



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

August 15, 2003

### **S. 720**

### **Patient Safety and Quality Improvement Act of 2003**

*As ordered reported by the Senate Committee on Health, Education, Labor, and Pensions  
on July 23, 2003*

#### **SUMMARY**

S. 720 would establish certification procedures for patient safety organizations (PSOs) and require the Secretary of Health and Human Services to maintain a list of certified PSOs, which collect patient safety data voluntarily submitted by health care providers for inclusion in a patient safety network of databases. The bill also would establish privacy protections and impose civil monetary penalties for violations of those protections. The bill would require the Secretary to report to the Congress on effective strategies for reducing medical errors and increasing patient safety.

CBO estimates that implementing S. 720 would cost \$4 million in 2004 and \$51 million over the 2004-2008 period, assuming the appropriation of the necessary amounts. CBO estimates that receipts from fines for violation of the privacy protections would amount to less than \$500,000 a year.

The bill would require the Secretary of Health and Human Services to develop methodologies for the collection of patient safety data and provide technical assistance to PSOs. In addition, the Secretary would develop voluntary national standards that promote the comparability of medical information technology systems.

S. 720 would preempt state laws that govern the disclosure of information provided to patient safety organizations. While that preemption would be intergovernmental mandates as defined in the Unfunded Mandate Reform Act (UMRA), it would impose no requirements on states that would result in additional spending; thus, the threshold as established by UMRA would not be exceeded (\$59 million in 2003, adjusted annually for inflation).

The bill would impose a private-sector mandate on health care providers, as defined in UMRA, by not allowing them to use the fact that an employee reported patient safety data

in an adverse employment action against the employee. This mandate would not have any direct cost, however, because patient safety data as defined in the bill does not exist under current law.

**ESTIMATED COST TO THE FEDERAL GOVERNMENT**

The estimated cost of S. 720 is shown in the following table. The bill could also result in an increase in revenues from fines, but CBO estimates that any such increase would be less than \$500,000 a year. The costs of this legislation fall within budget function 550 (health).

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	By Fiscal Year, in Millions of Dollars				
	2004	2005	2006	2007	2008
<b>CHANGES IN SPENDING SUBJECT TO APPROPRIATION</b>					
Estimated Authorization Level	12	13	12	13	13
Estimated Outlays	4	9	12	13	13

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**BASIS OF ESTIMATE**

**Spending Subject to Appropriation**

S. 720 would expand the current duties of the Agency for Healthcare Research and Quality (AHRQ). Although not specifically named, the AHRQ is the most likely and appropriate agency within the Department of Health and Human Services to carry out the provisions of the bill. The new duties would include providing technical assistance to PSOs that have (or are developing) systems for reporting medical errors. AHRQ also would oversee the certification and listing of PSOs, which collect patient safety data from health care providers. (PSOs are private or public organizations that conduct activities to improve patient safety and the quality of health care delivery.) PSOs would not receive funding under this bill.

In addition, the bill would require AHRQ to maintain a patient safety network of databases to collect, support, and coordinate the analysis of patient safety data that is reported on a voluntary basis. Based on information from AHRQ, CBO expects that these tasks would require increased staff for providing assistance to PSOs, oversight of PSOs, and collection

and maintenance of the patient safety database. CBO estimates that the agency would need additional appropriations of \$12 million in 2004 and \$63 million over the 2004-2008 period to carry out these responsibilities. We estimate that outlays would total \$51 million over the 2004-2008 period, assuming the necessary amounts are appropriated. In 2004, we estimate that the agency would spend about \$4 million, primarily on maintaining the patient safety database.

The bill would require the Secretary to develop methodologies for collecting data on patient safety. In addition, S. 720 would require the Secretary to develop voluntary, national standards that promote the compatibility of health care information technology systems across all health care settings. CBO estimates that these efforts would cost less than \$500,000 a year.

## **Revenues**

Because those prosecuted and convicted for violation of the bill's privacy provisions could be subject to civil monetary penalties, the federal government might collect additional fines if the bill is enacted. Collections of civil fines are recorded in the budget as governmental receipts (i.e., revenues). CBO estimates that any additional receipts would be less than \$500,000 a year.

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

S. 720 would preempt any state freedom of information law or other laws governing civil or administrative procedure that require the disclosure of information provided by a health care provider to a certified patient safety organization. This preemption would be an intergovernmental mandate as defined in UMRA, because it would limit the application of those state laws. CBO estimates that this mandate would impose no requirement on states that would result in additional spending; thus, the threshold as established by UMRA would not be exceeded (\$59 million in 2003, adjusted annually for inflation).

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

The bill would impose a private-sector mandate on health care providers, as defined in UMRA, by not allowing them to use the fact that an employee reported patient safety data in an adverse employment action against the employee. This mandate would not have any direct cost, however, because patient safety data as defined in the bill does not exist under current law.

## **PREVIOUS CBO ESTIMATES**

On March 3, 2003, CBO transmitted a cost estimate for H.R. 663, the Patient Safety Quality Improvement Act, as ordered reported by the House Committee on Energy and Commerce on February 12, 2003. CBO estimated that implementing the provisions of that bill would increase discretionary spending by \$104 million over five years. The difference in the estimates for S. 720 and H.R. 663 is largely due to the grant program for establishing an electronic prescription program authorized by H.R. 663. In addition, H.R. 663 would require the inclusion of a unique product identifier on packaging of a drug or biological product that is subject to regulation by the FDA. This provision, which would be a private-sector mandate, is not included in S. 720.

On March 5, 2003, CBO transmitted a cost estimate for H.R. 877, the Patient Safety Improvement Act, as ordered reported by the House Committee on Ways and Means on February 27, 2003. CBO estimated that implementing the provisions of that bill would increase direct spending by \$59 million and increase discretionary spending by \$4 million over five years. The difference in the estimates for S. 720 and H.R. 877 is largely due to the provision in H.R. 877 that would establish the Medical Information Technology Board to provide recommendations regarding medical information technology.

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