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Health, Education, Labor, and Pensions,
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April 2001

MEDICAL PRIVACY REGULATION

Questions Remain About Implementing the New Consent Requirement



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Abstract Although there is a strong consensus supporting the protection of patient confidentiality, views differ as to the best ways in practice to achieve that goal. Pressures are increasing from insurers, providers, and researchers to draw on medical records to study treatment outcomes and monitor expenditures, activities that are becoming increasingly common as medical records are computerized and large databases compiled. In recognition of these trends, the Health Insurance Portability and Accountability Act of 1996 called for the development of comprehensive privacy standards that would establish rights for patients with respect to their medical records and define the conditions for using and disclosing personally identifiable health information. 1 On December 28, 2000, the Department of Health and Human Services (HHS) issued the final regulation on privacy, and it is now under review by the Congress and the new Secretary of HHS. 2		Monitoring Agency Acronym
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Abbreviations

AHA	American Hospital Association
AMA	American Medical Association
HHS	Department of Health and Human Services
HPP	Health Privacy Project
MGMA	Medical Group Management Association



United States General Accounting Office
Washington, DC 20548

April 6, 2001

The Honorable James M. Jeffords
Chairman, Committee on Health, Education,
Labor, and Pensions
United States Senate

Dear Mr. Chairman:

Although there is a strong consensus supporting the protection of patient confidentiality, views differ as to the best ways in practice to achieve that goal. Pressures are increasing from insurers, providers, and researchers to draw on medical records to study treatment outcomes and monitor expenditures, activities that are becoming increasingly common as medical records are computerized and large databases compiled. In recognition of these trends, the Health Insurance Portability and Accountability Act of 1996 called for the development of comprehensive privacy standards that would establish rights for patients with respect to their medical records and define the conditions for using and disclosing personally identifiable health information.¹ On December 28, 2000, the Department of Health and Human Services (HHS) issued the final regulation on privacy, and it is now under review by the Congress and the new Secretary of HHS.²

One prominent point of disagreement is whether the federal government should require health providers to obtain patient consent prior to their use or disclosure of personal medical information for purposes of treatment, payment, and routine health care management activities. You asked us to examine the consent requirement in the federal privacy regulation and assess (1) how it differs from the types of consent providers currently obtain from patients and (2) its potential consequences for patients and providers. You also asked us to review how states that have passed health privacy laws addressed the patient consent issue, and we have included

¹P.L. 104-191, sec. 264, 110 Stat. 1936, 2033.

²65 Fed. Reg. 82,462 (2000). The final regulation was originally set to become effective February 26, 2001, with most entities required to comply no later than February 26, 2003. To comply with the requirements of the Congressional Review Act, however, HHS changed the effective date to April 14, 2001, with most entities required to comply no later than April 14, 2003. 66 Fed. Reg. 12,434 (2001). Subsequently, HHS published notice that it would accept comments on the regulation through March 30, 2001. 66 Fed. Reg. 12,738 (2001).

this information in appendix I. To meet your request, we contacted 18 organizations, including groups representing patients, providers, and health plans as well as a group practice, an integrated health care system, a large chain pharmacy, and a regional health plan. (See app. II.) In addition, we reviewed the regulation and spoke with HHS representatives responsible for its development. We performed our work in March 2001 in accordance with generally accepted government auditing standards.

Results in Brief

The privacy regulation's consent requirement will be more of a departure from current practice for some providers than for others. Most health care providers, with the exception of pharmacists, obtain consent from patients to release information to insurers for payment purposes. The new requirement adds pharmacists to those providers obligated to obtain written consent before they can use or disclose patient information for routine health care purposes. These purposes now include treatment and a range of health care management activities as well as payment. Supporters of the requirement believe that the process of signing a consent form provides an opportunity to inform and focus patients on their privacy rights. Others, however, are skeptical and assert that most patients will simply sign the form with little thought. In addition, provider and other organizations interviewed are concerned that the new consent requirement poses implementation difficulties. They contend that it could cause delays in filling prescriptions for patients who do not have written consents on file with their pharmacies, impede the ability of hospitals to obtain patient information prior to admission, hamper efforts to assess health care quality by precluding the use of patient records from years past, and increase administrative burdens on providers.

Background

The final medical privacy regulation requires that most providers obtain patient consent to use or disclose health information before engaging in treatment, payment, or health care operations.³ As defined in the regulation, health care operations include a variety of activities such as undertaking quality assessments and improvement initiatives, training future health care professionals, conducting medical reviews, and case

³The regulation uses the term "consent" when referring to written permission sought prior to use or disclosure of personal health information for these purposes. It uses the term "authorization" when referring to written permission required for nonroutine uses and disclosures of information, such as releases to a patient's attorney or to an employer for personnel decisions.

management and care coordination programs. The consent form must alert patients to the provider's notice of privacy practices (described in a separate document) and notify them of their right to request restrictions on the use and disclosure of their information for routine health care purposes. Providers are not required to treat patients who refuse to sign a consent form, nor are they required to agree to requested restrictions. The consent provision applies to all covered providers that have a direct treatment relationship with patients.⁴ The regulation also specifies several circumstances where such prior patient consent is not required.⁵ The privacy regulation does not require health plans to obtain written patient consent.⁶

This approach to patient consent for information disclosures differs from that in HHS' proposed privacy regulation, issued for public comment November 3, 1999. The proposed regulation would have permitted providers to use and disclose information for treatment, payment, and health care operations without written consent. At the time, HHS stated that the existing consent process had not adequately informed patients of how their medical records could be used. Comments HHS received on this provision were mixed. Some groups approved of this approach, saying it would ensure that covered entities could share information to provide effective clinical care and operate efficiently, while not creating administrative requirements that would add little to individual privacy. However, others wrote that individuals should be able to control to whom, and under what circumstances, their individually identifiable health

⁴For example, primary care physicians and surgeons have a direct treatment relationship with patients. In addition, outpatient pharmacists are generally considered to have such a relationship. They fill prescriptions written by other providers, but they furnish the prescription and advice about the prescription directly to the patient, not through another treating provider. On the other hand, radiologists and pathologists generally have indirect treatment relationships with patients because they deliver diagnostic services based on the orders of other providers and the results of those services are furnished to the patient through the direct treating provider. Consequently, for these providers, medical records could be used for management reviews of their performance without patient consent.

⁵These include (1) in emergency treatment situations, if the provider attempts to obtain such consent as soon as reasonably practicable after the delivery of treatment, (2) if the provider is required by law to treat the individual, and attempts to obtain consent but is unable to do so, and (3) if a provider attempts to obtain consent from the individual but is unable to do so because of communication barriers, and he or she determines that the individual's consent to receive treatment is clearly implied from the circumstances.

⁶Industry representatives told us that health plans often obtain patient consent. Plans may ask new enrollees to sign a form that allows access to their medical records for payment and, sometimes, health care operations.

information would be disclosed, even for routine treatment, payment, or health care operations.

Most Providers Obtain Consent to Disclose Patient Data for Insurance Payment

The extent to which the privacy regulation's consent requirement will be a departure from business as usual varies by type of provider. Under current practices, physicians and hospitals generally obtain consent to use patient data for processing insurance claims, but they obtain consent substantially less often for treatment or health care operations.⁷ Pharmacists, however, typically do not have consent procedures in place for any of the routine purposes included in the regulation. Specifically:

- Most, but not all, physicians get signed written consent to use patient data for health insurance payment. Exceptions to this practice include emergency situations and patients who choose to pay for their treatment “out of pocket” to avoid sharing sensitive information with an insurer. However, physicians do not typically seek approval to use patient data to carry out treatment or health care operations.
- Nearly all hospitals routinely obtain written consent at the time of admission, at least for release of information to insurance companies for payment purposes.⁸ A 1998 study of large hospitals found that 97 percent of patient consent forms sought release of information for payment, 50 percent addressed disclosure of records to other providers, and 45 percent requested consent for utilization review, peer review, quality assurance, or prospective review—the types of health care management activities considered health care operations in the federal privacy regulation.⁹
- Pharmacies do not routinely obtain patient consent related to treatment (i.e., before filling a prescription), payment, or health care operations. However, industry representatives told us that pharmacies conducting disease management programs (specialized efforts to ensure appropriate pharmaceutical use by patients with certain chronic conditions) typically

⁷It is also common for patients to sign consent forms before undergoing an invasive procedure. However, these consents have to do with informing the patient about possible risks and benefits of the treatment, not disclosure and use of the data.

⁸Similar to physician practices, hospital exceptions include patients who choose to “self-pay” for treatment, and emergency situations, such as when a patient arrives unconscious at the emergency room with no one to act on his or her behalf.

⁹J. F. Merz, P. Sankar, S. S. Yoo, “Hospital Consent for Disclosure of Medical Records,” *Journal of Law, Medicine and Ethics* (Fall 1998), p. 241.

seek consent to share information with physicians about the patients' condition, medical regimen, and progress.

The new consent requirement makes several important changes to current practices that have implications for patients and providers. For patients, they will be made aware that their personal health information may be used or disclosed for a broad range of purposes including health care operations. Other provisions of the privacy regulation grant patients additional protections, including the right to access their records, to request that their records be amended, to obtain a history of disclosures, and to request restrictions on how their information is used. For providers directly treating patients, they will have a legal obligation to obtain prior written consent and to use a form that meets specific content requirements.

Perceived Benefits for Patients and Implementation Concerns Among Industry Groups

Supporters of the consent requirement argue that the provision gives patients an opportunity to be actively involved in decisions about the use of their data. Yet, many groups recognize that signing a provider's consent form does not, per se, better inform patients of how their information will be used or disclosed. In addition, most provider organizations we interviewed told us that the privacy regulation's consent requirement will be a challenge to implement and may impede some health care operations.

Consent Requirement Intended to Raise Privacy Awareness

The American Medical Association (AMA), the Bazelon Center for Mental Health Law, and the Health Privacy Project (HPP) indicated that the consent process offers important benefits to patients. These groups view the process of signing a consent form as a critical tool in focusing patient attention on how personal health information is being used. They assert that only providing patients with a notice of privacy practices is not sufficient because most patients are not likely to understand its importance, much less read it. The patient advocacy groups told us that the act of signing the consent can help make patients aware of their ability to affect how their information is used. This heightened awareness, in turn, may make patients more likely to read the notice of privacy practices or to discuss privacy issues with their health care provider. HPP cited the process of signing consent as offering an "initial moment" in which patients have an opportunity to raise questions about privacy concerns and learn more about the options available to them. This opportunity may be especially valuable to patients seeking mental health and other sensitive health care services.

In contrast, many groups we interviewed question the value of the consent form for patients. For example, the Medical Group Management Association (MGMA) and the American Hospital Association (AHA) assert that the process of signing a consent form may be perfunctory, at best, and confusing, at worst. To some extent, patient advocacy groups we spoke with agree. They say that patients will be under pressure to sign the form without reading the notice, as providers can condition treatment upon obtaining consent. They contend that many patients may not find the consent process meaningful. They maintain that nevertheless it should be required for the benefit it offers patients who may be particularly interested in having a say about how their health information will be used.

Industry Representatives Anticipate Difficulties in Implementing the Consent Requirement

Health plan and provider organizations we interviewed told us that the consent requirement poses implementation difficulties for patients and providers both during the regulation's initial implementation and beyond. The extent of these challenges and their potential implications vary by type of provider. In general, these organizations do not favor written consents for routine uses of patient information, although they support the regulation's requirement to provide patients with privacy notices.

The consent requirement would require pharmacists to change their current practices. Under the regulation, a patient must sign a consent form before a pharmacist can begin filling the prescription. According to the American Pharmaceutical Association and the National Association of Chain Drug Stores, this requirement would result in delays and inconvenience for patients when they use a pharmacy for the first time.¹⁰ Also, pharmacies would not be able to use patient information currently in their systems to refill prescriptions or send out refill reminders before receiving patient consent to do so. In addition, patients who spent time in different parts of the country and were accustomed to transferring their prescriptions to out-of-state pharmacies would have to provide consent to one or more pharmacies before their prescriptions could be filled. Pharmacy and other organizations have suggested that the privacy regulation should recognize a physician-signed prescription as indicative of patient consent or that pharmacies could be considered indirect providers and thus not subject to the consent requirement.

¹⁰These organizations believe that a consent form obtained by one retailer could serve for others in a chain within the same state.

Hospital organizations also raised concern about disruption of current practice and some loss of efficiency. AHA and Allina Health System representatives stated that the consent requirement could impede the ability of hospitals to collect patient information prior to admission, thus creating administrative delays for hospitals and inconvenience for some patients. In advance of nonemergency admissions, hospitals often gather personal data needed for scheduling patient time in operating rooms, surgical staff assignments, and other hospital resources. If the regulation is interpreted to include such activities as part of treatment or health care operations, hospitals would be required to get the patient's signed consent before setting the preadmissions process in motion. Either a form would have to be mailed or faxed to the patient and sent back, or the patient would have to travel to the hospital to sign it.

Physician and hospital groups expressed concern that the requirement would hinder their ability to conduct health care management reviews using archived records. For example, AMA and AHA told us that the regulation will not permit them to use much of the patient data gathered under previous consent forms. While the regulation has a transition provision that allows providers to rely on consents acquired before the regulation takes effect, the continuing validity of those preexisting consents would be limited to the purposes specified on the consent form. In most cases, the purposes specified were either treatment or billing. This means that providers would not be able to draw on those data for other purposes, including common health care management functions, such as provider performance evaluations, outcome analyses, and other types of quality assessments.¹¹ Moreover, they said that in many cases it might not be feasible to retroactively obtain consent from former patients. Some have suggested revising the regulation to allow providers to use, without consent, all health information created prior to the regulation's effective date.

All of the organizations representing providers and health plans anticipate an additional administrative burden associated with implementing the new consent procedures, but the magnitude of the potential burden is uncertain. For example, if the use of new forms elicits more questions from patients about medical records privacy, as the provision's supporters expect will happen, providers will have to devote more staff time to

¹¹In commenting on a draft of this report, HHS took issue with this interpretation of the transition provision. See Agency Comments.

explaining consent and discussing their information policies. Similarly, health plan and provider advocates contend that focusing patients' attention on their right to request restrictions on how their information is used could result in many more patients seeking to exercise that right. This, some believe, would require increased staff time for considering, documenting, and tracking restrictions.

Concluding Observations

The privacy regulation expands the scope of the consent process to include the use and disclosure of personal health information for a wide range of purposes. This may help some patients become aware of how their medical information may be used. However, in general, provider and health plan representatives believe that the consent requirement's benefits are outweighed by its shortcomings, including delays in filling prescriptions, impediments to hospital preadmission procedures, and difficulty in using archived patient information. Regardless of the presence of the consent requirement, providers are obligated under the regulation to protect the confidentiality of patient information. Moreover, with or without the consent requirement, patients' rights established by the privacy regulation—to see and amend their records, to learn of all authorized uses of their information, and to request restrictions on disclosures—remain unchanged.

Agency Comments

HHS provided written technical comments on a draft of this report. In them, HHS remarked on the consent requirement's applicability to archived patient medical records. Agency officials explained that a consent for either treatment, payment, or health care operations acquired before the regulation's compliance date would be valid for continued use or disclosure of those data for all three of these purposes after that date. Under this interpretation, for example, prior consents to disclose patient information for insurance claims would permit uses for the full range of health care operations as well, unless specifically excluded in the consent that the patient signed. In our view, a better understanding of the implications of this provision may emerge from any revisions to the final regulation.

Referring to material in appendix I, the agency expressed concern that we overgeneralized current state consent laws, which have complex requirements and vary significantly from one to another. HHS pointed out that some state laws require written consent in some circumstances that would be considered treatment, payment, or health care operations. We recognize that state laws are complex and vary widely in the type of health

care information that is protected and the stringency of those protections. While it is difficult to generalize about state laws, we found that the statutes in the 10 states we examined were fairly consistent in not requiring written consent for the full range of uses and disclosures of patient information for treatment, payment, and health care operations.

The agency provided other technical comments that we incorporated where appropriate.

We are sending copies of this report to the Honorable Tommy G. Thompson, Secretary of HHS, and others who are interested. We will also make copies available to others on request.

If your or your staff have any questions, please call me at (312) 220-7600 or Rosamond Katz, Assistant Director, at (202) 512-7148. Other key contributors to this report were Jennifer Grover, Joel Hamilton, Eric Peterson, and Craig Winslow.

Sincerely yours,

A handwritten signature in black ink, reading "Leslie G. Aronovitz". The signature is written in a cursive, flowing style.

Leslie G. Aronovitz, Director
Health Care—Program Administration
and Integrity Issues

Appendix I: Selected State Statutes on Consent

To examine how state privacy laws address the issue of patient consent to use health information, we reviewed certain laws in 10 states (Hawaii, Maine, Maryland, Minnesota, Montana, Rhode Island, Texas, Virginia, Washington, and Wyoming).¹ We found that none of these state privacy statutes include a consent requirement as broad as that found in the privacy regulation.² Although they generally prohibit using or disclosing protected health information without the patient's permission, they include significant exceptions not present in the federal regulation. Essentially, none of the state statutes we reviewed requires consent for the full range of uses and disclosures of patient information for treatment and health care operations. The Minnesota and Wyoming statutes require consent to use patient health information for payment purposes.³

Two states recently attempted to enhance patient control over their personal health information. In 1996, Minnesota enacted a law that placed stringent consent requirements on the use of patient data for research. It stipulated that patient records created since January 1, 1997, not be used for research without the patient's written authorization. Because such authorization was not obtained at the start of treatment, researchers had to retroactively seek permission. They soon found that many patients did not respond to requests for such authorization, either to approve or to reject the use of their data. The law was amended to permit the use of records in cases where the patient had not responded to two requests for

¹These states were suggested to us by privacy law experts. The state laws reviewed were: Haw. Rev. Stat. §§ 323C-1 – 323C-55 (2000); Me. Rev. Stat. Ann. tit. 22, § 1711-C (West 2000); Md. Code Ann., Health-General §§ 4-301 – 4-307 (2000); Minn. Stat. § 144.335 (2000); Mont. Code Ann. §§ 50-16-501 – 50-16-553 (2000); R. I. Code R. § 5-37.3-1 – 5-37.3-11; Tex. Health & Safety Code Ann. §§ 241.151 – 241-156 (West 2000); Va. Code Ann. § 32.1-127.1:03 (Michie 2000); Wash. Rev. Code §§ 70.02.005 – 70.02.904 (2000); Wyo. Stat. §§ 35-2-605 – 35-2-617 (Michie 2000).

²Some state laws require additional safeguards related to the use or disclosure of certain types of health care information, such as HIV status or mental health records. However, none of the laws we examined established the type of two-tiered system of written permission involving both consent for treatment, payment, and health care operations and authorization for most other uses and disclosures. Two recent comprehensive surveys of state laws related to the protection of health care information are Lisa L. Dahm, *50-State Survey on Patient Health Care Record Confidentiality*, Health Lawyers: Expert Series (Washington, D.C.: American Health Lawyers Association, June 1999) and Joy Pritts and others, *The State of Health Privacy: An Uneven Terrain* (Washington, D.C.: Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, Aug. 1999).

³The relevant language in the Washington statute is nearly identical to that in the Wyoming law. According to an official in the Washington attorney general's office, however, consent is not required to use or disclose health information for payment purposes in Washington.

authorization mailed to the patient's last known address. At one major research institution in Minnesota, the Mayo Clinic, that change decreased the percentage of patient records that the patient consent requirement made unavailable for studies from 20.7 percent to 3.2 percent.⁴

In late 1998, Maine enacted a comprehensive law requiring specific patient authorization for many types of disclosures and uses of health information. The law took effect January 1, 1999, but was soon suspended by the state legislature in response to numerous complaints from the public. Particularly problematic was that "hospital directory" information could not be released without the patient's specific written authorization. Therefore, until routine paperwork was completed, hospitals could not disclose patients' room or telephone numbers when friends, family, or clergy tried to contact or visit them. Based on this experience, the Maine legislature substantially modified the law, which became effective on February 1, 2000. Among other changes, the revised law allows a hospital to list current patients in a publicly available directory unless a patient specifically requests to be excluded.⁵

⁴See S. J. Jacobsen and others, "Potential Effect of Authorization Bias on Medical Record Research," *Mayo Clinic Proceedings*, Vol. 74, No. 3 (April 1999), p. 333. Mayo Clinic researchers remain concerned that variations in the rate of refusal among different patient groups, for example, young versus old, may tend to skew the results obtained from these data.

⁵The federal privacy regulation permits hospital directory information to be disclosed as long as the patient has been given an opportunity to object to its disclosure and has not done so.

**Appendix I: Selected State Statutes on
Consent**

Appendix II: Organizations Interviewed

We included the following organizations in our review:

Allina Health System
American Association of Health Plans
American Cancer Society
American Hospital Association
American Medical Association
American Pharmaceutical Association
AvMed Health Plan
Bazelon Center for Mental Health Law
Beaver Medical Group
Blue Cross and Blue Shield Association
CVS Pharmacy, Inc.
Health Care Compliance Association
Healthcare Leadership Council
Health Privacy Project
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Medical Group Management Association
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