

# Medicaid Cost Containment and Potential Effects on Diabetic Beneficiaries

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## Executive Summary

In an effort to curb state spending and adapt to severe budget crises, many states have begun implementing cost containment strategies for the Medicaid pharmaceutical benefit. These policies, especially quantity limits and preferred drug lists (PDLs), may restrict access to drugs and therefore require close scrutiny, particularly for vulnerable populations. Patients with diabetes are typically older and more likely to be minorities. They also typically have many comorbidities and highly complex drug regimens.

The purpose of this study was to characterize the state Medicaid pharmaceutical cost containment environment facing diabetic patients, to assess what states are doing to monitor and address clinical quality issues, and identify opportunities for further study. After reviewing all states with either PDLs or quantity limits, we identified nine states as having diabetes disease management programs for Medicaid beneficiaries, qualifying them for further review. Of these, only Washington both collected clinical outcomes data for its diabetic Medicaid population for a clinical effectiveness study of its PDL, as well as expressed interest in studying these data.

Our findings raise questions about whether states are focusing adequately on the welfare of patients with medically complex situations such as diabetes. Further study of this population—and particularly of Washington—is necessary to test whether these policies reduce standard outcomes measures associated with clinical improvement in diabetic patients.

# Medicaid Cost Containment and Potential Effects on Diabetic Beneficiaries

## Introduction

Medicaid provides a vital safety net for poor Americans and is particularly crucial for those with chronic illnesses and high medical costs. Under pressure from state fiscal crises, many Medicaid programs have initiated PDLs and other cost containment mechanisms intended to control patient access to prescription drugs and thereby hold down rising costs.

Diabetes is a major cause of morbidity and mortality in the United States, and represents the sixth leading cause of death among adults.<sup>1</sup> This chronic illness is one of the U.S.'s most expensive conditions, affecting approximately 8 percent of the adult population.<sup>2</sup> The high prevalence of diabetes among minority populations coupled with the high percentage of minority Medicaid beneficiaries suggests that a disproportionate number of Medicaid beneficiaries suffer from diabetes. Thus, it is crucial to understand the impact of cost containment policies on diabetes care to ensure that diabetic Medicaid beneficiaries continue to have access to adequate care.

The following report provides an overview of the current Medicaid environment and describes the particular importance of state Medicaid cost containment initiatives to the diabetes population. The report provides insight from nine case study states that have implemented pharmaceutical cost controls and disease management programs. Furthermore, the report raises questions about the potential impact of these cost containment programs on diabetic Medicaid beneficiaries. Of these nine case study states, only one collects the clinical outcomes data necessary to evaluate the impact of stringent pharmaceutical cost controls on diabetics, and has expressed interest in further study. To avoid potentially harmful consequences (both clinical and fiscal) state policy makers and legislators should require clinical evaluation of any cost containment policy, especially of such policies' impact on high-risk beneficiaries like diabetics.

## Medicaid Cost Containment

In 1965, Medicaid was implemented with the primary intention of insuring the health care costs of poor families, who otherwise would not have access to health care insurance. Medicaid has since evolved to provide health care services not only to low-income families, but also to the low-income elderly and individuals with chronic, disabling medical conditions. Medicaid now addresses the needs of over forty million people and insures approximately one in seven Americans.

Unfortunately, due to an economic downturn that has been exacerbated by increasing Medicaid rolls, states are facing the worst budget deficits in decades. Medicaid constitutes about fifteen percent of state general fund spending and is the second largest program in most states' budgets after education, so it is an obvious target for cost-saving measures.<sup>3</sup> Within the total Medicaid budget, prescription drug spending is typically small but is growing rapidly. In fiscal year 2000, Medicaid fee-for-service prescription drug costs increased by 21.5% (to a combined federal and state level of \$16.6 billion) compared to a total Medicaid expenditure growth of approximately 8.8%.<sup>4</sup> In fiscal year 2001, Medicaid fee-for-service prescription drug costs were \$24.7 billion (combined federal and state), and in 2003 the Centers for Medicare and Medicaid Services (CMS) projected costs to grow by approximately 24 percent to \$32.5 billion.<sup>5</sup> Thus, Medicaid prescription drug spending has become a specific target for states' cost-containment strategies.

Even though Medicaid plays a crucial role in underwriting care for the poorest and sickest members of our society, recent economic situations have caused states to restrict access to certain benefits, including treatments for diabetes. For example, forty-five states reportedly plan to implement new controls on prescription drug spending this year.<sup>6</sup> Some of these cost containment techniques include developing PDLs, introducing quantity limits, and expanding upon prior authorization programs. Diabetics' treatments have not been exempt from such strategies.

### Preferred Drug Lists

One of Medicaid's key cost containment tools are PDLs. Medicaid laws require states to cover all FDA-approved prescription drugs sold by manufacturers who enter into prescription drug rebate agreements with the federal government (with certain exceptions). Some state Medicaid agencies have used the flexibility provided through prior authorization programs to establish a PDL. Drugs on the PDL can be dispensed without condition when prescribed; drugs not on the PDL usually require prior authorization (PA), a process by which prescribing physicians must interact with the Medicaid pharmacy bureaucracy to obtain permission to prescribe a non-preferred drug. Some states that have initiated PDLs have sought supplemental rebates from manufacturers in order to have their products included on the PDL.

Florida initiated this trend by implementing a PDL with supplemental rebates in 2001, and many other states have followed suit. As of September 2003, twenty states have implemented PDLs, and eighteen others have announced plans to implement a PDL or have passed legislation authorizing a PDL. Though several states, including Michigan, Florida, Washington and others, claim significant cost savings have resulted from their PDLs, initial evaluations have not examined patient outcomes. The clinical effects of this cost containment strategy and the attending costs to Medicaid programs have not been evaluated to date.

Currently, twenty states have implemented preferred drug lists. Though cost savings have been realized, clinical outcomes data have not been reviewed since the inception of this cost containment mechanism.

The lack of clinical evaluation is especially of concern given the high numbers of drugs commonly prescribed to diabetics. Even though many states have exempted certain populations and therapeutic classes from their PDLs, diabetic beneficiaries and products directly related to diabetes care have generally not enjoyed such exemption. Several states, including California, Michigan, Florida and Georgia require PA for non-preferred diabetic products on their PDLs. In addition to the pharmaceutical products directly related to diabetes, states commonly require PA for other products often used by diabetics relating to their comorbidities. The clinical effectiveness of pharmacotherapy for a diabetic is likely affected by a PDL, and therefore should be monitored following such policy changes.

## Quantity Limitations

Quantity limitations are a second major cost containment tool used by Medicaid, and these policies fall into two major categories: “hard” limits and “soft” limits. Hard quantity limitations include: (1) limitations on the number of prescriptions a beneficiary may receive each month or during some other time period (strict monthly quantity limits on prescriptions are a unique cost containment tool of Medicaid programs); and (2) dollar limits on the payments for prescriptions per beneficiary. Florida’s four brand-name drug limit is an example of a hard limit. Soft quantity limitations include limits on the amount of medicine that can be dispensed per prescription or on the number of refills per prescription. Soft limitations generally promote economy in dispensing and aim to prevent polypharmacy and other forms of inappropriate drug use.

In 2001, many state Medicaid agencies (forty-four, including the District of Columbia) had some form of quantity limitations on Medicaid prescription drug benefits.<sup>7</sup> Currently, fourteen state Medicaid agencies use “hard” limits; twelve states apply the cap to all covered medications while two states (Florida and Washington) limit the policy to brand products only. In a number of states, Medicaid beneficiaries can ultimately access additional prescriptions beyond the PDL limitations through a PA program. Providers may be discouraged from pursuing PA due to the administrative burden often associated with the procedure (i.e. paperwork burden, office space, phone calls, and other expenses).

## Diabetes Background

Diabetes is a unique disease, affecting about eight percent of the American population.<sup>8</sup> Diabetes clinical management is costly and focuses heavily on pharmacotherapy. In a recent study of the fifteen most costly medical conditions, diabetes was the sixth most expensive condition in terms of total spending and accounted for the highest prescription drug expenditures per person compared to all the other conditions reviewed.<sup>9</sup> Despite recent efforts by many Medicaid programs to contain pharmaceutical spending, Medicaid pays more for the direct overall costs of diabetes than for any of eleven other costly diseases, such as cancer, heart disease, and hypertension.<sup>10</sup>

Three factors make diabetes a critical target for evaluating the effects of Medicaid pharmaceutical cost containment efforts on patient outcomes: (1) the prevalence of the disease,

(2) the common occurrence of diabetes comorbidities, and (3) the variety of pharmaceutical products associated with the disease. Each of these characteristics is described in greater detail below.

## Demographics

Approximately seventeen million individuals in the United States have diabetes, with over eleven million diagnosed and nearly six million undiagnosed cases, but it is unclear how many of these are Medicaid beneficiaries. The prevalence of diabetes increases with age, ranging from 2.1 percent for ages 18-29 years to 15.5 percent for those aged over 70 years. Also, women have a higher prevalence rate of diabetes (8.9 percent) compared to men (6.8 percent), while African-American and Hispanics/Latinos have higher incidences of diabetes compared to other ethnicities.<sup>11</sup> African Americans and Latinos also comprise a disproportionately high percentage of Medicaid recipients compared to the general population.

Recent studies have shown that prevalence of diabetes not only varies according to age, sex and ethnicity, but also by geography (see prevalence map, below). Diabetes prevalence ranges from a low of five percent (Minnesota) to a high of 10.5 percent in Alabama. Three states (Alabama, Florida and Mississippi) have diabetes prevalence rates over ten percent, well above the national average of 7.9 percent. Evaluating the impact of Medicaid cost containment on diabetes outcomes is particularly important in states with the highest prevalence of diabetes.<sup>12</sup>

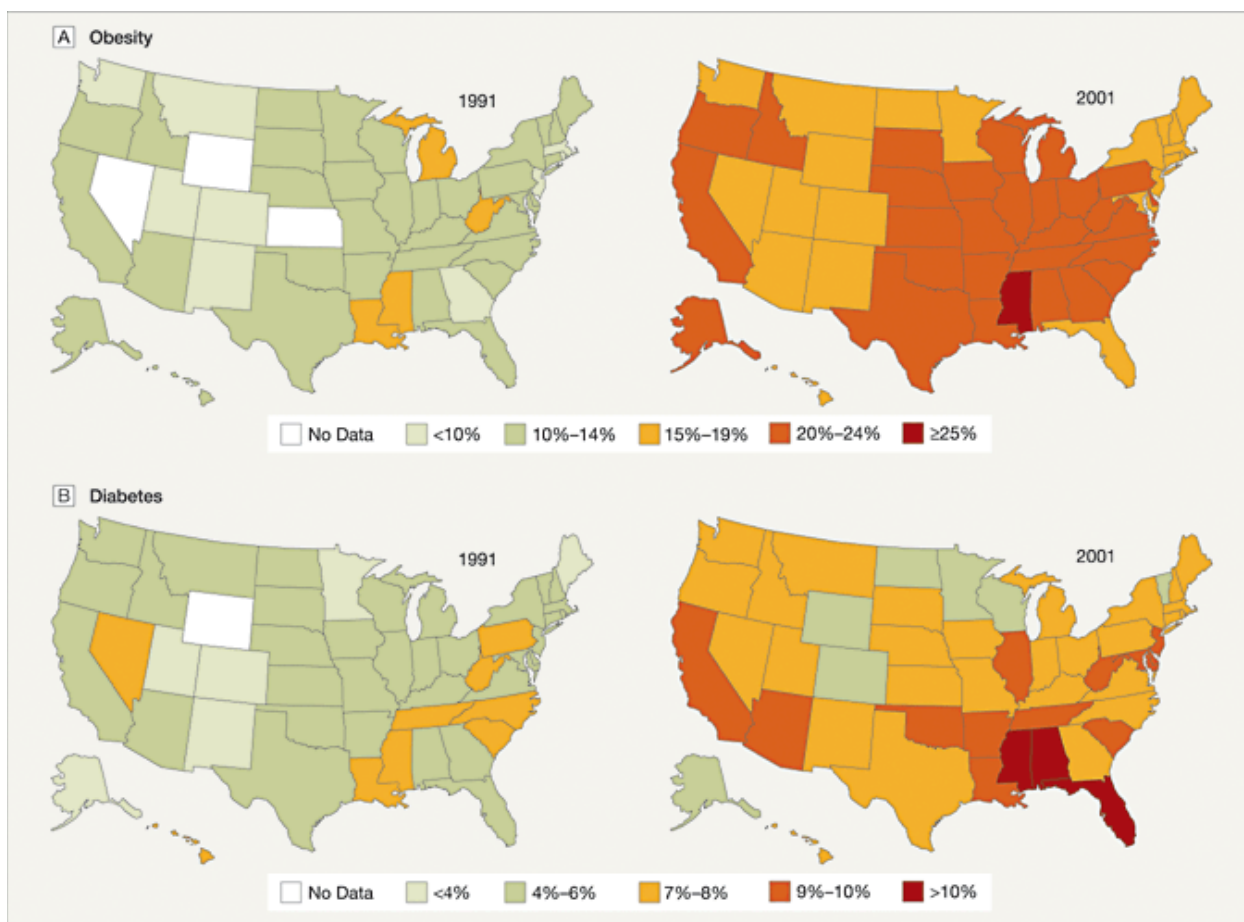
**Table 1. Obesity and Diabetes Prevalence Among US Adults by Selected Characteristics, Behavioral Risk Factor Surveillance System, 2001\***

	Obesity, % (SE)	Diabetes, % (SE)
Total	20.9 (0.16)	7.9 (0.11)
Sex		
Men	21.0 (0.24)	6.8 (0.14)
Women	20.8 (0.21)	8.9 (0.15)
Age, y		
18-29	14.0 (0.32)	2.1 (0.12)
30-39	20.5 (0.36)	4.1 (0.16)
40-49	24.7 (0.39)	6.6 (0.27)
50-59	26.1 (0.42)	11.2 (0.31)
60-69	25.3 (0.51)	15.1 (0.41)
≥70	17.1 (0.39)	15.5 (0.36)
Race		
White	19.6 (0.16)	7.2 (0.10)
Black	31.1 (0.59)	11.2 (0.39)
Hispanic	23.7 (0.73)	9.0 (0.45)
Other	15.7 (0.63)	8.2 (0.59)
Education		
<High school	27.4 (0.59)	13.0 (0.40)
High school	23.2 (0.29)	8.2 (0.18)
Some college	21.0 (0.30)	7.5 (0.20)
>College	15.7 (0.24)	5.5 (0.18)
Smoking status		
Never	20.9 (0.23)	7.1 (0.15)
Ex-smoker	23.9 (0.33)	11.1 (0.24)
Current	17.8 (0.31)	6.1 (0.18)

\*Data reflect national estimates.

Source: Mokdad AH et al. Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA*. 2003;289:76-79.

**Figure 1.** Prevalence of Obesity and Diagnosed Diabetes Among US Adults, 1991 and 2001



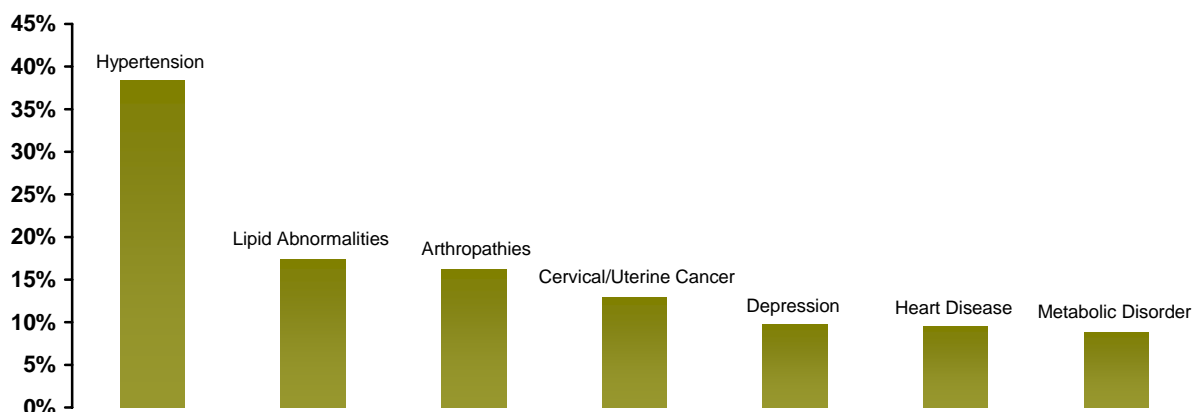
Source: Mokdad AH et al. Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA*. 2003;289:76-79.

## Comorbidities

Many diabetics suffer from additional conditions and diseases that complicate their treatment. As shown in the chart below, based on analysis of the Medical Expenditure Panel Survey (1999 data) nearly forty percent of Medicaid beneficiaries with diabetes also report having hypertension. Other common comorbidities include lipid abnormalities (sixteen percent), cervical and/or uterine cancer (twelve percent), and depression (nine percent).

The common occurrence of such comorbidities creates a complex pharmaceutical regimen for many diabetics. In addition to pharmaceuticals for diabetes treatment, diabetic Medicaid beneficiaries also commonly use products such as Lipitor (cholesterol), Zestril (hypertension), Atenolol (hypertension) and Lanoxin (atrial fibrillation).

**Figure 2. Common Comorbidities of Diabetes**



Source: The Health Strategies Consultancy LLC and Duke University analyses of 1999 Medical Expenditure Panel Survey (MEPS) data.

## Impact Analysis of Medicaid Cost Containment Initiatives on Diabetes

Given the variety and number of medications diabetics typically require, Medicaid program limits on pharmaceuticals have the potential to greatly impact these beneficiaries. While there is a general belief that Medicaid cost control programs will save money, the clinical and economic impacts of these programs have not been systematically explored for the general Medicaid population, or for particularly vulnerable Medicaid beneficiaries, such as those with diabetes. However, previous studies have concluded that Medicaid quantity limits resulted in adverse clinical and economic outcomes for certain patients<sup>13,14</sup>, raising serious concerns about such cost containment efforts.

The potential impact of prescription drug restrictions on diabetes outcomes makes monitoring the clinical effects of these programs on diabetic patients crucial. Clinical studies have shown that maintaining normal blood glucose levels through insulin treatment and regularly monitored hemoglobin A<sub>1C</sub> values has prevented complications.<sup>15</sup> If pharmaceutical cost containment techniques adversely affect providers' ability to care for diabetic patients and patients' ability to care for themselves, one would expect decreased control of blood glucose levels and a resulting rise in hemoglobin A<sub>1C</sub> values. Increased hemoglobin A<sub>1C</sub> values have been demonstrated to accurately predict increased future complications in patients with diabetes.<sup>16</sup>

Tracking hemoglobin A<sub>1C</sub> values immediately following policy implementation to measure the long-term effects of Medicaid pharmaceutical cost containment initiatives on diabetes outcomes is feasible for states. The results of a controlled comparison of hemoglobin A<sub>1C</sub> values before and after policy implementation would be invaluable in understanding the effects of pharmaceutical cost containment on patients with diabetes. Furthermore, the resulting data would provide evidence to state policy makers of any harmful clinical consequences associated with restricting access to care for diabetic beneficiaries.

## Case Studies

Two different types of data must be available for Medicaid diabetics in order to perform a clinical evaluation of a PDL or quantity limits policy: clinical outcomes data (e.g., hemoglobin A<sub>1C</sub> values, blood pressure, etc) and expenditure data. These cost containment policies have traditionally been applied to the unmanaged portions of each state's Medicaid population (i.e., the fee-for-service population).<sup>17</sup> Though many state Medicaid programs have expenditure data readily available for all aspects of the program, most state Medicaid agencies do not monitor clinical information for their fee-for service populations. The exception is within states that operate diabetes disease management programs, which provide a mechanism for state Medicaid agencies to monitor clinical data for Medicaid diabetics as well as manage the care for a traditionally unmanaged population. Most diabetes disease management programs collect the clinical outcomes data needed to conduct a clinical evaluation of pharmaceutical cost containment policies.

Therefore, we limited the case study states for this report to those with the following characteristics: (1) A PDL in place, announced, planned or authorized and/or a monthly quantity limit policy in place and (2) An active diabetes disease management program.

In early 2003, nine states were identified as having either a PDL or a monthly quantity limit, and a disease management program: California, Florida, Louisiana, Maryland, Mississippi, North Carolina, Texas, Washington, and West Virginia. We contacted all nine states regarding the availability of data needed to compare outcomes before and after implementation of cost containment policies, as shown in the table below.

To successfully evaluate the impact of cost containment initiatives on diabetes outcomes, states would need to have data on hemoglobin A<sub>1C</sub> values *both before and after* implementation of their cost containment programs. While many states began collecting such data after implementation of cost containment programs, only Washington responded to our request and collected data both before and after implementation. Washington has been collecting clinical outcomes data in a subset of beneficiaries with diabetes since July 2002. Therefore, there is sufficient data prior to inclusion of diabetes drugs on the state's PDL (diabetes products will not be placed upon the PDL until later in 2003 or early 2004).

Our findings around state data collection practices underscores the potential that states are not equipped to monitor and understand the clinical impact that their cost containment measures may have on vulnerable populations. This information suggests that few answers will be available to address Medicaid stakeholders' questions regarding the clinical impact of PDLs and other emerging policies.

**Table 2. States With Both a PDL or Quantity Limitation Plus a Disease Management Program Within Medicaid**

State	PDL Status	Quantity Limits	Disease Management (DM)	Data Availability
California	Implemented	6 Rx/mo.	In select counties	Not as relevant due to age of program
Florida	Implemented	4 Rx brand/mo.	Several programs	Non-response from state
Louisiana	Implemented	8 Rx/mo.	None	Non-response from state
Maryland	Proposed	None	Through MMC*	No clinical outcomes data collected
Mississippi	Proposed	5 Rx/mo.	McKesson telephonic model	Data will be collected when DM program is initiated 4/03
North Carolina	Proposed	6 Rx/mo.	Through PCCM* model	Data only from MMC*
Texas	Proposed	3 Rx/mo.	Through PCCM* model	Data not available
Washington	Implemented	4 Rx brand/mo.	McKesson telephonic model	<b>Data available from subset</b>
West Virginia	Implemented	10 Rx/mo.	Small provider education model in past, currently on hold	Pre-data available for small subset, no post-data currently being collected.

Source: The Health Strategies Consultancy LLC and Duke University analyses.  
MMC indicates Medicaid managed care; and PCCM, primary care case management.

## Conclusion

Monitoring clinical and quality indicators of diabetic beneficiaries is an important consideration when developing cost containment policies. The potentially profound medical and fiscal consequences justify critical review of these policies. State Medicaid programs should monitor clinical and quality indicators of diabetic beneficiaries, as these patients are more likely to be subjected to cost containment policies that can have profound medical effects. Most states do not currently collect clinical outcomes data for populations affected by pharmaceutical cost containment policies, or, alternatively, they are not making these data available to researchers in a confidential way. Reasons for this dearth of study may be financial, or may reflect a relative lack of interest in this issue.

Among the states reviewed in this study, only Washington was found to be collecting clinical outcomes data of affected diabetic populations and interested in making these data available for study. Even though the state is collecting clinical outcomes data for a subset of this population, the state has not yet begun to include diabetic products in the state's PDL program. Therefore the state cannot yet analyze how their cost containment policies will affect Medicaid diabetics. However, the results of these evaluations, when they are obtained, will be critical to better understand the impact PDL policies have on the Medicaid diabetic population.

The unique nature of the diabetes patient population, including heavy use of prescription drugs and multiple comorbidities, makes it particularly important to understand the clinical impact of pharmaceutical cost containment programs. As more Medicaid programs develop cost containment policies, state policy makers and legislators should require evaluation activities when these policies are introduced, through regulation or legislation. By having available clinical outcomes data, diabetics and other high-risk Medicaid beneficiaries can be monitored to ensure that their quality of care is maintained.

Understanding the impact of pharmaceutical cost containment policies on diabetes care and utilization of other health care services is essential to ensure that Medicaid beneficiaries with diabetes continue to have access to quality care. Because Washington is the only state that can reasonably provide the data needed for a clinical evaluation of Medicaid pharmaceutical cost containment and diabetes, evaluation of these programs is an essential next step for the diabetes community as well as state and national policy makers. Study of the Washington State experience, including analysis of clinical outcomes, laboratory values, and claims data is an important next step in this line of research.

## Notes

- 1 “10 leading causes of death, United States, 2000, all sexes, all races, all ages”. Office of Statistics and Programming, National Center for Injury Prevention and Control, CDC. <<http://webapp.cdc.gov/cgi-bin/broker.exe>> Accessed 8/18/03.
- 2 Mokdad, Ali H. et al. (2003) Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA* 289: 76-79.
- 3 Smith, et.al., “Medicaid Spending Growth: A 50 State Update for FY 2003,” Kaiser Commission on Medicaid and the Uninsured. January 2003.
- 4 Levit, Katharine, et al. Trends in U.S. Health Care Spending, 2001. (2003) *Health Affairs*. 22 (1): 154-164.
- 5 Office of the Actuary, Centers for Medicare and Medicaid Services, fiscal year 2002 mid-session review of Medicaid spending projections.
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- 8 Mokdad, Ali H. et al. (2003) Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA* 289: 76-79.
- 9 Cohen JW, Krauss NA. (2003) Spending and service use among people with the fifteen most costly medical conditions, 1997. *Health Affairs* 22 (2): 129-138.
- 10 Ibid.
- 11 Mokdad, Ali H. et al. (2003) Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA* 289: 76-79.12 ibid
- 13 Fortess EE, et al. (2001) Utilization of essential medications by vulnerable older people after a drug benefit cap: importance of mental disorders, chronic pain, and practice setting. *Journal of the American Geriatric Society*. Jun; 49(6): 793-7.
- 14 Soumerai SB, et al. (1991) Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes. *New England Journal of Medicine*. 325(15): 1072-7.
- 15 The Diabetes Control and Complications Trial Research Group. (1993) The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine* Sep 30;329(14):977-86.
- 16 Ibid.
- 17 Tennessee has recently proposed creating a preferred drug list for all seven of its Medicaid managed care plans (Kaiser Daily Health Policy Report, 5/6/03).