



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

October 29, 1999

### **H.R. 2634** **Drug Addiction Treatment Act of 1999**

*As ordered reported by the House Committee on Commerce on October 13, 1999*

#### **SUMMARY**

H.R. 2634 would amend the Controlled Substances Act of 1970 to enable qualifying practitioners who wish to dispense narcotic drugs in schedule IV or V for detoxification treatment to apply to the Secretary of Health and Human Services (HHS) for a waiver of the Drug Enforcement Administration's (DEA's) registration requirements. The program would be implemented by the Substance Abuse and Mental Health Services Administration (SAMHSA). The bill would authorize the appropriation of such sums as may be necessary for fiscal year 2000 and each subsequent year to pay for implementing the program and processing the waiver applications, but specifies that no more than \$5 million per year may be obligated for this activity. Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 2634 would cost the federal government about \$80 million over the 2000-2004 period—\$23 million in administrative costs for SAMHSA and \$30 million in additional Medicaid spending. Because the bill would affect direct spending, pay-as-you-go procedures would apply.

H.R. 2634 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA), but CBO estimates that the costs would not be significant and would not exceed the threshold established in that act (\$50 million in 1996, adjusted annually for inflation). This bill would impose no new private-sector mandates as defined in UMRA.

#### **ESTIMATED COST TO THE FEDERAL GOVERNMENT**

The estimated budgetary impact of H.R. 2634 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars				
	2000	2001	2002	2003	2004
<b>CHANGE IN SPENDING SUBJECT TO APPROPRIATION</b>					
SAMHSA					
Authorization Level	5	5	5	5	5
Estimated Outlays	3	5	5	5	5
<b>CHANGE IN DIRECT SPENDING</b>					
Medicaid					
Estimated Budget Authority	a	5	5	10	10
Estimated Outlays	a	5	5	10	10
a. Less than \$500,000.					

## **BASIS OF ESTIMATE**

Under current law, physicians wishing to dispense narcotic drugs to treat narcotic dependence must first apply to HHS, which determines whether they are qualified to provide such treatment. Qualified physicians must then apply to DEA to be registered separately to dispense (not prescribe) such narcotic drugs in treatment. H.R. 2634 would permit physicians to dispense and prescribe narcotic drugs in schedule IV or V (the drugs rated the lowest risk for abuse) for maintenance or detoxification treatment, under certain conditions, instead of obtaining a separate DEA registration.

Under the waiver program in H.R. 2634, interested qualified practitioners would notify the Secretary of HHS, in writing, of their intent and certify that they meet the conditions in the bill relating to state licensing, training and experience, and other requirements. Physicians would proceed to provide such treatment unless they were notified otherwise by the Secretary. The bill would also authorize the Secretary to establish, by regulation, criteria for determining the necessary training and experience for qualified physicians. At any time during the three-year period following the enactment of this legislation, the Secretary, in consultation with the Attorney General, would be able to publish a decision to terminate the program based on specific adverse findings. If such a decision were published, the program would be eliminated within 60 days.

## **Spending Subject to Appropriation Action**

H.R. 2634 would create several new responsibilities for SAMHSA. Based on information from SAMHSA, CBO estimates that \$5 million per year would be required to fund the additional staff to formulate and publish regulations, establish an appropriate training curriculum, design practice guidelines, oversee practitioners, set up a data base containing the names of practitioners who receive waivers, process providers' applications, and assess their qualifications. In addition, during the first three years, SAMHSA would collect data and provide information to the Attorney General to evaluate the impact of the program and make a determination of adverse use. Provided the program is not terminated, the provisions in H.R. 2634 would increase discretionary spending by a total of \$23 million over fiscal years 2000 through 2004. This estimate assumes that the necessary amounts would be appropriated for each fiscal year and that outlays would follow historical spending rates for similar activities.

## **Direct Spending**

**Medicaid.** CBO estimates that enacting H.R. 2634 would increase federal Medicaid spending by \$30 million over the 2000-2004 period because more Medicaid beneficiaries would receive new schedule IV and V narcotics over that period than under current law. Currently, no schedule IV or V narcotics are approved for outpatient maintenance or detoxification treatment. Methadone, a schedule II narcotic, is the principal narcotic currently used in treating opiate addiction. The distribution of methadone is regulated so that only certain providers who are registered with DEA may dispense it, and the daily doses usually must be provided in clinical settings and combined with counseling and other treatment services.

Later this year, the Food and Drug Administration (FDA) is expected to approve a new substance, buprenorphine, for the treatment of opiate addiction. According to HHS, buprenorphine is likely to be approved as a schedule IV or V narcotic because it has been found to have limited euphorogenic effects and therefore low desirability for sale on the street. Under current law, it is unclear exactly how buprenorphine will be distributed. Assuming FDA approves the drug, HHS and DEA will develop regulations to govern its distribution. Many experts believe that it would be appropriate to allow physicians to prescribe the drug from their office-based settings and to distribute it through commercial pharmacies, but final decisions and regulations will probably take about a year. Furthermore, under current law, many states have their own regulations governing the distribution of narcotics.

H.R. 2634 would specifically waive the DEA registration requirement that would otherwise apply to physicians who wish to prescribe buprenorphine and would allow physicians to prescribe that drug from their office-based settings. In addition, the bill would supersede state regulations for three years. CBO expects that enacting the bill would lead to somewhat wider distribution of buprenorphine than would otherwise occur—for two reasons. First, implementation of office-based distribution would probably occur faster than under current law and, second, the regulations that the Administration would issue under current law would probably be more restrictive than the procedures allowed by the bill.

Based on information from the National Institute on Drug Abuse, CBO estimates that ultimately about 100,000 individuals will receive buprenorphine each year if it is distributed through office-based settings. CBO expects that enactment of the bill would speed up the penetration of buprenorphine by one to two years and would ultimately lead to 10 percent more people receiving the drug. CBO further estimates that the average annual cost of treatment with buprenorphine would be about \$4,300 per person in 2000, evenly divided between the cost of the drug itself and the cost of related medical and mental health services. According to a report by the Institute of Medicine, in 1992 about 12 percent of all methadone treatment was paid for by Medicaid. For this estimate, CBO assumes that the same proportion of buprenorphine treatment would be covered by Medicaid, and that 57 percent of those costs would be reimbursed by the federal government. In addition, CBO estimates that one quarter of the costs of buprenorphine treatment under the bill either would occur under current law or would be offset by reduced use of other medical or mental health services.

**Drug Enforcement Administration.** CBO estimates that implementing H.R. 2634 would have a negligible effect on the DEA. The agency collects a fee—\$70 a year, or \$210 every three years—from each practitioner for dispensing controlled substances (including narcotics) and uses these collections to fund its registration activities. Because most, if not all, practitioners will dispense some controlled substances that are not covered by the waiver provided by the bill, enacting H.R. 2634 would probably not affect the amount of collections. The bill's effect on DEA's spending for registration activities would be very small because relatively few practitioners are expected to apply for the waiver.

## **PAY-AS-YOU-GO CONSIDERATIONS**

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in the

following table. For the purposes of enforcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted.

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Summary of Pay-As-You-Go Effects of H.R. 2634

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	By Fiscal Year, in Millions of Dollars										
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	
Changes in outlays	0	5	5	10	10	10	5	5	5	5	
Changes in receipts					Not Applicable						

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### **ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS**

H.R. 2634 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA). The bill would preempt, for three years, a state's ability to regulate the distribution of certain narcotic drugs for detoxification treatment. If, within that period, a state enacted a law in conflict with the bill, that law would go into effect at the end of the three-year period. Because states would not be required to take any action, however, CBO estimates the cost of this preemption would be insignificant.

Because the bill would increase the number of Medicaid beneficiaries that receive new schedule IV or V narcotics for detoxification treatment, CBO estimates that Medicaid spending by states would increase by about \$20 million over the 2000-2004 period.

### **ESTIMATED IMPACT ON THE PRIVATE SECTOR**

This bill would impose no new private-sector mandates as defined in UMRA.

### **PREVIOUS CBO ESTIMATES**

In September 1999, CBO provided an estimate of S. 486, the Methamphetamine Anti-proliferation Act of 1999. That bill contained provisions similar to those in H.R. 2634. In that estimate, CBO did not include the costs to the Medicaid program of changing the law to make schedule IV and IV narcotics more easily distributed.

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