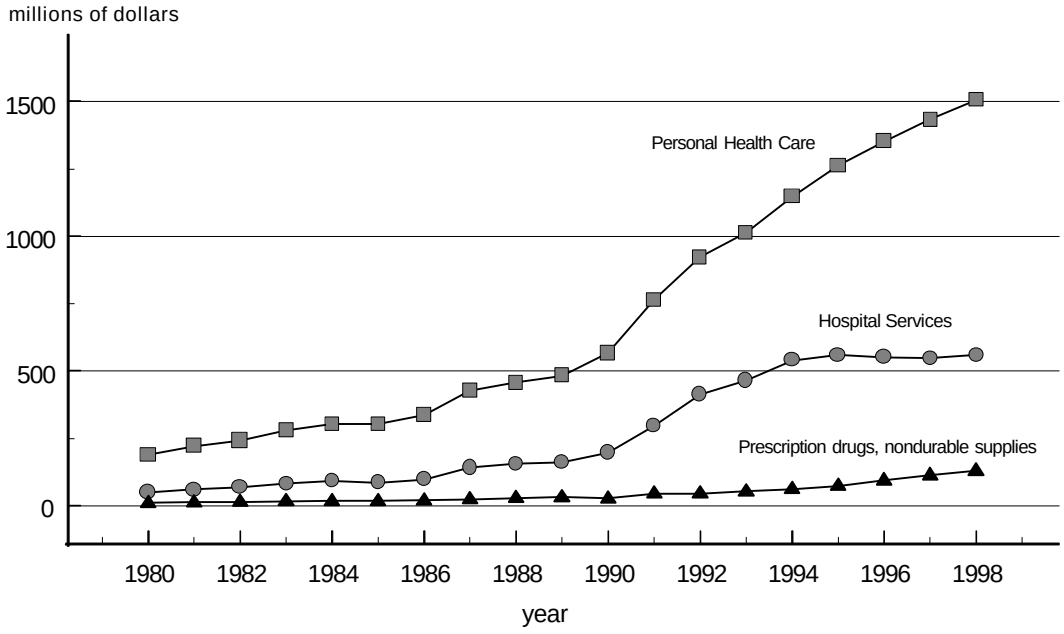
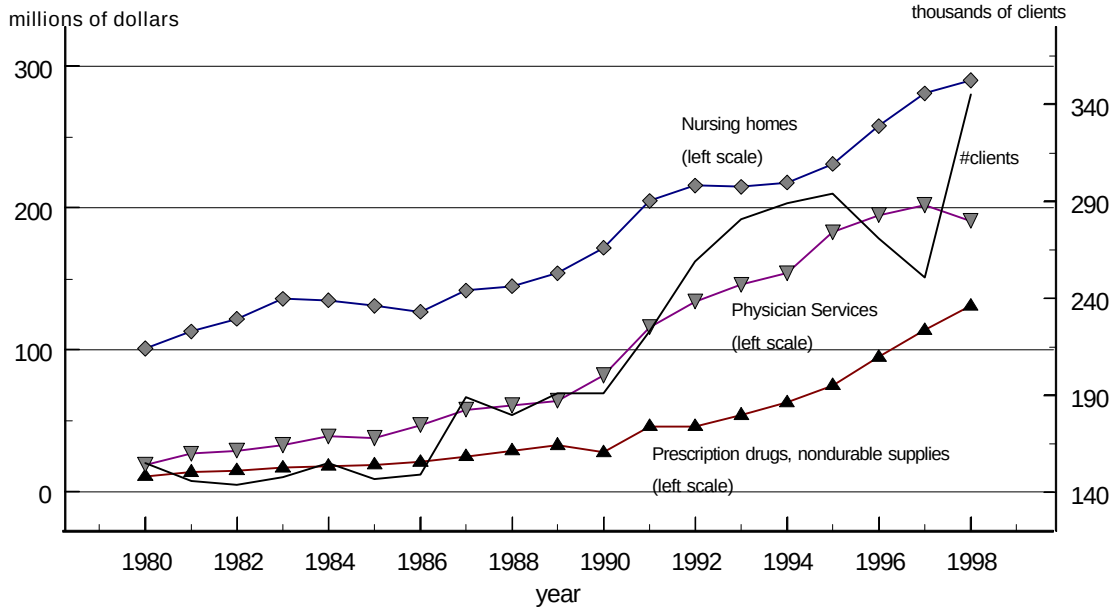
[50] William Orzechowski and Robert C. Walker. December 2001. *Florida's Folly: The Darker Side of the Sunshinetate's Drug-Pricing Scheme.* The National Taxpayer's Union, Washington, D.C. *www.ntu.org.*

Appendix

Medicaid Spending in Colorado, Selected Categories 1980-1998*





*Source: Centers for Medicare and Medicaid Services, 1998 State Medicaid Estimates.
Total includes both state and federal shares.

ROUGH ESTIMATES OF CASELOAD AND PER CAPITA COSTS FOR COLORADO MEDICAID, FISCAL YEAR 04-05.

Population	Cases	Per Capita Expenditure	Approximate Total Expenditure	Percent of Total Expenditure	Percent of Total Caseload
Old Age Pension >64 years old	36,060	$18,222	$657,106,956	34.4%	9.5%
Old Age Pension 60-64 years old	5,730	11,956	68,513,037	3.6%	1.5%
Needy Disabled and Blind	51,119	11,361	580,798,742	30.4%	13.5%
Aid to Families with Dependent Children/TANF	49,488	3,071	152,003,382	8.0%	13.1%
Children	200,080	1,569	314,103,591	16.5%	52.9%
Foster Care Children	13,593	2,771	37,679,116	2.0%	3.6%
Baby Care Adults	6,511	6,367	41,460,746	2.2%	1.7%
Non-Citizen	5,965	8,756	52,230,077	2.7%	1.6%
Qualified Medicare Beneficiary/Special Low Income Medicare Beneficiaries	9,488	1,104	10,476,934	0.5%	2.5%
Breast and Cervical Cancer Program	168	32,267	5,420,985	0.3%	<1%
Total	378,200	$5,044	$1,900,000,000	~ 100.0%	~ 100.0%

Source: Department of Health Care Policy and Finance, State of Colorado. November 1, 2002. Assumptions and Calculations, Executive Budget Request FY 03-04, p. K-76 and author's calculations.