

Law and the Public's Health

LEGAL ISSUES IN HEALTH INFORMATION: IMPLICATIONS FOR PUBLIC HEALTH PRACTICE AND POLICY

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In this issue, *Law and the Public's Health* examines the legal issues that arise in the context of health information. The effort to secure more comprehensive and better health information about patient care has intensified in recent years, as a result of concerns over health care quality and the effectiveness of health care for an increasingly diverse patient population.¹ Expert consensus regarding the value of incorporating personal health information into the health care process has reached the point at which it is possible to see the day when the routine collection and analysis of such information becomes a basic element of the professional standard of care for all patients. Indeed, in December 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published draft standards that would, if adopted, require managed care organizations and integrated delivery systems to collect patient information on race, ethnicity, and language. These draft standards follow on the heels of earlier JCAHO standards covering other accredited institutions.

The professional standard of care evolves slowly over time and in response to advances in science, information, and technology.^{2,3} When the professional standard of care is poised to take a leap of the magnitude envisioned by the information revolution in health care, it is important to understand the legal landscape in which such a transformation would occur. The law can strongly affect the course of events, and longstanding legal principles may need revisiting as part of the evolution of health care itself.

Most readers are familiar with the legal issue of health information privacy because of the enormous attention paid to the subject in recent years as a result of federal HIPAA health information privacy standards. (For an excellent discussion of HIPAA in a public health practice context, see James G. Hodge, *Health Information Privacy & Public Health*, 31 J.L. Med. & Ethics, 2003.) But the legal issues related to health information extend beyond privacy considerations. The law can affect the development of modern electronic health care information systems and the growth of Regional Health Information Networks (RHIOs), as well as the extent to which data collected for patient health care management ultimately can be aggregated, assembled, and disseminated for broader public use.

It is important to remember in considering the legal landscape for health information that although the conversion to electronic data systems is technologically complex

and raises legal issues of its own, many of the most important legal considerations now on the radar screen have long been part of the legal landscape, even when information was collected purely in paper form. Indeed, some of the legal that move to the fore in today's world (such as privacy considerations and liability for health care quality) date back hundreds of years, to the origins of the modern physician/patient relationship.

THE EVOLUTION OF HEALTH INFORMATION AND INFORMATION TECHNOLOGY

There was a time when, for much of health care practice, patient information was sparse, scattered, and not subject to organizational expectations. Exceptions could be found in highly integrated health care delivery systems such as Kaiser Permanente, but by and large, health care information and its connection to patient quality was undeveloped as an aspect of health care practice.

Two developments altered this prevailing view. The first was the Institute of Medicine's seminal study *To Err is Human*,⁴ which contained hard estimates of the numbers of avoidable patient deaths through changes in practice, including more advanced and detailed use of health information. This study helped spur the current, intense interest in health care quality improvement, which focuses heavily on the use of information to improve quality.

The second development was a growing body of literature showing significant racial, ethnic, language, and socioeconomic disparities in the processes and outcomes of health care, thereby making information about race, ethnicity, and language a critical dimension of health care quality itself. As major studies, most notably the Institute of Medicine's landmark report *Unequal Treatment*,⁵ increasingly documented a link between medical practice patterns and patient characteristics, the notion that cultural competency is basic to medical quality began to take hold in earnest.

As the focus on health information grew, interest increased exponentially in the manner in which information is collected, analyzed, and incorporated into quality improvement efforts. Furthermore, in an age of consumerism and transparency, there has been growing consensus that part of the health system's accountability to patients, consumers, and health care purchasers is publicly accessible data on performance generally, as well as performance for patients of diverse backgrounds.

Major private foundations such as the Robert Wood Johnson Foundation have made health care quality improvement and public reporting a focus of their work. Government agencies such as the Agency for Healthcare Quality Research and the Centers for Medicare and Medicaid Services (CMS) are similarly focused heavily on health information.

This evolution in interest has helped spur the development of electronic health information systems. Dozens of e-information systems currently exist in various forms, but

three distinct models are beginning to emerge. The first two models are "decentralized," meaning they do not store standardized information in a central location but instead leave data stored in various "warehouses" maintained by insurers and health care providers and suppliers. The primary purpose of these systems is claims payment. This structure minimizes the potential for the unauthorized use of personal health information, but also reduces the potential for larger aggregated studies essential to public accountability and quality research. The third model differs from the others because it is capable of storing standardized information in a central database, thus facilitating aggregation and comparisons that may be used for quality improvement. The potential for unauthorized access to detailed patient treatment information may be somewhat greater (although this problem may be addressed by maintaining the software that permits connectivity in a separate location), but the potential for aggregation and public accountability is increased.

The emergence of e-information systems allows for health information to be utilized on a population-wide scale to assess patients' health status and quality of care, discover differences in treatment and outcomes according to age, sex, race, language spoken, and economic status, as well as numerous other public health initiatives. The federal government has been a major catalyst in driving these uses of health information. The Medicare Modernization Act of 2003, for example, grants the government the authority to reduce reimbursement for each hospital failing to report annually on several quality indicators, which is essential not possible without e-information systems.⁶ More recently, the Department of Health & Human Services called for a national move to e-information in order to improve health care quality, reduce errors, prevent unnecessary treatment, and decrease unjustifiable health care variations.⁷ Even before the dramatic move by JCAHO, certain large health insurers such as Aetna had begun to collect racial and ethnic data from their practice networks.^{8,9}

LEGAL ISSUES RAISED BY THE GROWTH OF HEALTH INFORMATION AS PART OF THE STANDARD OF CARE

As can be expected with any major industrial leap, several distinct groups of legal issues arise in the context of the health information revolution. The first is the legal issues related to the development of e-information systems themselves. The second set focuses on liabilities (including, but in addition to liability for breaches of patient privacy) that providers conceivably could face.

Developing e-information systems

Developing e-information systems requires the development of new corporate business models. In some cases, these new models may entail modification of existing principles of federal and state antitrust laws, federal and state tax laws, and laws regulating fraud and abuse, in order to permit enterprises of otherwise unassociated health care providers and insurers to come together to create new information business arrangements. These arrangements also will raise important new questions regarding who owns the patient

information itself, as well as who owns the intellectual property that is created when personal data are combined with other data and reassembled into new arrangements yielding previously unknown information.

Liabilities stemming from the growing collection and use of personal patient data

Health information privacy. HIPAA privacy standards establish ground rules for the collection and use of personal health information. While HIPAA itself does not create a private right of action permitting patients to sue providers who breach these standards, some experts believe that the HIPAA standards essentially "raise the bar" for how providers should treat protected information and therefore could create new liabilities under state privacy law (HIPAA does not preempt stricter state privacy laws or extinguish causes of action for violation of state law). States are allowed to enact stricter privacy protections over and above HIPAA, and some indeed have (e.g. CA, RI, MD, MT, and WA).⁹ Most states also maintain laws paralleling the Federal Privacy Act of 1974, which establish broad and comprehensive protections of privacy.¹⁰ Additionally, the federal government maintains specific privacy rules regarding personal information regarding substance abuse,¹¹ and states have a variety of disease-specific laws aimed at protecting certain types of health information. (Concurrently of course, many states have laws mandating disclosure of certain disease information to public health agencies.)¹²

Other potential liabilities. As the expectation of culturally competent practice grows, providers could potentially become liable for adverse patient outcomes experienced by patients with certain racial or ethnic backgrounds. A key question is whether data collected to assess health care quality for certain racial or ethnic subgroups would be discoverable during a malpractice liability case. In this regard, state privilege laws become crucial. Aside from privacy, the law still comes into play in a number of areas when dealing with electronic health information.

Another form of liability could be liability for violation of federal or state fraud and abuse laws. The availability of greater amounts of health information has, in recent years, enabled the federal government to prosecute certain health care facilities for Medicare and Medicaid fraud under the Federal False Claims Act, where the information reveals care of such grossly poor quality that the mere submission of a claim for payment becomes a false claim.¹³ As more and more information on patient care becomes accessible, concerns grow that this type of prosecution could increase.

What is not a source of liability. One common concern raised over the years has been the notion that the mere collection of racial and ethnic data would violate Title VI of the 1964 Civil Rights Act, which prohibits discrimination on the basis of race and national origin by recipients of federal assistance. The HHS Office for Civil Rights (OCR) never has issued a definitive ruling on this matter, but it is clear that OCR could mandate the collection of data as part of its civil rights enforcement authority. Furthermore, the recent growth of data collection efforts by the private sector for quality improvement purposes underscores that where data are

collected for affirmative reasons of improving health care quality for minority patients and not for use in ways that foster discrimination, such collection is completely proper under longstanding Title VI standards.¹⁴

IMPLICATIONS FOR PUBLIC HEALTH POLICY & PRACTICE

It is axiomatic that the rapid transfer and sharing of health information is essential to public health practice and policy, including population-wide health care quality measurement, the ability to monitor and predict patient conditions and treatments in relation to public health threats (including bioterrorism), population-wide research into health status and the effects of health intervention, and initiatives to reduce racial and ethnic disparities in health care. It will be important for public health practitioners to be intimately involved in the debate over how much—and how quickly—the legal landscape may change in order to foster information use and access. There are obvious tradeoffs that must be carefully weighed, particularly tradeoffs having to do with shielding health providers from certain types of liability in exchange for active participation in information collection and analysis.

Much of this legal debate will happen in states, because state law is the source of law for much provider liability in the areas of patient care quality and breach of privacy. State law also determines the extent to which, and under what circumstances, health care providers will be granted privileges that shield certain information from discovery during the course of litigation. These major questions, along with the legal issues that arise in the development of e-information technology, will demand a public health voice in order to promote decision-making that benefits the public's health to the maximum extent possible while maintaining essential patient protections.

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