

Assessing Legal Implications of Using Health Data to Improve Health Care Quality and Eliminate Health Care Disparities

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Introduction

Information is — and always has been — essential to virtually all aspects of health care. Clinical treatment as well as coverage, payment, care quality, and certainly one's own personal health care decisions all depend profoundly on robust, accurate, appropriate, timely, private and secure information. Further, the ability to conduct large-scale health services research is inextricably linked to information, as is the ability to measure population health and conduct surveillance of public health risks.

Over the past decade, the desire for more and better health information has become a pressing national health policy matter. A large body of research has documented significant gaps in the quality of care most Americans receive¹, and, perhaps even worse, disparities in the quality of care some groups receive compared to others². In addition, health care is plagued by rising health care costs, perplexing system inefficiencies, and increasing numbers of Americans without health care insurance. The nation has invested massively in health care research and has reaped dramatic scientific gains from that investment. At the same time, however, the health care system has a difficult time incorporating new information quickly into clinical care³. Advances in information technology offer the potential for widely available, yet private and secure, information of unprecedented depth and quality. Many observers view these advances in information technology as invaluable tools in the effort to improve health care quality and close gaps in care.⁴

¹ McGlynn EA, Asch SM, Adams J, et al., "The quality of health care delivered to adults in the United States." *N Engl J Med* 2003; 348: 2635-45.

² Smedley BD, Stith AY and Nelson AR, eds., *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (Washington: National Academies Press, 2002).

³ Balas EA, Boren SA, Managing clinical knowledge for healthcare improvement. In: *Yearbook of medical informatics*. Bethesda, Md.: National Library of Medicine, 200: 65-70.

⁴ Frist, WH, "Health care in the 21st century." *N Engl J Med* 2005; 352: 267-272; Frist, WH, "Overcoming disparities in U.S. Health Care," *Health Affairs*, 2005, 24: 445-451.

A series of seminal reports issued by the Institute of Medicine between 1999 and 2003 moved the field of health care quality in two critical respects.⁵ First, the IOM studies underscored the potential for information technology to reduce patient error and promote health quality. Second, the IOM drew a basic link between the concepts of health care quality and health care disparities based on race, ethnicity, and other personal characteristics unrelated to the need for, or clinical appropriateness of, health care. In these reports, the IOM called for a national investment in patient and population-based health information systems as a principal means of more effectively addressing issues of health care quality and health care disparities.

The IOM's emphasis on technology advances to improve health care quality is consistent with the evolution of medical care generally. Indeed, the use of technology innovation to identify and address major societal problems is as old as organized society itself. Equally as old, of course, is resistance to change. This resistance often increases exponentially when the short term costs are potentially enormous, and the risks associated with change, not inconsiderable, and professional customs and traditions, are heavily entrenched. Indeed, stakeholder interests in avoiding this complex transformation in health care to an information age can easily obscure the goal: more equitable and higher quality of health care for the nation. Indeed, as information becomes more available — and thus more central to our concept of health care quality — the liabilities associated with failing to properly use health information can rapidly eclipse those that arise in any innovation-driven undertaking.

In spite of the potential for health information to improve health care quality and reduce gaps, the American health care sector invests significantly less, indeed almost fifty percent less, in information technologies than do other sectors of the economy.⁶ The question is why. In the face of slowed progress, it is increasingly apparent that the legal environment for health information — both the actual environment and how it is perceived — plays a major role in the adaptation of health care to the promises and potential of electronic health information.

The law itself can both advance change and impede it. This tendency on the part of law to slow change is particularly evident in health care, where the nation's legal system is almost as complex as health care itself. This legal complexity is a function of policymakers' efforts to balance a range of competing interests: the rights of patients and their expectations of privacy; the autonomy and authority of health professionals; a market-based economy dominated by the buying and selling of health care; and the delicate balance of federal and state powers over health care quality, financing and accountability. No aspect of health care offers a better example of the challenges inherent in balancing these interests than the collection, management, disclosure and reporting of health information. For decades, questions related to personal health

⁵ Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001). Washington, DC, National Academy Press; Institute of Medicine. 1999. *To Err is Human* (National Academy Press, Washington D.C.).

⁶ Bates DW, "The quality case for information technology in healthcare," *BMC Med Inform Decis Mak* 2002: 2-7.

information have roiled legislatures and courts alike. Now that health care is entering an age of automated mass collection, production, and application of information, these longstanding legal issues are reemerging in new, and in some cases, amplified form.

Reforming laws to accommodate major social change is further complicated by the nature of law itself. Law can best be understood as a collection of formal and collective statements regarding a society's basic values and beliefs.⁷ When multiple and competing social, economic, and political forces are at work, the result can be a series of contentious and unsettling debates regarding which interests will be paramount in a changing legal system. As a result, it is inevitable that significant changes will produce significant legal battles, as society adjusts the legal system to encourage and support desirable advances.

The clash between systems change and the law is a longstanding and familiar theme in health care. Indeed, there exists perhaps no stronger example than the dramatic expansion of medical malpractice liability for substandard medical care. This liability expansion flowed in large part from the health care technology revolution that took place over the first half of the 20th century.⁸ The backlash against this expansion continues today, as the judicial and legislative branches of government grapple with limits both on medical liability, as well as on the right of patients to pursue individual recovery for alleged acts of medical negligence.

With the generation, production, and transmission of vast quantities of patient health information over far-flung systems designed to buy and sell health care, the legal challenges fall into two basic categories. The first concerns the design, implementation and operation of the technology needed to support the information technology enterprise. The second has to do with the enormous range of potential legal issues that arise simply because of the burgeoning quantity and availability of personal health information. Only a fraction of these potential issues relates directly to privacy and security; indeed, of greater significance may be the potential for legal accountability when a very large, very detailed body of health information becomes accessible to scrutiny. Concerns over the legal accountability that may flow from greater information may become even more acute if there are concerns about the legalities or potential liabilities of collecting the information in the first place.

The greatest challenge probably lies with the attempt to balance the interests of those who favor broad legal access to information against those who want access curbed. The fundamental irony, moreover, is that the very same forces that in certain contexts want broad access – consumers, patients, health care companies, insurers and health plan administrators, and governments – also want to curb access in other situations in which their interests are not, in their view, advanced by disclosure and information sharing. Understanding and addressing the range of emerging legal issues as health care moves

⁷ Lawrence M. Friedman. 2002. *Law in America* (Modern Library ed., NY).

⁸ Rosenbaum, S., "The Impact of United States Law on Medicine as a Profession," *JAMA* 2003: Vol. 289 No. 12.

into an information age is essential. At the same time, in order to resolve these issues society must be prepared to balance numerous, potentially competing interests.

Early Findings from The Robert Wood Johnson Foundation Project to Assess the Legal Implications of Using Health Data to Improve Care Quality and Eliminate Health Care Disparities

In 2004 the Robert Wood Johnson Foundation awarded a grant to the George Washington University School of Public Health and Health Services to undertake an initial exploration of the legal environment for health information. The grant had a two-fold purpose: (1) to identify the range of legal issues arising from expanded use of data to address quality and disparity matters; and (2) to formulate legal interventions that might lessen or remove these barriers. This summary of the project's initial findings, undertaken through research and a lengthy series of consultations with experts, is also available in longer form.⁹

Legal Issues in Health Information

For well over a hundred years,¹⁰ personal health information has raised legal questions. This longstanding link between health information and law has been particularly visible in a privacy context. The arrival of electronic information technology has inevitably triggered even more intense debate given the sheer volume and extent of available information.¹¹ Interestingly, stakeholders raise these concerns even though electronic systems may, in fact, increase information safety and security.

The legal issues linked to health information extend well beyond questions about unlawful information access and use. The GW project, in consultation with health information and legal experts, identified a series of major issue categories that arise from the use of health information. These categories, identified below, are understood by experts to exist regardless of whether health information is stored, disclosed or transmitted in electronic form, even though the volume and speed of information as a result of technology intensifies the importance of legal resolution:

1. Under what circumstances is it lawful to collect, store, use, and disclose information about the racial and ethnic characteristics of health plan members and health care patients?

⁹ The full analysis can be found at: Rosenbaum, S. et al., "Charting the Legal Environment of Health Information," The Robert Wood Johnson Foundation, May 2005.

¹⁰ For an extremely helpful article tracing the history of privacy law in numerous contexts, see Daniel Solove, "The Origins and Growth of Information Privacy Law," 748 PLI/PAT 29 (June 2003).

¹¹ See Paul M. Schwartz, *Privacy and the Economics of Personal Health Care Information*, 76 Texas L. Rev. 1 (1997); Paul T. Kostyack, "The Emergence of the Health Care Information Trust," 12 *Health Matrix* 393 (Summer 2002); Daniel Solove, *Access and Aggregation, Public Records, Privacy, and the Constitution*, 86 Minn. L. Rev. 1137, 1140 (2002); Daniel Solove, "The Origins and Growth of Information Privacy Law," 748 PLI/PAT 29 (June 2003).

2. Who owns health information, the consumer, provider, clinic or hospital? When must the owner of the health information provide access to others?
3. When is it proper to disclose patient information to third parties, particularly in the case of sensitive information such as psychiatric treatment notes?
4. Under what circumstances can or should the government compel the collection and reporting of personal health information?
5. Under what circumstances should health insurers and payers have the power to compel the collection and disclosure of health information as a condition of payment or performance measurement?
6. Should liability exist when payers and providers fail to use information to improve quality or reduce disparities, and under what circumstances should private litigants have legal access to data?
7. Should government have access to stored health information for law enforcement purposes, ranging from criminal prosecution under state and federal law to enforcement of civil rights laws barring discrimination?
8. Under what circumstances can health information be used for biomedical, behavioral, and health services research, and what types of conflict of interest notices must health care systems provide when personal information is to be used in research?
9. The project also identified a ninth category of legal questions that arises as a result of the health information industry itself: how should the law change to both encourage and accommodate the growth and rapid diffusion of new market technology and what conditions should be placed on this growth and diffusion?

The Factual Context in Which Legal Issues in Health Information are Considered

Many of the legal questions raised by health information and health information technology will depend, for their answer, on the context of the analysis. Where the information pertains to improving quality and reducing disparities, actions otherwise considered unlawful might be tolerated, indeed, encouraged. For example, the application of laws that prohibit certain types of information sharing as a form of anti-competitive conduct may lead to one result where the information in question involves a consumer product such as television sets. On the other hand, society may encourage cooperation and collaboration among health care competitors to improve the quality of care.

Moreover, where the purpose of the information sharing is to understand and improve health care quality for diverse populations, and safeguards are in place to avoid

improper uses of data, practices that could be viewed with enormous suspicion become desirable. For example, efforts to identify the race of health plan members or hospital patients could be thought of as a form of “racial profiling,” with a purpose of denying or limiting health care. However, health care providers arguably should collect the very same data and use it in order to reduce disparities and improve quality for all. In the latter context, data collection becomes a way to achieve, rather than undermine, the overarching social goal of population-wide fairness.

Highlighting Specific Issues

A number of issues identified by experts as meriting legal action have to do with balancing individual privacy considerations against the accessibility of health information. Others relate to the need to delineate both the required and permissible purposes for which vast new amounts of health information can be collected, stored, transmitted, used, and disclosed.

Our discussions with legal experts suggest that many of these legal issues may lend themselves to partial or full resolution through agency action and without the need for new legislation. One very clear-cut example pertains to the collection of racial and ethnic demographic data. Federal and most state law permit the collection of this data. A relatively simple resolution step, then, would be straightforward clarification from federal and state civil rights authorities that this collection is desirable and, further, the simple collection of the data could, in fact, be strong evidence *against* allegations of discrimination. Other examples of legal issues that, according to experts, may lend themselves to agency action can be found in a number of other areas, including: tax law, laws designed to curb anti-competitive conduct and health care fraud, laws pertaining to property ownership and intellectual property ownership, privacy law, civil rights laws generally, and laws whose purpose is to protect certain forms of information communication as privileged and exempt from discovery in liability actions.¹²

To be sure, certain legal matters will necessitate changes in statute. Experts also identified a few fundamental questions of unresolved Constitutional law. At the same time, our consultations underscored that much can be done to broaden the use of health information to improve quality and reduce disparities by simply clarifying areas of flexibility and permissibility under current law.

Legal issues related to health information privacy and security

Constitutional considerations: The Constitution itself does not expressly provide for a right to informational privacy. In the case of *Whalen v. Roe*,¹³ however, the United States Supreme Court recognized a limited Constitutional right to privacy with respect to information held in governmental data bases. Attempts to apply *Whalen* to health

¹² For example, the legality of the collection of race and ethnicity data for permissible purposes under federal civil rights law has been clarified. 42 U.S.C.A. §2000e et. seq. (2004).

¹³ See *Whalen v. Roe*, 429 U.S. 589 (1977).

information privacy more generally have been inconsistent at best.¹⁴ Just how far the Constitution protects health information privacy remains unresolved. Important questions remain: what type and level of state involvement is necessary to trigger a potential Constitutional issue? Do different types of health information systems affect the answer to the question? Will the sensitivity of the data affect the answer?

State common law: State common law principles typically impose a duty of confidentiality and non-disclosure on health care professionals. However, this duty of confidentiality and non-disclosure is predicated on a formal relationship between a health professional and a patient. Much of the data transmitted in the modern health care system is based only in part on a formal professional relationship. How to balance the need for confidentiality and non-disclosure against the reality of a layered health system that needs to transmit information remains a key area for resolution. Are aggregated and de-identified data still confidential? Do formal disclosure incentives overcome common law liabilities, just as compulsory reporting laws might?

Federal privacy laws. The “Privacy Rule” promulgated under the 1997 Health Insurance Portability and Accountability Act (HIPAA) regulates uses and disclosures of protected health information (PHI) by “covered entities” (health plans, health care clearinghouses, and certain health care providers).¹⁵ The Privacy Rule regulates the use and disclosure of personal health information, as well as the types of disclosures that remain permissible because they represent aggregated and de-identified information. HIPAA’s security rule also establishes safeguards for the storage and transmission of data.

Questions in the HIPAA arena cover both information privacy and security. These questions also involve the extent to which information systems that “pass” the federal HIPAA test may, nonetheless, run into difficulties under more stringent, coexisting state laws. To what extent are the types of individual and de-identified and aggregated data transmissions that take place within modern health information systems consistent with HIPAA standards? Under what circumstances must the information industry be concerned not only with federal law but also with more stringent state law?

The health information enterprise must also examine other federal privacy laws, such as The Privacy Act of 1974 (regulating disclosure of individual health information maintained in federal government records), and The Gramm-Leach-Bliley Financial Services Modernization Act of 1999 (establishing information privacy protections for financial institutions (defined to include health insurers)). Further, special federal laws apply to the disclosure of information regarding behavioral health conditions.

¹⁴ Paul M. Schwartz, *The Protection of Privacy in Health Care Reform*, 48 Vand. L. Rev. 295, 317 (1995) (citing *Walls v. City of Petersburg*, 895 F.2d 188 (4th Cir. 1990) (applying a non-disclosure interest to a right of privacy); *but see Gutierrez v. Lynch*, 826 F.2d 1534, 1539 (6th Cir. 1987) (“legitimate requests for medical information do not constitute an invasion of the right to privacy”)).

¹⁵ 45 C.F.R. §§ 160-164.

State statutes. A patchwork of state laws regulating health information can also implicate emerging health information systems. In some cases, state laws are comprehensive and apply generally to system participants who collect, acquire, use, or disclose information within the state. Other states maintain laws specific to certain diseases or populations such as persons with HIV, sexual abuse, sexually transmitted diseases, public health information, and genetics. Resolving extensive interstate variation in information protection laws represents one of the most complex legal activities associated with the rapid expansion of health information. This resolution will depend on greater consensus regarding common standards.

Legal issues related to health system accountability and formation of the information industry

Many of the legal questions that arise relate to the formation of the information industry. Others, including some of the most difficult-to-resolve issues, involve complex balancing questions. Who should have access to certain types of information? Can health care providers become liable simply for the mere collection of certain information regardless of its use? Should industry members enjoy protections against certain types of liability for conduct that may become more evident as the volume of information expands? In other words, should the law recognize certain privileges, “safety zones,” and “safe harbors,” in exchange for the creation, collection, sharing, and use of certain valued information, and if so, what conditions should be placed on sanctioned activities? Finally, are there extreme cases in which the government should compel, rather than merely incentivize and encourage, the creation and production of certain information?

Health care fraud and abuse. Both federal and state governments, as well as private insurers alike use health care information to detect fraudulent or abusive conduct by health care providers. Even care of grossly substandard quality can be considered a “false claim” and thus an act of fraud under current law. Could care that demonstrably provides disparate outcomes to different racial and ethnic groups likewise constitute an act of fraud? Should expanded information systems be expected to provide expanded information on possible misconduct? Should “safe harbors” be developed to protect the health care industry against liability under certain circumstances, such as maintaining an active self-policing program, and if so, what would such safe harbors look like?

Other laws designed to prevent fraud prohibit financial conflicts of interest that can arise when physicians and health professionals enter into potentially lucrative arrangements with other health care entities. Should we consider shared investment in health information systems, and donation of hardware and software to physician practices and health care corporations, an exempt activity, and if so, under what circumstances? The Medicare Modernization Act of 2003 provides for exceptions to federal fraud statutes in order to facilitate electronic prescribing, and the federal government is currently engaged in new rules designed to create broad exceptions for the building of “community-wide health information systems.” Because of rapidly changing and

emerging technology, government will need to evaluate continuously the legal sufficiency of these efforts and the ongoing applicability of these exceptions to state law.

Antitrust considerations. Antitrust laws exist to promote competition by averting anti-competitive conduct that impedes the operation of an open and fair market. Health care is subject to antitrust law, but the law is frequently ambiguous in the health care arena. Although the Department of Justice, which enforces federal antitrust law, has issued opinions that seemingly encourage information sharing, the rulings to date are viewed as incomplete by a number of experts. Many question whether contractual and information sharing arrangements now coming into operation will be considered lawful. Furthermore, states maintain their own antitrust laws. Contractual information exchange and sharing arrangements that appear to pass muster in one state could potentially fail in another. As with state privacy laws, the challenge of state law variation suggests that we develop common approaches to the state regulation of information systems.

Tax law. As with other areas of law, both the federal government and state governments maintain intricate tax laws. In health information systems, the tax implications of both the system and the shared information are tremendous. These systems include numerous participants, many of whom may be tax-exempt. Tax law prohibits tax-exempt organizations from providing financial or other benefits to private individuals and entities that are not themselves non-profit in nature. This prohibition against “private inurement,” as the term is known, is rigorously enforced and the implications for shared information sharing are enormous.

Complex tax questions for nonprofit entities also arise in the case of “unrelated business income.” Unrelated business income includes income generated by a tax-exempt organization from a business activity that is not substantially related to the undertaking that led to the creation of the tax-exempt organization. The tax liabilities that can flow from unrelated business income can have a chilling effect on the willingness of tax-exempt entities to undertake certain activities. This potential chilling effect should prompt us to find ways to classify enterprises in order to encourage rather than undermine the production of robust health information.

Civil liability under health care quality and civil rights laws. A host of federal and state laws create potential civil liability by health care providers against individuals and the government. Remedies may include money damages in situations in which the law permits suits by private individuals. Remedies for breach of civil liability statutes also can include fines, penalties and orders to cease prohibited practices and take steps to come into compliance with applicable legal requirements. The prime example of civil liability laws that carry with them the potential for individual damages is, of course, state medical malpractice law. Under certain circumstances, federal civil rights laws create potential liability for both unintentional and intentional discrimination against patients by health care providers; a 2000 United States Supreme Court effectively has outlawed private lawsuits brought by racial and ethnic minority patients for unintentional civil rights violations.¹⁶

¹⁶ See *Alexander v. Sandoval*, 532 U.S. 275 (2001).

In a civil action brought either by an injured person or the government, a key question is the extent to which a health care provider must disclose information as part of the legal process. Numerous state and federal laws create shields (known as privilege laws) against the disclosure of information in certain types of litigation situations. A critical issue is whether, and to what degree, privilege statutes should cover information maintained in expanded information systems. An even more basic question is whether health care providers and institutions should be required to generate and divulge large amounts of information related to health care quality or treatment of racial and ethnic minority patients, as well as other subgroups of patients protected by federal and state non-discrimination laws (e.g., persons with physical or mental disabilities protected by the Americans with Disabilities Act).

Confusion over the meaning of civil rights laws and the absence of clear guidance from the federal government has led some observers even to question whether the mere act of seeking information on the race or ethnicity of a member or patient could be a basis for civil liability under U.S. civil rights law. This assertion appears to contravene both the terms of federal civil rights laws allowing the government to collect racial data to ensure compliance, as well as other laws. For example, the State Children's Health Insurance Program (SCHIP) provides for the quarterly government reporting of racial and ethnic data related to the use of health care services. At the same time, the absence of clarifying and encouraging statements from government or perhaps standards for the collection of racial and ethnic demographic data are substantial obstacles to the expansion of information dependent efforts to improve quality and reduce disparities.

Beyond medical malpractice liability or liability for violation of civil rights laws, the production of health information raises other types of liability questions. For example, could information on poor quality care or racial and ethnic disparities generated by a health care system form the legal basis for a defamation action? How will questions of information ownership be resolved? Will courts honor the terms of written contracts developed to resolve disputes having to do with information and data ownership, intellectual property rights, confidentiality of health data, the use of trade names, system security, medical malpractice liability stemming from data errors, and in the data, and data standardization? In addition to intellectual property notions regarding ownership of the information system, certain personal property rights also exist in the data itself. Likewise, personal property rights involving individual medical records are a longstanding area of contention and will continue to attract analysis and debate in an information age.

Liability also may spring from perceived violation of state licensure statutes on the part of health professionals whose practice, as a result of electronically shared information, crosses state lines. Because state licensure questions tend to turn on where the patient is located, physicians who expand their practice to interstate arrangements through the use of modern information systems may find themselves accountable under numerous state laws.

Questions of intellectual and personal property. Experts agree that we should consider ownership of health information and health information systems as distinct legal concepts. Health information data may carry personal property rights, with numerous stakeholders making cognizable claims to ownership. The rights to a health information system involve the ascertainment of intellectual property.

Both types of property rights - personal and intellectual - are immensely valuable. Modern health information systems elevate issues of ownership. For instance, business investors seek to own the personal property or intellectual property associated with the systems and to generate profits through licensure or use fees. Federal and state laws attempt to protect the rights and income that arise from proprietary interests. These protections take many forms, such as reservations of rights through copyright, trademark, licensing, franchising, and trade secrets. Under these laws, the use of property may be conditioned on compliance with ownership laws, and ownership laws in turn may depend on the granting of certain rights by the owner. Experts agree that we will likely need to resolve the questions of data ownership and use.

System governance. An issue closely related to the personal and intellectual property questions is how the data sharing arrangement will be governed. Although typically governed by formal or informal agreements or contracts, governance issues can raise state and federal legal questions as well. Is a separate legal entity necessary to accomplish the data sharing functions, and if so, what corporate form should the entity take? Other issues might arise regarding the ability of corporations and other legal entities to enter into contracts, the ability of organizations of health professionals to participate in data sharing arrangements, and the additional obligations incurred by a corporate enterprise if public funds are involved in its support. Who decides which individuals and entities may participate in the electronic data sharing system and what are the criteria for participation? Who decides if the conditions for participation have been violated? What sanctions exist if agreed-upon protocols for use are violated? Resolution of governance issues can be very difficult, especially if the participants in a data sharing arrangement span more than one state.

Implications

As the health care system increases its reliance on better and wider access to more accurate and timely health information, policy makers will continue to grapple with legal and other barriers. The creation and diffusion of health information technology, as well as the growth of a vibrant information-driven health care system are essential components of quality improvement and the reduction of health care disparities. Legal considerations are, however, a common impediment to change. As in countless other occasions, the task of lowering these legal barriers for quality improvement is a familiar one. For both good reasons and otherwise, the law frequently slows the pace of change. Furthermore, because the points of interaction between law and health care are so complex and the range of often-countervailing interests so powerful, finding pathways to resolution can be a significant challenge.

The list of legal barriers and potential legal barriers can seem daunting. Nonetheless, the fact that the road to legal resolution is a difficult one should not be a deterrent. Law is a creation of society, and as social norms and expectations shift, so does the law. The strength of the link between health information and improved health care quality for all Americans can hardly be over-emphasized. As with past technological advances in the field of health care, we expect that the social imperative for progress ultimately will lead to the resolution of legal barriers to change.

Our work to date suggests that several key legal interventions might speed this resolution. First, government agencies might carefully identify those legal issues that lend themselves to relatively rapid agency clarification. In these situations, governmental agencies could consider not only clarifying the range of information collection conduct that is lawful but could actually encourage the collection and reporting of information by treating such active efforts to understand and act on health information as evidence of legal compliance.

We believe that the collection of data related to race and ethnicity is just such an issue. Agency clarification and incentivization of active information collection efforts for the purpose of quality improvement would be a major step forward. There is precedent for this type of affirmative effort to incentivize desired conduct in the area of health care for members of racial and ethnic minority groups. The HHS Office for Civil Rights has taken precisely this approach in its Limited English Proficiency guidelines, which seek to foster more accessible services by outlining positive approaches to LEP services and by treating health care providers that adopt one or more of these approaches as compliant with civil rights requirements under Title VI of the 1964 Civil Rights Act.

This incentivization approach effectively depends on affirmative efforts by the private sector rather than active regulatory oversight by public agencies. This LEP approach effectively creates a “safe harbor” against legal liability. In other words, the Office of Civil Rights created a “safe harbor” against legal liability by articulating standards of conduct that, if followed, will be deemed to be evidence of compliance. This kind of “safe harbor” has long been used as a tool for promoting voluntary compliance with complex laws in the areas of health care fraud and antitrust law (in the field of antitrust for instance, safe harbors are referred to as “safety zones”). Given the use of this “safe harbor” concept to promote the goal of language access, the same strategy could be employed to promote active self examination of health care quality data by race and ethnicity.

A second step, less simple but doable, would be the joint issuance of comprehensive standards across a series of federal agencies, in order to clarify the ways in which the emerging electronic information enterprise can proceed without running afoul of existing health privacy, tax, antitrust, and fraud laws. On numerous occasions in the past, federal government agencies have worked closely to jointly develop common standards covering a range of federal undertakings. We find examples of coordinated federal activities to further health care activities in uniform federal standards governing human subject research, health care information privacy, and civil rights compliance.

A third step is, of course, legislation when warranted. The emerging political and policy consensus around the importance of comprehensive, reliable, widely available, and secure health information may well make the legislative process relatively easier to maneuver.

Finally, and in some ways the most complex, we will look to joint efforts on behalf of state and federal policy makers, acting within their individual spheres of legal authority, to devise common approaches to complex problems. As with other important technologies, health information knows no jurisdictional boundaries, and yet its ability to gain rapid diffusion will be significantly affected by conflicting legal standards across a range of topical areas. Common approaches to these cross-jurisdictional issues could be enormously helpful.

In the end, the relative speed with which society can lower legal barriers to health information for quality improvement will depend on the identification of necessary reforms, and the development of practical approaches that promise to address problems while carefully balancing competing interests. Given what is at stake, namely the quality and equity of American health care, one would hope we, as a society, can summon the will and the wherewithal to seize the potentially immense opportunities these new technologies afford.