



**CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE**

October 28, 1999

Health Information Confidentiality Act of 1999

Chairman's Mark of June 11, 1999

SUMMARY

The Health Information Confidentiality Act of 1999 (HICA) would establish certain rights for individuals regarding their personal health information and limit the unauthorized use and disclosure of that information by others. The bill would affect all those who create, maintain, or receive medical records, including health care providers, health plans, health researchers, health oversight agencies, public health authorities, employers, law enforcement officials, life insurers, schools, and universities. Federal and state health programs would also be affected.

The bill would increase spending on programs administered by federal agencies, including Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP). It would also reduce federal revenues. Therefore, pay-as-you-go procedures would apply. However, CBO cannot estimate the budgetary impact of the bill. There is considerable uncertainty about the extent to which confidentiality protections already exist or will develop in the absence of any change in federal law. Without that information, and with little information about the potential costs of complying with the new requirements in the bill, CBO has no basis for such an estimate.

The bill would impose both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Because of the broad scope of the legislation, CBO estimates that the costs of both the intergovernmental and private-sector mandates in the bill would exceed the thresholds specified in UMRA, at least during the first year following the bill's enactment. (Those thresholds are \$50 million for intergovernmental mandates and \$100 million for private-sector mandates, adjusted annually for inflation since 1996.)

DESCRIPTION OF THE BILL'S MAJOR PROVISIONS

Several provisions in titles I, II, and IV could have significant impacts on costs to the federal government, to state and local governments, and to the private sector.

Title I

Title I would establish the rights of individuals concerning their medical records. Individuals could inspect and copy their personal health information (referred to in the bill as “protected health information”) unless doing so would endanger their health or reveal a confidential source of information. Inspection could also be denied if litigation was anticipated or if the information was collected solely for research purposes. Individuals could request to amend their records and would have to be given reasons if that request was denied. Entities maintaining protected health information, such as health plans, health care providers, and other health care organizations, would be allowed to charge a reasonable fee for copying medical records, but would be required to reduce the fee if it prevented individuals from gaining access to their records.

All entities maintaining protected health information would have to provide notice of their confidentiality practices and implement appropriate safeguards. They would be required to designate an information protection officer who would be responsible for determining the form the safeguards would take. They would also have to keep records of all disclosures of protected health information other than those made to their agents or their employees.

Title II

Title II would restrict the use and disclosure of protected health information. In general, entities maintaining a person’s health information could use or disclose it only as authorized under the bill or as authorized to do so by that person.

Employers and health plans could obtain a consolidated authorization from the enrollee at the time of enrollment to cover the use and disclosure of records for treatment, payment, or plan operations. Providers would have to obtain the authorization for all patients who had not previously signed one. Individuals could revoke the authorization at any time unless the authorization was required to complete a course of treatment, effectuate payment, or conduct health care operations for care that had already been provided to the individual. Entities maintaining protected health information would have to keep a record of all authorizations and revocations for a period of seven years. Disclosures for purposes other than treatment,

payment, or health care operations would generally require a separate authorization by the individual who was the subject of the information. But the bill would permit disclosures without the individual's authorization for a variety of other functions, such as emergency situations and law-enforcement.

The bill's provisions governing the use of protected health information for research distinguish between research that is governed by the "common rule" and research that is not. (The common rule is the federal policy, promulgated in June 1991, that governs the protection of human subjects from research risk, as adopted and implemented by a federal department or agency.) Under the bill, entities could use or disclose protected information to a researcher if the research involved human subjects, or involved individually identifiable information, and the researcher complied with the common rule. If the common rule did not apply, the researcher would have to obtain informed consent from the individual or the individual's representative; have the research proposal reviewed and approved by an institutional review board; or have the proposal reviewed and approved by the information protection officer, who would be responsible for determining when it was appropriate to waive informed consent.

Title IV

Title IV specifies the relationship of the bill to other laws and its applicability to certain federal agencies. In general, it would preempt all future state laws that relate to: copying, inspection, and amendment of medical records; use and disclosure of protected health information for treatment, payment, and health care operations; and use and disclosure of protected health information for research. The bill would also preempt less protective state laws in effect prior to its enactment, but would not preempt already existing laws that are more protective. Some federal agencies, including the Department of Defense (DoD), the Coast Guard, and the Central Intelligence Agency, would be exempted from any requirements of the bill that could compromise the fulfillment of the agencies' statutory responsibilities.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The Health Information Confidentiality Act would add to the costs of programs administered by federal agencies, including Medicare, Medicaid, and the Federal Employees Health Benefits Program. It would also cause federal revenues to decline because premiums for employer-sponsored health insurance coverage would increase as a result of the higher costs faced by providers and health plans. As a result, employers and employees would substitute

nontaxable employer-paid premiums for taxable wages. However, CBO does not have sufficient data to estimate the federal budgetary costs of the bill.

BASIS OF ESTIMATE

The bill would make sweeping changes that would affect disclosures of personal health information not only within the practice of health care, but also in medical research, law enforcement, employment, electronic transactions, and civil, judicial, and administrative actions. In general, few data exist on the volume of transactions involving personal health information that would be affected or on the cost per transaction that would be generated by compliance with the law. Little also is known about the nature and costs of existing confidentiality protections and how those protections might evolve in the future in the absence of new federal legislation. Along with a wide variety of state laws, many non-governmental organizations, both nonprofit and for-profit, have established their own confidentiality requirements. The scope of those private-sector protections is not well understood and probably varies broadly both within and among the various groups that would be affected by the bill. Therefore, CBO can make only qualitative statements about the effects of the bill on both the private sector and the federal budget.

HICA would impose requirements on federal programs that create, maintain, and receive medical records for beneficiaries or enrollees. Those requirements would include processing requests to inspect, copy, and amend protected health information. Because the bill states that any fees charged must not prevent individuals from gaining access to protected health information, CBO expects that it would increase administrative costs for federal health programs such as Medicare, Medicaid, health programs in the Department of Veterans Affairs, and other federal agencies. Similarly, CBO anticipates that administrative costs would increase for insurance carriers participating in FEHBP and the DoD TriCare program. Because those costs would be factored into premium rates, federal payments for the government's share of health insurance premiums would increase.

The bill also would require federal programs in possession of protected health information to develop detailed regulations, produce notices of new medical privacy requirements, and keep records of disclosures of protected health information. In addition to agencies specifically administering health care programs, those requirements would affect other agencies that need to disclose personal health information in the course of performing various administrative functions. However, the cost to federal agencies of complying with HICA would be lower to the extent that federal protections have already been implemented, or would be implemented, without legislation.

Finally, the bill would cause federal income and payroll tax revenues to fall. CBO assumes that total employee compensation would not be affected by the legislation. Therefore, to the extent that compliance with new privacy regulations in the bill caused premiums for employer-sponsored health insurance to increase, employers and employees would substitute nontaxable employer-paid premiums for taxable wages.

Action has recently been taken by federal agencies to enhance protections of personal health information. For example, the Health Care Financing Administration (HCFA) recently announced new regulations that require hospitals participating in the Medicare and Medicaid programs to abide by heightened patient confidentiality protections. HCFA has also instituted regulations that strengthen the protections that must be provided by health plans participating in the Medicare+Choice and Medicaid programs. Because actions such as these provide additional protection for personal information in federal health programs, any subsequent legislation would require fewer administrative changes than would otherwise have been necessary, thus reducing the incremental cost to federal programs of complying with the bill.

The Secretary of Health and Human Services is required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to promulgate regulations because the Congress did not pass confidentiality legislation by August 1999. Those regulations would protect the privacy of personal health information stored in electronic form, but the precise nature of the regulations will not be known for some time. Although electronic records currently comprise a relatively small proportion of all personal health information, that share is likely to grow rapidly in the future. Some organizations might choose to adopt some or all of the Secretary's regulations for all of the personal health information they maintain and not just that portion stored electronically.

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. Because this bill would affect federal revenues and a number of direct spending programs (including Medicare, Medicaid, and FEHBP), pay-as-you-go procedures would apply. CBO estimates that the bill would result in lower revenues and higher outlays, but cannot estimate the amount of those changes.

ESTIMATED IMPACT ON STATE, LOCAL AND TRIBAL GOVERNMENTS

The bill would place a number of requirements on state, local, and tribal governments concerning the gathering, use, and disclosure of health information. Those requirements, along with preemptions of future state laws and some existing state laws governing health information, would be intergovernmental mandates as defined in UMRA. The requirements governing the gathering, use, and disclosure of health information could result in significant administrative and procedural costs, especially during the first year of implementation. Because a large number of state, local, and tribal entities (including public hospitals, schools, universities, insurance regulators, and administrators of health and welfare benefit programs) could be affected by the bill, the total costs of the intergovernmental mandates in the bill would probably exceed the threshold established in UMRA (\$50 million in 1996, adjusted annually for inflation) during the first year of implementation. However, CBO cannot estimate whether the threshold would be exceeded in subsequent years.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains several mandates on private-sector entities that create, maintain, or receive medical records, including health plans, providers of health care, employers, researchers, and life insurers. As described in more detail above, these mandates would restrict the use and disclosure of personal health information and impose several procedural requirements on affected entities. Because of the broad scope of the legislation, it is likely that the costs of the private-sector mandates in the bill would exceed the threshold specified in UMRA for private-sector costs (\$100 million in 1996, adjusted annually for inflation), at least during the first year of implementation.

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