

HEALTH PRIVACY PROJECT

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KEY HEALTH PRIVACY ISSUES

Proposals to establish a federal health privacy law have been debated for more than 20 years, but a consensus has yet to emerge. However, most of the recent federal health privacy bills include provisions in the following areas:

Patient Access to Medical Records

When and how can individuals access, supplement, or amend their medical records? As more medical information is shared, it becomes increasingly important for consumers to see and understand the contents of their own medical records. Only about half the states give individuals a right to see and copy their medical records. Allowing patients to see their own medical records serves many purposes: it allows patients to flag incorrect information, to supplement the record, and to engage in a more informed, meaningful discussion with their provider or insurer about what information can be disclosed.

Consent

Under what circumstances, how, and how often should patient consent be obtained prior to the release of health information that identifies them individually? Developing a meaningful consent process remains a challenge. Are there some activities that do not require a patient's consent? Under what circumstances should consumers be allowed to "opt-out" - or "opt-in" - of disclosures? When and where should patient consent be obtained: at the time of application, enrollment, treatment, or periodically? Should consent be limited to the "minimum amount of information necessary" to accomplish the purpose?

Notice

When and how should individuals be notified about how their medical records are used, and when health information is disclosed to third parties? All current federal proposals require that people be given written, easy-to-understand information about how their health information will be used.

Security

What security safeguards should be required to protect medical records? All of the federal proposals require security safeguards for the use and disclosure of personal health information. Although it is critical to acknowledge that networked health information systems can pose a risk of greater magnitude of harm, technology can be used to better safeguard personal health information in electronic form than it might be protected in paper form.

Research

What protections should be in place for identifiable medical records to be used for research? Currently, federal regulations regarding privacy apply only to researchers who receive federal funds or are conducting research in anticipation of FDA review. The regulations require that prior to using identifiable health information, the research study must be approved by an Institutional Review Board (IRB) and that participants give their informed consent; however, the law allows the IRB to grant a waiver

of informed consent under some circumstances. Increasingly, research is privately funded and may not involve direct contact with patients. As a result, more research that relies primarily on the patient record or "encounter data" is falling outside the scope of these federal regulations. Almost every recent federal medical privacy bill requests a formal study of the issue to determine whether existing patient protections for research studies are adequate, and to identify what research falls outside current regulations.

Law Enforcement Access, Oversight

Under what circumstances can law enforcement officials access medical records? What safeguards or protections do individuals have when their medical records are used in criminal investigations of providers or plans, or for the purposes of health care oversight? Most of the legislative proposals to date require law enforcement officials to present a warrant, court order, or subpoena prior to obtaining medical records. No federal privacy statute now provides a broad exemption for law enforcement to get access to personal information. All other federal privacy statutes (i.e., those protecting video rental records, credit reports, and bank and

education records) protect individuals from unfettered government access to their records.

Penalties

What penalties will apply to those that violate the law? What remedies should be available to individuals whose medical information was improperly disclosed? All federal proposals establish strict penalties for those who misuse personal health information.

Preemption

Will a federal law create a "floor" above which states would be free to enact greater protections, or will a federal law enact a "ceiling" eliminating both weaker and stronger state laws? Each of the federal proposals takes a different approach to the issue of federal preemption. All of the bills that preempt state law establish different exceptions to the preemption rule related to state communicable disease, mental health and public health laws. No precedent exists in federal privacy, consumer protection and civil rights laws for preempting state law. The Health Privacy Project has compiled a comprehensive survey of state health privacy statutes that can be used to assess the impact that preemption would have on the states.