



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

March 3, 2003

H.R. 663 **Patient Safety and Quality Improvement Act**

*As ordered reported by the House Committee on Energy and Commerce
on February 12, 2003*

SUMMARY

H.R. 663 would require the Secretary of Health and Human Services to establish credentialing procedures for patient safety organizations (PSOs), which collect patient safety data voluntarily submitted by health care providers for inclusion in a patient safety database. The bill also would establish privacy protections and impose civil monetary penalties for violations of those protections. The Secretary would be required to report to the Congress on effective strategies for reducing medical errors and increasing patient safety.

CBO estimates that implementing H.R. 663 would cost \$20 million in 2004 and \$104 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 and states. In addition, the Secretary would, with the National Committee for Vital and Health Statistics, develop voluntary national standards that promote the comparability of medical information technology systems.

H.R. 663 would authorize grants to qualified practitioners for the purpose of establishing electronic prescription programs, and would authorize the Health Resources and Services Administration (HRSA) to make grants to hospitals and other health care providers for acquiring or implementing information technologies. The bill would require the inclusion of a unique product identifier on packaging of a drug or biological product that is subject to regulation by the Food and Drug Administration (FDA). Drugs and biological products that do not comply with FDA's labeling requirements would be deemed misbranded, and their manufacturers and packagers would be subject to civil penalties.

H.R. 663 would preempt state laws that would govern the disclosure of information provided to patient safety organizations, and it would prevent health care providers from taking certain actions against employees because the employee provided information to patient safety organizations. While these provisions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA), they 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 private-sector mandates, as defined in UMRA, on health care providers and on manufacturers, packagers, and labelers of drugs and biological products. Because the specific requirements of the bill would depend on future actions by the Secretary of Health and Human Services, however, CBO cannot determine whether the direct cost of the mandates would exceed the annual threshold specified in UMRA (\$117 million in 2003, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated cost of H.R. 663 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).

	By Fiscal Year, in Millions of Dollars				
	2004	2005	2006	2007	2008
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated Authorization Level	39	38	13	13	13
Estimated Outlays	20	39	20	13	13

BASIS OF ESTIMATE

Spending Subject to Appropriation

H.R. 663 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 states that have (or are developing) systems for reporting medical errors. AHRQ also would oversee the certification and recertification 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 establish a patient safety database to collect, support, and coordinate the analysis of patient safety data that is reported on a voluntary basis. AHRQ also would develop an Internet-based mathematical model that simulates the cost and effectiveness of electronic prescription programs. Based on information from AHRQ, CBO expects that these tasks would require increased staff for providing assistance to states, oversight of PSOs, and collection and maintenance of the patient safety database. They would also require additional computer resources for the database. CBO estimates that the agency would need additional appropriations of \$14 million in 2004 and \$64 million over the 2004-2008 period to carry out these responsibilities. We estimate that outlays would total \$54 million over the 2004-2008 period, assuming the necessary amounts are appropriated. In 2004, we estimate that the agency would spend about \$5 million, primarily on developing and maintaining the patient safety database.

The bill would require the Secretary to provide scientific support to PSOs and to develop methodologies for collecting data on patient safety. In addition, H.R. 663 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.

H.R. 663 would allow the Secretary to make grants to qualified practitioners for the purpose of establishing electronic prescription programs. AHRQ would conduct a study and report to the Congress on the effectiveness of electronic prescription programs. HRSA would make grants available to hospitals and other health care providers for acquisition or implementation of information technology systems.

CBO assumes that grants would be awarded starting in 2004. The bill would authorize appropriations for these grants at \$25 million in fiscal year 2004 and \$50 million over the 2004-2008 period. Based on historical spending patterns for similar activities, CBO estimates that outlays would total \$50 million over the 2004-2008 period, assuming appropriation of the authorized amounts.

The bill would require the inclusion of a unique product identifier on packaging of a drug or biological product that is subject to regulation by the Food and Drug Administration. This provision would cost the FDA less than \$500,000 per year to implement.

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. Drugs and biological products that do not comply with FDA's labeling requirements would be deemed misbranded, and their manufacturers and packagers would be subject to civil penalties. 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

H.R. 663 would preempt any state freedom of information law or other laws governing civil or administrative procedure that would 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. Another intergovernmental mandate in the bill would prohibit health care providers (including public entities) from using the fact that an employee reported patient safety data in an adverse employment action against the employee. CBO estimates that these mandates 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).

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains private-sector mandates, as defined in UMRA, on manufacturers, packagers, and labelers of drugs and biological products and on health care providers. Because the specific requirements of the bill would depend on the future actions of the Secretary of Health and Human Services, however, CBO cannot determine whether the direct cost of the mandates would exceed the annual threshold specified in UMRA (\$117 million in 2003, adjusted annually for inflation).

Under the bill, manufacturers, packagers, and labelers would be required to include a computer-scannable unique product identifier on the packaging of drugs and biological products. Many drug products are currently labeled with such identifiers, but many are not. Of the approximately 200,000 over-the-counter and prescription drug products currently on the market, over one quarter are over-the-counter drugs—nearly all of which already contain universal product codes at the shelf-keeping unit level. In addition, a growing percentage of prescription drugs administered in hospitals are labeled with computer-scannable unique product identifiers. It is unclear whether existing identifiers would meet the requirements of the Secretary.

Adding unique product identifiers would impose costs for products that do not now contain them, and potentially for products that already contain similar information. Under the bill, the Secretary would determine how much standardization of identifiers would be required. The Secretary also would determine what information would have to be included on the identifiers. If identifiers were required to include only the National Drug Code associated with that product, for example, industry costs would be lower than if the identifiers also had to include the lot number and expiration date of the product. The specific details of the requirements imposed by the Secretary, including how quickly the new requirements would have to be implemented, would determine whether the cost of this mandate would exceed the threshold specified in UMRA.

The bill also would impose a mandate on health care providers, 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 there are no activities that health care providers would undertake under current law that they would be prohibited from undertaking under the bill (because patient safety data, as defined in the bill, do not exist under current law).

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