

HIT News

Emerging and Secondary Uses of Health Information Affinity Group Spotlight

Emerging and Secondary Uses of Health Information: An Overview of Uses and Legal Issues

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I. Introduction

Beyond “treatment, payment and operations,” health information increasingly is being created, distributed, and used in many new ways. Some of these uses of health information have been around for some time and now are becoming more widespread, such as use in quality and outcomes measurement and clinical research. Others have emerged only recently, such as healthcare peer-to-peer networking and the use of personal health records. This article identifies a number of these “emerging and secondary uses” of health information as well as some of the potential legal issues associated with them.

This article does not attempt to identify every emerging and secondary use of health information. Instead, it focuses on some of the more prevalent uses and also examines a number of key legal issues associated with these uses. Another taxonomy of emerging and secondary uses that is worth consulting is “Secondary Uses and Re-uses of Healthcare Data: Taxonomy for Policy Formulation and Planning,” published by the American Medical Informatics Association.¹



Table of Contents

Emerging and Secondary Uses of Health Information: An Overview of Uses and Legal Issues
Daniel Orenstein, Esq., Stephen Bernstein, Esq., and Linda Ross, Esq......1

Editor’s Corner
Rebecca Williams, RN, JD.....11

The CMS Value-Based Purchasing Transformation: Starting on the Edges and Moving In
Gerald Tracy JD, MPH.....12

Chair’s Corner
Edward Shay, Esq.19

Staying Safe in the Internet’s Wild Wild West
Patricia King, Esq......20



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—from a declaration of the American Bar Association



Many of the legal issues are familiar, such as compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security standards, but they may in some cases present unsettled concerns or require novel applications. Others, such as permissible uses of consumer-generated health content under private website terms and conditions of use, are new legal concerns that typically do not arise in a traditional healthcare context. This article does not attempt to draw conclusions on these issues; rather, it seeks to raise them for awareness and further exploration by members of the Health Information and Technology (HIT) Practice Group.

II. Healthcare Social Networking

A. Description of Use

Traffic on social networking websites where users can share information on specific medical conditions, such as TauMed.com, WegoHealth.com, Healingwell.com, and PatientsLikeMe.com, has increased significantly. These websites use forums, chat rooms, newsletters, user queries, and other methods of information exchange to facilitate sharing of experiences, advice, support, and knowledge on various health conditions. Peer-to-peer interaction,

rather than expert opinions and guidance, are the focus of these online websites.

What is unique about these social networking sites is that the information shared is primarily user-created (i.e., patient-created) content and often is individually identifiable. Typically, no covered entity is involved in the cycle of use, creation, and disclosure of the health information. The website host usually is not a covered entity, and the users offer the content on their own without a provider, payor, or other third party acting as an intermediary. Ultimately, research organizations, payors, providers, and others might be end users of data generated by the websites.

B. Legal Issues

When individual users share information about a health condition, personal identifying information usually is required. This means that the information provided is personally identifiable health information; however, it might not be protected health information (PHI) as defined under the HIPAA privacy standards (the Privacy Rule) because it is not “created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse.”² The use and disclosure of this health information is subject to the terms and conditions of use agreed upon between the user and the host of the social networking website. In some cases, these terms and conditions simply promise standard confidentiality protections. In others, a good deal of thought has gone into the terms and conditions of use, including the right to disclose aggregated information to end users. In other cases, if the health information includes information obtained from or linked to a medical record, there may be third party end users, such as payors or providers, raising the issue of whether the information is PHI subject to the Privacy Rule.

Another issue to consider is whether certain uses contemplated by the website host are permitted by the terms and conditions of use, for instance, using discussions or demographic information posted on the site for marketing or to provide data on the perceived outcomes of a particular therapy. Even if certain uses are permitted by the website terms and conditions of use, there may be state laws that prohibit certain uses and disclosures of the health information. Website hosts walk a fine line when attempting to offer functionality that supports the exchange of medical information, medical opinions, and judgments, which activities could be construed as offering clinical advice. Usually, the terms and conditions of use for the sites typically provide that the information found on the site is for informational or educational purposes only, is not medical diagnosis or treatment advice, and should not substitute for the advice of a medical professional.

Another issue that promises to be contentious is the ownership of the health data on the site. Although the terms of use might grant various rights to the site host to use and disclose information submitted to the site, there may be competing claims on the ownership of the information. For example, if the terms and conditions

of use grant ownership to the site host, those terms may be at odds with a state law that gives a patient ownership of his or her health information.

III. Personal Health Records

A. Description of Use

While definitions of personal health records (PHRs) vary, PHRs essentially offer a means by which individuals can store and access some or all of their health information for their own use and health management. A PHR can be in any form; however, in recent years, the development and availability of electronic PHRs has expanded rapidly. These offer an electronic means, ideally in a confidential and secure environment, by which individuals can access, maintain, manage, and share their health information, including personal information that can be entered into the record by the individual and/or by physicians, labs, and other healthcare providers or organizations.

Like electronic health records, PHRs are touted for their potential to improve healthcare, reduce costs, and confer on individuals a means by which they can better coordinate their own care. Employers, hospitals, and health plans are among those offering PHRs. PHRs also have become increasingly available to consumers over the Internet by companies such as WebMD, Google, Microsoft, and other consumer-focused companies.

PHRs vary in sophistication from a simple repository of information to an integrated tool enabling the individual to manage a medical condition. The notion of establishing a networked environment enabling individuals to establish secure connections with multiple entities that maintain PHI about them or their families has been endorsed by the Markle Foundation in its publication, "Connecting Americans to Their Healthcare: A Common Framework for Networked Personal Health Information,"³ as beneficial not only to individuals but to healthcare entities as well. Such a networked environment potentially would enable a consumer to download copies of his or her medical history, review and update a medication history and allergies list, check immunization records, and review post-operative instructions, among other functions. Not surprisingly, vendors have established various programs providing interfaces between electronic health records (EHRs) and PHRs enabling information recorded in the EHR to flow through to the PHR. The potential use of PHRs on a more interactive basis by others has drawn attention in the wake of disasters such as Hurricane Katrina due to the need to enable patients to access their health information during a crisis.

B. Legal Issues

The principal legal concerns about PHRs are patient privacy, security, and integrity of the information stored or made accessible by the PHR. While HIPAA offers some protection, those protections can be viewed as limited and even inadequate because



many secondary users of PHI simply are not subject to HIPAA. Likewise, state privacy laws may not address the evolving uses of PHI. The lack of adequate privacy and security creates concerns that PHRs may be subject to security breaches and unauthorized acquisition of PHI stored on them.

Among other legal issues to consider are:

1. Who may appropriately own or control access to and use of, information contained in a PHR and under what circumstances? How should access to the PHR be managed and who decides, for example, what type of user authentication will be required to access a PHR? The answers to these and other concerns may vary based on a number of factors, such as whether the source of the information in the PHR is the individual or a provider, or both, and whether the PHR is provided by an employer, a health plan, or is created by the patient from an Internet site.
2. Under what circumstances will an individual be deemed to have authorized or consented to access or use of information housed in a PHR?
3. How can the accuracy and reliability of the information in a PHR be protected? Accuracy can be of concern depending on how the information included in a PHR is created and updated. Inaccurate and stale information may give rise to professional liability claims. The potential for such claims are of natural concern to physicians and other healthcare providers. What is their duty to provide, transfer, or update information into a patient's PHR or to rely on information included in a patient PHR?

Appropriate terms and conditions of use should be established to address these and other issues. Although guidelines for best practices for the use of PHRs are developing, the lack of widely adopted uniform standards and policies for such use makes it difficult, at this time, to point to an industry standard by which such use should be judged.



IV. Consumer-Directed Financial Management Websites

A. Description of Use

Consumer-directed healthcare typically refers to programs, plans, and efforts by employers, payors, and other purchasers of healthcare to increase involvement of consumers in making healthcare decisions and choices. These “hands-on” initiatives are attracting attention as a means of controlling healthcare costs and enhancing quality by giving consumers greater financial control and decision-making authority over their healthcare. Consumer-directed healthcare initiatives commonly have some type of a health fund or savings account (such as a health reimbursement account, medical savings account, health savings account, or flexible spending account), a high deductible and co-payments for medical coverage (other than for preventive care), and online tools to facilitate smart healthcare decision-making by consumers. Typically, these programs set aside funds for medical expenses to be managed by consumers and seek to incentivize consumers to become more knowledgeable, responsible, and efficient in their use of healthcare services without sacrificing quality. This movement of consumers assuming personal and financial responsibility for their own care should only continue to grow.

Information technology is an essential component of a consumer-directed healthcare program. For example, health plans are expanding their technology offerings beyond the management of claims to more widespread management of health and benefits by employees. Product offerings for such items as healthcare, dental care, long term care, and pharmacy coverage are being coupled with online health assessment and prevention tools intended to enhance consumer healthcare decision-making and promote smarter decision-making by consumers. Such tools enable consumers to evaluate health risks and symptoms and to discern when immediate medical attention is needed. Many such programs are managed by consumers online and require the transmittal of personal health and financial information to a

sponsoring site where that information is processed and managed by the sponsor. Users access the site through user identification and passwords and can access links to information about cost and quality of healthcare providers and services as well as links to review past expenditures, project future needs, and to otherwise manage their financial accounts.

It is not unusual for a company, such as a bank, to partner with an information technology company to create platforms enabling health plans, employers, and third party administrators to administer consumer-directed healthcare accounts. The programs may offer “full service” by way of features such as financial claims adjudication, account management, a single sign-on portal to access account management and tools, investment options, and a payment card that automatically deducts amounts for selections made by consumers, among other services.

B. Legal Issues

Legal issues associated with consumer-directed healthcare programs also principally involve concerns about privacy and security of PHI and other financial information. Information housed on the site on which consumers direct their care and financing of that care may be accessed and used not only by the consumer but also by employers, plans, other payors, banks, or others involved in administering parts of the program. The risk of a breach of confidentiality is greater given the expanded access to such information. It is important to identify exactly who will use and access the information; under what circumstances; and which laws apply to such access, use, and disclosure. Although some of those accessing the information are subject to HIPAA, some (e.g., banks administering payment accounts) are not. Other legal concerns include the potential for misappropriation of information; identity theft and fraud; and proper authorization or consent to the access, use, and disclosure of the information.

V. Pay for Performance, Quality Reporting, and Outcomes Measurement

A. Description of Use

Governmental and private payors as well as consumers have begun to demand performance as a basis for reimbursement of healthcare providers, creating a demand for patient information, both individually and in the aggregate, that is readily available, accurate, and tracks the outcomes of particular treatments. Sometimes referred to as “pay-for-performance” or “P4P” which also is discussed in another article of this issue of *HIT News*, this concept is taking hold and is showing some promise as a basis for payment that can promote best practices.

Accurately measuring health outcomes is difficult in many respects, including proving that a particular treatment protocol caused a particular clinical outcome. As a result, many P4P methodologies currently embrace an “activity” tracking methodology that measures whether certain tests and other actions were performed at certain intervals. For example a P4P program

might track whether a diabetes patient's HbA1C test was taken regularly, or whether regular cholesterol and blood pressure screenings were performed and corresponding prescriptions of statins and other medicines were prescribed. An alternative, and arguably more useful methodology, involves measuring indicia of a patient's health over time (such as the absence of sick-visits or hospitalizations), not simply activity or compliance with treatment protocols.

A recent example of this methodology is Medicare's Home Health Pay for Performance Demonstration program in which an incentive pool will be funded from savings accrued from the reduction in the use of more costly Medicare services. The pool will be shared by home health agencies that produce the highest level of patient care based on the following seven measures: incidence of acute care hospitalization, incidence of emergent care, improvement in bathing, improvement in ambulation, improvement in transferring, improvement in management of oral medications, and improvement of status of surgical wounds. Seventy-five percent of the incentive pool will be shared with those agencies in the top 20% of the highest level of patient care; 25% of the pool will be shared with the top 20% of those making the biggest improvements in patient care. If there are no savings, there will be no incentives.



Measuring and evaluating various health indicators not only will require more sophisticated data categories, but also better methods to capture data about specific patients as they move through the healthcare system among different providers, while at the same time identifying methods of attributing outcomes to particular care protocols. In its December 21, 2007, report to the Department of Health and Human Services, the National Committee on Vital and Health Statistics noted that reaching this kind of reporting ideal can be challenging because it “require[s] more clinical rich information than what is available solely from claims data.”⁴ In other words, methodologies for capturing this kind of information remain imperfect.

B. Legal Issues

Although many of the challenges that payors face in obtaining information to implement P4P is technological, e.g., the technology simply is not sophisticated enough or available to clinicians, there are legal barriers as well, real or perceived. Due to privacy concerns, some providers are reluctant to voluntarily provide health information to payors. While HIPAA permits a physician to share a patient's health information with the patient's health plan for certain purposes, some physicians believe that health plans request too much information in a manner that conflicts with the physicians' contract with the plan.

A legal issue also arises with respect to remote access of EHRs. Some health plans have offered to provide case nurse reviewers to review patient paper records or in instances where a provider does maintain an EHR, remote access to the health plan's case nurse reviewers. Remote access presents privacy and security concerns, including whether the provider has satisfied HIPAA's minimum-necessary standard.

Among other issues are:

1. Once the information is obtained, if used by the acquiring health plan to generalize about particular populations and such conclusions are drawn from the collation of PHI, has the participating physician and the recipient health plan engaged in research without patient authorization in violation of HIPAA?
2. What should patients be told about data gathered about them, or should they be left to assume that the information is being gathered ultimately for their benefit, both in terms of quality and cost-effectiveness of care and pursuant to their agreement with their health plan?
3. What rights, if any, should physicians have with respect to publication of their own performance statistics? This last issue has gained prominence because at least three states in the past year (New Hampshire, Maine, and Vermont) passed legislation to limit or prohibit access to prescribing data without *physician* consent. Each of these statutes, however, has been the subject of intense litigation and, in at least two cases, has been struck down as unconstitutional (but remain subject to appeal).⁵

P4P is here to stay as a concept, but it appears to have a long way to go from a logistical, technological, and legal standpoint.

VI. Payor Access to Electronic Health Records

A. Description of Use

In addition to more typical uses of health information by payors for quality and utilization management, payors have become interested in tapping into the growing availability of health information available through EHR systems. The EHR systems might be part of a regional health information exchange (or other health information exchange), or part of the information system of an academic medical center. The payor knows that it is technically possible to access the health information for purposes of (i) determining appropriateness of medical payments; (ii) evaluating treatment patterns; (iii) monitoring quality of treatment protocols and other potential uses; and (iv) to detect fraud and abuse.

While payors historically have had access to patient medical records to determine medical necessity and for auditing purposes, there is an increased push by payors for access to EHRs on a broader scale at any time for the above purposes. It is the quantity of available information along with the unprecedented levels of access to health records that raises new legal concerns.

B. Legal Issues

Among the key legal concerns raised are:

1. On what basis does a payor have the right to access and use health information of a provider and patients in an EHR system? The requested uses and disclosures should be reviewed carefully to determine whether they are permitted under the treatment, payment, and healthcare operations provisions of the Privacy Rule. Also, depending on the scope of uses or disclosures, the access by payors may need to be disclosed to patients in the provider's Notice of Privacy Practices;
2. Whether the scope of use of the information is permitted under the terms and conditions of use of the relevant EHR system or health information exchange through which the payor obtains the information;
3. If the information accessed is de-identified, then scope of access is not an issue, provided that the information was properly de-identified. If the information is a limited data set, then the use must be permissible (e.g., healthcare operations) and comply with the terms of the data use agreement.

VII. Clinical And Database Research

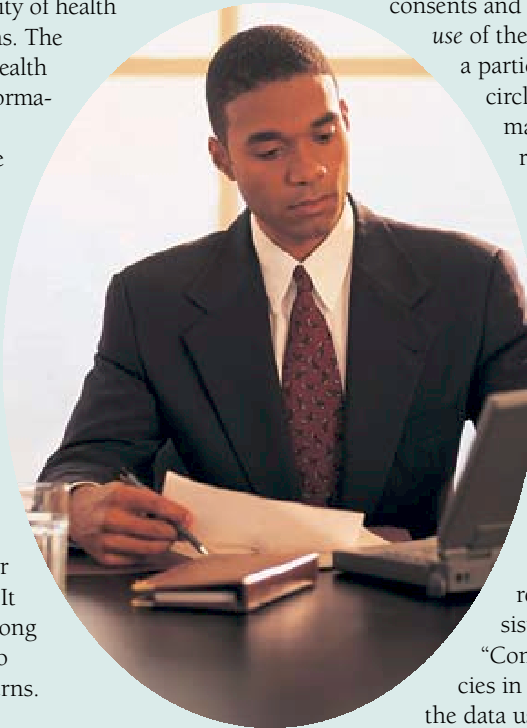
A. Description of Use

The increasing availability of electronic databases and powerful computing tools that can perform queries and analyses across multiple databases is generating a new level of complexity in the field of clinical research. In the case of prospective clinical research, patients typically are required to sign informed consents and HIPAA authorizations that permit the use of their identifiable clinical information for a particular research project within a limited circle of parties to whom such information may be disclosed, e.g., researchers, sponsors, regulatory bodies, and subcontractors such as contract research organizations engaged by sponsors, statisticians, and others hired to facilitate the conduct of research. In the case of retrospective clinical research, records created for clinical purposes are collected, but then reviewed *retrospectively* through electronic queries, with the aim of identifying information components correlated to improvements in care.

B. Legal Issues

The most salient legal issue in the research context arises from the inconsistency between HIPAA and the so-called "Common Rule," specifically inconsistencies in the level of detail required to describe the data use to a subject/patient. For instance, it may be sufficient under the Common Rule to obtain a patient's consent to use the data for "cancer research." HIPAA, arguably, may require more specificity, such as that the use is for "pancreatic cancer research." Similar scope of informed consent/authorization issues arise in other contexts, such as: (i) if some of the data is moved into a limited data set, which is in turn used for yet another form of research such as cardiac research; (ii) another researcher uses additional databases to cross-match and correlate the data, or to identify research subjects; (iii) stored pancreatic tissue, without identifiers, is used for different and later research, such as cardiac research; and (iv) data stored in an electronic health record for treatment purposes is later used for research purposes.

Organizations confronting these issues must determine, among other things, whether it is better to obtain a waiver of HIPAA authorization and informed consent from an Institutional Review Board for these secondary uses, or instead to de-identify the data or create a limited data set and then use only those resulting data sets to conduct the research. A detailed analysis of the context and scope of potential uses must be performed to determine the best approach on these and other issues that may arise.



VIII. Public Health Reporting

A. Description of Use

From the very first public health study in which cholera was traced to a town's water well, the analysis of aggregated population data has been at the core of many public health activities. Especially in view of today's threats of bioterrorism, a critical public health function is to quickly identify clinical trends across multiple providers, to determine whether there is a threat to the larger population, and to identify the source of the health hazard.

Although available technology is at the level to effectively execute these data searches, it has been only with concerted and coordinated efforts by third parties, health information exchange or health departments, for example, working with clinical laboratories, that the effort to streamline this approach has begun to occur. In a recent example, an outbreak of measles in the Boston area quickly was traced to those working in a particular office building, but only after data became available through medical detective work and the sharing of data through a common clearinghouse, in this case the Massachusetts Department of Public Health. If providers do not report timely or departments of public health do not receive diagnosis reports quickly, then the speed at which these outbreaks can be identified is significantly compromised. With powerful computing tools and the widespread use of EHRs containing structured data (which allow, for example, meningitis to be coded the same way by every clinical laboratory), there is at least the theoretical possibility that an outbreak of meningitis could be identified quickly and the relevant organizations alerted.

B. Legal Issues

HIPAA permits the reporting of health information to public health authorities. Similarly, most state laws address, and sometimes mandate, the reporting by healthcare providers of certain communicable diseases to state and/or local departments of health. Unfortunately, the number and complexity of these reporting laws make it difficult for the average physician to know his or her reporting duties. Further, the laws often are vague about whether conditions *must* be reported or simply *may* be reported. Due to privacy concerns, physicians increasingly are wary about whether a report must identify the patient by name.

For example, providing patient identifiable data can be a condition to federal funding of certain state HIV-prevention programs. The simple logistics of gathering the data presents legal issues for providers if they fail to report certain conditions as required by state law. As more providers implement EHRs and begin to enter into health information exchanges, there is the greater possibility of streamlining these reporting efforts by tagging reportable conditions such that they are *automatically* reported from a provider's EHR to the applicable department of health. Nevertheless, concern on the part of providers as to whether there might be "false-positive" reports,

i.e., reporting certain conditions that when viewed in context by the clinician (as opposed to a computer) should not have been reported, also presents legal concerns. To address these concerns, some health information exchanges are beginning to experiment with engaging a neutral third party clinician able to determine from coded, but de-identified, data whether a condition is reportable, and then flagging for the attending physician's review the case so the physician can determine affirmatively the need and the appropriateness of reporting such information to the department of health.

There is no doubt that the power of aggregating data across populations is key to fine-tuning the tracking of public health events and, in turn, improving public health. Although these efforts are beginning to take hold, there remains a strong need to educate both the public and the healthcare provider community about the technology involved and the corresponding legal pathways that currently exist—or that need to be created—to ensure that these efforts succeed.

IX. Marketing

A. Description of Use

PHI has significant value as a marketing tool because it enables hospitals, health plans, and other businesses to better tailor marketing initiatives to their target audiences. On the positive side, such information can be used by pharmacies to remind patients to refill their prescriptions for medication. It also can enable businesses to offer coupons or promote specific treatment, equipment, products, or regimens to individuals with certain health conditions or risks. Disease-specific information also can be disseminated more strategically through the use of PHI. The proliferation of PHI online provides broader access to those engaged in marketing initiatives. For example, marketing companies may monitor social/medical networking websites focused on a particular condition to assemble a targeted marketing list for a particular product.

On the negative side, businesses could seek to purchase, sell, and exploit PHI for less altruistic (i.e., commercial) purposes. Collecting PHI-related information based on consumers' Internet activity is a growing field for marketing firms and is called "behavioral tracking" or "behavioral targeting." In this process, an ever-evolving profile of individuals is created based on the web searches they run and the websites they visit. Based on this information, advertisements are targeted to particular individuals.

B. Legal Issues

As more and more personal information becomes available on the Internet, the question becomes who may properly access, use, disclose, and even exploit the information. Are there or should there be disclosure statements or terms and conditions of use on the site agreed to by users? Who enforces violations of those conditions and at whose expense? Is there or should there be an overall data steward? What is a reasonable expectation of privacy

and security under these circumstances? Again, HIPAA offers some protection with respect to marketing but only with respect to uses and disclosures by covered entities and business associates. For example, to the extent that HIPAA applies, it requires covered entities to obtain patient authorization to use PHI for marketing purposes, with some exceptions.

If HIPAA does not apply, then PHI could be exploited in ways that may have other legal ramifications, especially in the consumer protection arena. In 2006, the Federal Trade Commission held public hearings to examine the emerging consumer protection issues arising due to technological advances. Behavioral tracking received significant attention in the hearings. The hearings and subsequent discussions on the topic highlighted potential legal concerns regarding a lack of transparency, damage to consumer autonomy, and information falling into the wrong hands or being used for unintended purposes.

Also, some companies have faced lawsuits for their attempts to track the Internet activity of their consumers. In 2002, a class action suit was brought against a marketing firm along with numerous other pharmaceutical companies. The marketing firm engaged in behavioral tracking, using software that gathered information submitted by consumers and that tracked their activities at the sites. The plaintiffs alleged violations under the Electronic Communications Privacy Act and the Computer Fraud and Abuse Act. Although defendants in that case won on summary judgment,⁶ future cases with different facts could subject such companies to liability for tracking consumer health information.

Other potential legal concerns arising in the context of the purchase and sale of PHI include exposure under the federal Anti-kickback Statute and the Stark Law (as well as state counterparts).

X. Business Analytics

A. Description of Use

Many organizations in the healthcare industry have begun to use health information to better understand their business and organization. Organizations have been analyzing patient data, transaction data, service delivery data, and benchmarking, for example, to improve service, to control costs, and for risk management and strategic planning. These uses have expanded from the more common uses of health information for quality and utilization management. Organizations are establishing systems to monitor key performance indicators for their businesses. They have been drawing on internal resources to perform these analyses, as well as engaging external consultants.

B. Legal Issues

Health information involved in business analytics might involve the use of limited data sets, de-identified information, or aggregated PHI. Some key legal issues to consider include:

1. If PHI is used, then the use or disclosure should be permitted by the Privacy Rule and/or the terms of a business associate contract. Many of the uses by a covered entity will be permitted as “healthcare operations.” If, however, the permitted use of “healthcare operations” (or another Privacy Rule permitted use) is not available, then patient authorization might be required. Use of PHI by a business associate for its “proper management and administration” may cover many of these uses.
2. If the data that is used is de-identified, then the organization must ensure that the data is properly de-identified in accordance with the methods set forth in the Privacy Rule and cannot easily be re-identified (matched back up with individually identifiable information).
3. If the data that is used is a limited data set, then the parties must ensure that the data is a proper limited data set, and used only for the purposes and in the manner permitted by the Privacy Rule and subject to a data use agreement. The Privacy Rule and any contractual provisions should be reviewed carefully to ensure that the use is in fact permitted.

XI. Conclusion

Many of the trends described in this article represent subsets of overall societal and economic trends—for example peer-to-peer networking, enhanced consumer control, and accountability and critical analysis of more widely available data—and signs indicate that they will become important and powerful trends in the healthcare industry as well. The area of emerging and secondary uses of health information is dynamic and evolving, and the issues described above represent only a snapshot in time. These new uses of health information, and variations on existing uses, will continually challenge the legal framework within which they occur, promising much stimulating legal thinking and work in building and advising on appropriate legal pathways and models.

1 See www.hhs.gov/healthit/documents/m20071113/07b-amia.pdf.

2 See 45 C.F.R. § 160.103, definition of “individually identifiable health information.”

3 See http://connectingforhealth.org/commonframework/docs/P9_NetworkedPHRs.pdf.

4 See www.ncvhs.hhs.gov/071221lt.pdf.

5 See *IMS Health Incorporated et al. v. Sorrell*, No. 07-188, (D. Vt., filed 8/29/07), Defendants’ Consented-to Motion for Extension of Time to Respond to Pharma’s Motion for Partial Summary Judgment, 4/4/08; *IMS Health Incorporated; Verispan, LLC; Source Healthcare Analytics, Inc. v. G. Steven Rowe*, United States Court of Appeals for the First Circuit, No. 08-1248, (filed 3/4/08), Order entered by Judge Sandra L. Lynch, the consent motion to stay appellate proceedings is granted until *IMS Health, Inc. v. Ayotte*, No. 07-1945, is decided, 3/24/08; *IMS Health Incorporated; Verispan, LLC v. Kelly A. Ayotte*, United States Court of Appeals for the First Circuit, No. 07-1945, (filed 6/20/07), Case argued, 1/9/08.

6 See *In re Pharmatrak, Inc. Privacy Litig.*, 220 F. Supp. 2d 4 (D. Mass 2002); 329 F.3d 9 (1st Cir 2003); 292 F. Supp. 2d 263 (D. Mass 2003).

The Emerging and Secondary Uses of Health Information Affinity Group

About the Emerging and Secondary Uses of Health Information Affinity Group.

The Affinity Group addresses issues concerning emerging and secondary uses of de-identified, limited data set, and individually identifiable health information and other health information. The uses and disclosures that are considered include, for example, uses in transparency programs, peer-to-peer information exchange, research, pay for performance programs, quality and utilization review programs, and business analytics, in other words primary and secondary use beyond treatment and payment activities.

If you are interested in joining the Emerging and Secondary Uses of Health Information Affinity Group and exploring these

issues further, including thinking through legal models and best practices in addressing the legal issues associated with emerging and secondary uses, then proceed as follows:

1. Go to the AHLA website and pull down the menu for Practice Groups. Select Practice Group websites. Go to HIT.
2. On the HIT Practice Group website, select the option in the left column for **Task Forces and Affinity Groups**. Click on that link.
3. When you get to the Affinity Group web page, it will look as follows:

Task Forces and Affinity Groups

Affinity Groups

Affinity Groups are created to facilitate networking opportunities with other Practice Group members who share similar professional interests. Enroll in an affinity group. *Please note: You must be a member of the Health Information and Technology Practice Group to enroll in an Affinity Group.*

• Electronic Health Records

This Affinity Group will cover issues related to the development and implementation of electronic health records (EHR), including interoperable EHR, the National Health Information Infrastructure, personal health records, and related developments.

Co-Leaders: Bill Roach, McDermott Will & Emery LLP, Chicago, IL, Laird Pisto, MultiCare Health System, Tacoma, WA, and Ben Butler, Crowell & Moring LLP, Washington, DC

Related Materials:

- The Quest for Interoperable Electronic Health Records Member Briefing
- Riding the Electronic Health Record Tidal Wave: An Exploration of the Potential Legal Barriers to the Interoperable EHR – 2004 HIT Think Tank Materials

• Emerging Uses of Health Information

This Affinity Group will address issues concerning emerging uses of health information, including but not limited to de-identified, limited data set, individually identifiable health information, Transparency and provider profiling such as uses in research, pay for performance programs, quality and utilization review programs, and business analytics (essentially primary and secondary use beyond treatment and payment activities).

Co-Leaders: Linda Ross, Honigman Miller Schwartz & Cohn LLP, Detroit, MI, Stephen Bernstein, McDermott Will & Emery LLP, Boston, MA, and Daniel Orenstein, athenahealth, Inc., Watertown, MA

• Privacy and Security Compliance and Enforcement

This Affinity Group will cover HIPAA and state privacy and security compliance and enforcement.

Co-Leaders: Trish Markus, Smith Moore LLP, Raleigh, NC and Bob Coffield, Flaherty Sensabaugh & Bonasso PLLC, Charleston, WV

Related Materials:

- OCR HIPAA Guidance Letters

• Tech Licensing and Intellectual Property

This Affinity Group will address technology licensing and contracting and intellectual property issues related to health information technology.

Co-Leaders: Kevin Lyles, Jones Day, Columbus, OH, Heidi Echols, McDermott Will & Emery LLP, Chicago, IL, and Mark Mildenerger, Children's Hospital, Seattle, WA

• Telemedicine and E-Health

This Affinity Group will address the multiple issues related to telemedicine, including technology issues, regulatory compliance, professional licensing, and billing and those issues relate to telemedicine and telehealth. The Affinity Group will also address e-health issues, excluding electronic health records. For example, this group will address e-prescribing, computer physician order entry, remote patient monitoring, and other related developments. The group will coordinate with the EHR Affinity Group when their interests and issues converge.

Leader: Amy S. Leopard, Walter & Haverfield LLP, Cleveland, OH

Task Forces

• Medicare Part D Task Force

The Part D Task Force will work to educate AHLA membership about Part D's structure and operation, providing information of interest to providers and suppliers as well as to manufacturers, Prescription Drug Plans (PDPs), and Medicare Advantage (MA) plans. Educational efforts will include various types of publications, teleconferences, live presentations, and a listserv that address issues of interest to AHLA members, such as the basic Part D benefit (e.g., beneficiary liability, low income subsidies, dual eligibles), Plan requirements (from drug formularies to marketing guidelines), employer subsidies, patient assistance programs, and the relationship between Part D and Part B. The Task Force will also address drug pricing and reporting issues, including Average Sales Price (ASP), Average Manufacturers Price (AMP), Best Price, treatment of administrative and service fees, and rebates. Fraud and abuse topics will be an important part of Task Force activities in light of the extensive reference to Part D-related issues in the OIG's 2006 Work Plan, and the numerous potential risk areas throughout the program, such as off-label usage, Best Price exemptions, and problems arising in the long term care context.

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Editor's Corner

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In February 2008, the Centers for Medicare and Medicaid Services (CMS), the enforcement agency for the HIPAA security regulations, issued a list of the types and sources of information that may be requested as part of a “compliance review” or an on-site investigation concerning compliance with the security regulations. See www.cms.hhs.gov/enforcement/025_generalenforcementinformation.asp. This list comes two years after the promulgation of the final HIPAA enforcement regulations, which recognized the authority of CMS (as well as the Office for Civil Rights, its counterpart with respect to the HIPAA privacy regulations) to investigate complaints and to initiate compliance audits.

Not surprisingly, the list includes documents specifically contemplated by the security regulations. These include the organization's most recent security analysis (reinforcing the concept that such security analyses need to be revisited) and the risk management plan that responds to the risks identified in the analysis. Policies, procedures, inventories, and plans addressing critical security standards, as well as business associate contracts, also make the list.

Of interest, the contents of the list suggest an expansion beyond the strict language of the security regulations, with references to confidentiality agreements, vulnerability scanning plans, entity-wide security plans, employee background checks, and encryption/de-encryption documents. All of these concepts are consistent with the security regulations but not necessarily specifically mandated.

Personnel who may be interviewed are also identified, beginning with the CEO. This supports the concept that security should permeate all aspects of operations and not just be limited to the information technology department.

CMS stressed that this list is not comprehensive and that the individual circumstances of each situation will dictate the course of the investigation. For more information, see an email alert entitled “New CMS Compliance Reviews and Checklist for HIPAA Security” (issued on February 26, 2008) that can be found on the HIT Practice Group's website under “Email Alerts.”

The HIT Practice Group, specifically the Privacy and Security Compliance and Enforcement Affinity Group, is generating a new toolkit for addressing enforcement actions and security audits, so be sure to periodically check our website for new developments and resources.



This CMS list, coupled with reports of at least eight (at last count) on-site security investigations conducted by the Office of Inspector General (OIG) on behalf of CMS and/or by the Office of E-Health Standards and Services (OEHS), further highlights the government's expressed concerns over high profile data breaches and risks to individually identifiable health information.

Many of these concerns over security, as well as over privacy, confidentiality, and myriad other legal issues, are heightened given the expanding ways that health information can be used, manipulated, and exploited. For good or for ill, we are seeing only the tip of the iceberg—the future of such expanded uses of health information can push as far as our imaginations, subject, of course, to the limitations that may be imposed by society and public and private (i.e., contract) law. As the cornerstone of this issue of *HIT News*, our *Affinity Group Spotlight* puts center stage our newly created Emerging and Secondary Uses Affinity Group. This Affinity Group's focus responds to the questions and concerns of the membership of the HIT Practice Group. “Emerging and Secondary Uses of Health Information: An Overview of Uses and Legal Issues” by **Daniel Orenstein, Stephen Bernstein, and Linda Ross** identifies prominent emerging health information issues and legal ramifications of these emerging uses, which are also reflected in the other articles in this issue of *HIT News*.

In a related article, **Gerald Tracy** discusses Pay for Performance in “The CMS Value-Based Purchasing Transformation: Starting on the Edges and Moving In.”

Patricia D. King then walks us through legal issues associated with the wild frontier of the Internet, where its role is ever-expanding in healthcare. See “Staying Safe In the Internet's Wild Wild West.”

We want this to be a valuable publication for your practice. Therefore, please let me know if you would like to contribute an article or have any ideas concerning the *HIT News*. I can be reached at beckywilliams@dwt.com.

The CMS Value-Based Purchasing Transformation: Starting on the Edges and Moving In¹

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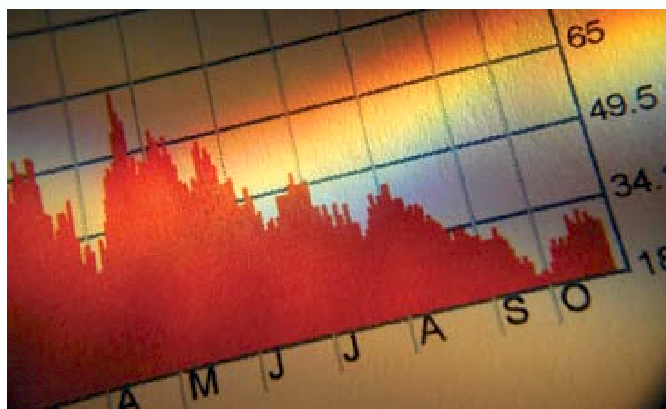
I. Introduction

By its own report, the Centers for Medicare and Medicaid Services (CMS) has begun to transform itself from “a passive payer of claims to an active purchaser of high quality efficient health care,” and will achieve this metamorphosis through its commitment to value-based purchasing.² CMS defines value-based purchasing (VBP) as the linkage of payment of healthcare services to the quality of services provided, and uses the Institute of Medicine’s (IOM’s) definition of quality. Quality care is safe, effective, timely, patient-centered, efficient, and equitable care.³ The term “pay for performance” (P4P) is sometimes used synonymously with VBP, and sometimes as a component of VBP. We will use the two terms interchangeably in this article.

VBP is the new grail in American healthcare reform—following its predecessor ideal—managed care—which became increasingly embroiled in controversy and litigation in the late 1990s. The VBP movement is driven by several powerful trends in American healthcare:

- Serious problems documented in quality of care (overuse, under-use, and misuse);
- Current payment methods fail to reduce costs, fail to reward quality care, and in some cases reward poor quality care;
- Healthcare quality data collection, measurement, and reporting methods improving, coupled with advances in health information technology; and
- Payors, patients, providers, and regulators seeking transparent, objective, and accurate quality and cost performance data.

CMS is the nation’s largest purchaser of health services and also a major force driving the burgeoning American national healthcare quality movement. CMS’ payment and regulatory actions significantly will determine how widely VBP will be adopted throughout the nation, and will strongly influence VBP policies, methodologies, information technologies, and laws. This article will review CMS’ current major hospital VBP initiatives, including the Hospital-Acquired Conditions/Present on Admission (HAC/POA) initiative, the Reporting Hospital Quality Data Annual Payment Update (RHQDAPU) program, the CMS Premier Quality Incentive Demonstration, and the proposed Medicare Hospital Value-Based Purchasing Plan (VBP Plan). Current law relating to quality of hospital care, and to pay-for-reporting and P4P programs will be summarized. Hospitals’ evolving responsibilities for quality



and financial oversight will be considered in response to CMS’ (and other payors’) commitment to VBP in addressing critical deficiencies in national healthcare quality and financing.

II. Federal VBP-Related Legislation

Following the IOM’s ground-breaking studies delineating serious and systematic problems in the quality of national healthcare, the U.S Congress responded with legislation authorizing and promoting development of P4P in the Medicare program, primarily focused on hospital services.⁴ The Medicare Modernization Act of 2003 required CMS to establish the RHQDAPU program and to modify their hospital inpatient prospective payment system to account for severity of illness, and also directed the IOM to develop, identify, and prioritize pay-for-performance options.⁵

The Deficit Reduction Act of 2005 (DRA) directed CMS to accelerate development of Medicare VBP for hospital services in several important ways:

- Expand number of quality indicators tracked in the RHQDAPU program and increase the level of pay-for-reporting bonuses and penalties;
- Establish preventable hospital-acquired conditions present on admission data collection and payment adjustment procedures (HAC/POA initiative); and
- Create and submit to Congress a plan to implement VPB (VBP Plan) beginning FY 2009 for Medicare services provided by hospitals covered under the federal Inpatient Prospective Payment System.⁶

The HAC/POA initiative employs penalties, the RHQDAPU and Premier Quality Demonstration programs contain both penalties and bonuses, and the proposed VBP Plan only bonuses, though none of them currently affect any significant fraction of hospital revenue (see Section V).

III. CMS Hospital-Acquired Conditions Initiative/Never Events

Section 5001(c) of the DRA directed CMS to establish procedures to eliminate financial rewards to hospitals for certain preventable conditions that were not present on admission.⁷ Effective FY 2008, CMS began requiring hospitals to code secondary diagnoses present on admission (POA) for Medicare patients and

identified eight preventable conditions for which hospitals will no longer receive additional payment effective FY 2009. (That is, these conditions will be disallowed as complications that would increase the DRG payment.) The selected conditions include serious preventable events (e.g., foreign object left in after surgery and delivery of incompatible blood) as well as preventable conditions (such as pressure ulcers and catheter-associated urinary tract infections). CMS intends to target additional preventable conditions for the HAC program in the future based on three selection criteria: burden, preventability, and measurability.⁸

The CMS HAC/POA initiative draws from work done on patient safety indicators by the U.S. Agency for Healthcare Research and Quality (AHRQ), The Joint Commission sentinel event program, and several national quality organizations. The National Quality Forum (NQF) lists twenty-eight “serious reportable events which should never occur,” commonly referred to as “never events.”⁹ The never event movement has garnered considerable support from hospitals and payors—and support has increased following CMS’ announcement of the HAC provisions of the FY 2008 Inpatient Prospective Payment System (IPPS) Final Rule. The Leapfrog Group has convinced 1300 hospitals to adopt its never events policy, in which the hospital agrees to report any of the NQF-defined never events to an appropriate authority, conduct a root cause analysis, apologize to the patient/family, and waive all costs directly related to the event.¹⁰ WellPoint and four other of the nation’s largest health insurers recently have announced their commitment to end payment for never events.¹¹ Twenty-four states require hospitals to publicly report never events, and Minnesota and Pennsylvania announced their plans to waive costs directly related to never events in their publicly funded healthcare programs.¹²

CMS views its implementation of the HAC/POA initiative as a key element of its VBP program and intends to add additional conditions/events over the next several years.¹³ Never events are the most straight-forward and uncontroversial of the current VBP strategies. Because of broad healthcare industry consensus that certain events should never occur on a hospital’s watch, it is hard for anyone to justify that the hospital should be financially rewarded for such care. The events themselves are definable, and the reimbursement implications are not complicated. Never events, however (fortunately) represent only a miniscule portion of hospital stays and (unfortunately) only a small portion of errors causing iatrogenic complications or death. For example, in Minnesota, where hospitals are required by law to report such errors, 154 never events were reported last year out of nine million hospital admissions.¹⁴ In contrast, the CMS HAC list of preventable conditions includes complications with much higher

frequencies and overall system costs (e.g., pressure ulcers and catheter-associated urinary tract infections). Some hospital groups have objected to CMS’ immediate establishment of a zero-tolerance standard for such prevalent conditions.¹⁵

IV. CMS Value-Based Purchasing Plan

The DRA required CMS to develop a VBP Plan for Medicare hospital services commencing FY 2009.¹⁶ CMS worked diligently on this VBP Plan throughout 2007, conducted two stakeholder listening sessions, and finally reported its Medicare Hospital VBP Plan to Congress on November 21, 2007. CMS employed a systematic and careful design process for the VBP Plan; used measures approved by the NQF; drew extensively from its RHQDAPU, Hospital Compare, and Premier Demonstration programs; and studiously avoided imposing additional burdens or challenges on the hospitals. The VBP Plan delineates many recommendations, options, and implementation phases, which are discussed below in Section IV. Further, the VBP Plan also identifies, but defers recommendations on, a number of crucial VBP issues (discussed in Section V).

A. Goals and Principles. CMS begins by defining a broad, non-controversial list of hospital VBP program goals: improvement of clinical quality and patient safety; reduction of over-use, under-use, and misuse of services; encouragement of patient-centered care, reduction of unnecessary costs, stimulation of investment in IT, and care re-engineering; and fostering transparent and comprehensible performance results.¹⁷ CMS then articulates several overarching principles: budget neutrality; use of existing RHQDAPU hospital performance management infrastructure; NQF-approved measures; broad range of measures addressing clinical quality, patient-centered care and efficiency; rapid expansion to a comprehensive measure system to foster transformation of the healthcare system; disparities prevention and reduction; and evaluation of program impact, utility of measures, and identification of unintended consequences.¹⁸

B. Measures. Selection of correct quality measures is critical to VBP design and the achievement of VBP program goals. Quality measures can be grouped into two general categories:

- Patient-focused measures: clinical outcomes, patient safety outcomes, patient perspective.
- Provider-focused measures: processes of care, structural (resources or programs).

For its initial VBP program, CMS proposes a selection of provider-focused measures drawn from its RHQDAPU program



and composed almost entirely of process of care measures along with two outcomes (mortality) and one patient perspective of care measure.¹⁹ They recommend that measures be introduced in stages; first for data collection, next for public reporting, and finally for financial incentives.²⁰

To date, CMS primarily has utilized process measures developed by the NQF to measure hospital quality performance: in RHQDAPU, Hospital Compare, and the Premier Demonstration. Process measures define industry-accepted best practices for specific medical conditions (e.g., beta blocker prescribed to AMI patients at discharge). CMS notes that these measures have high credibility within the hospital community and meet CMS' criteria for inclusion as VBP financial incentives. CMS, however, recognizes that processes of care measures are insufficient to achieving their goals to transform healthcare delivery and financing—and that clinical outcome and patient safety measures are essential.²¹ The HAC/POA initiative evidences CMS' commitment to apply VBP to patient safety outcomes—albeit in a limited manner. The complex and important methodological and political challenges involved in quality measure development, selection, and application are discussed in detail in Section V.

C. Data Collection/Validation/Reporting. CMS proposes that the existing RHQDAPU data infrastructure serve as the foundation for VBP data infrastructure—in line with its eventual goal to transition from RHQDAPU to VBP.²² A subsection of the measures currently required in the RHQDAPU pay for reporting could be selected for use in P4P. CMS acknowledges that some redesign of the current data submission and validation infrastructure would be needed for the higher-stakes VBP endeavor, to enable: hospital correction rights; more stringent auditing; and prevention of any delays in payment and public reporting.²³

D. Performance Assessment/Scoring. CMS outlines a methodology for scoring each hospital's performance and computing a total performance score for all measures applicable to that hospital. This score, in turn, will be used to determine the percentage the hospital receives of its incentive payment. The assessment process will calculate both an attainment score (comparing the hospital's performance to that of other hospitals) and an improvement score (comparing the hospital's current measure score with its own prior-period baseline performance)—and base incentive payments on the higher score. This approach is designed to reward current high-performing hospitals and to provide lower-performing hospitals incentives for improvement.²⁴

E. Incentive Payment. CMS proposes defining a small percentage of the hospital's total IPPS payment as incentive payment. The hospital would then receive zero to 100% of the incentive payment based on its total performance score (the higher of its attainment or improvement score).²⁵ CMS does not specifically define a percentage of set-aside for incentive payment, noting that no definitive research exists to define optimal payment parameters for P4P programs. They recommend that a range of 2% to 5% be considered, which is slightly higher than the bonus payment levels used in RHQDAPU pay for reporting and in the Premier Demonstration.²⁶ The CMS VBP Plan does not recommend penalties for poor performance at this time.

F. Public Reporting. CMS emphasizes the unique importance of public reporting of hospital quality performance results in VBP, separate from the financial incentives component. CMS will use its Hospital Compare reporting program as the foundation for displaying the hospital performance data on a growing number of performance measures. CMS acknowledges the weaknesses of current public hospital reporting programs and seeks to: make performance results more understandable to Medicare beneficiaries; employ decision supports and display methods to facilitate fair and accurate decision making; and address the needs of multiple stakeholders (patients, payers, regulators, researchers).²⁷ These recommendations do not account for the treating physician's typically decisive role in the selection of the hospital for the patient.

G. Phase-in of VBP Program. CMS emphasizes that implementation of full-scale VBP would be a multi-year process. Hospitals would need to receive notice of the measures and performance thresholds that will be used for public reporting and financial

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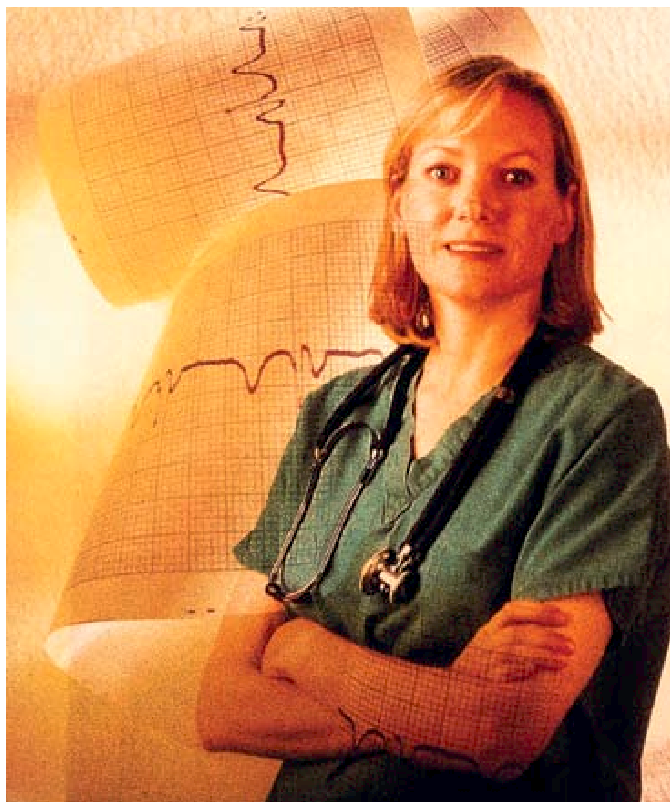
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incentive payment. A baseline year would be established, followed by a measurement period in the second year to enable CMS to collect baseline performance data and benchmarks to determine improvement scores and attainment scores, respectively. CMS recommends that VBP initially function solely as a pay-for-reporting program, which reimburses hospitals simply for reporting the required data to CMS—as now occurs under the RHQDAPU program. The transition from pay for reporting to P4P would occur over three years after the two-year set-up period. Full-scale VBP would not occur until well into the next decade.²⁸

V. CMS VBP Plan: Outstanding Issues

A. Insufficiency of Proposed Solutions. The IOM studies and others describe severe problems with the quality of American healthcare, outline the resultant human and financial costs, and demonstrate that current payment methods fail to reward good quality care and sometimes reward poor and/or unnecessary care. Accordingly, CMS designs its VBP Plan based on bold principles that will transform Medicare, correct and align provider financial incentives, and reward quality care provided to every person every time. But, unfortunately, the proposed VBP Plan does not begin to address the severe and systemic problems on which it is premised. CMS' caution is somewhat understandable given the infant state of VBP programs, the paucity of available research to guide decision-making that would foster high quality care, and the difficulties in motivating hospital cooperation with any P4P program.²⁹ CMS does demonstrate consistency in building its VBP foundation on programs and methodologies it has introduced to hospitals in the last several years. CMS clearly and systematically outlines each challenging design element of P4P

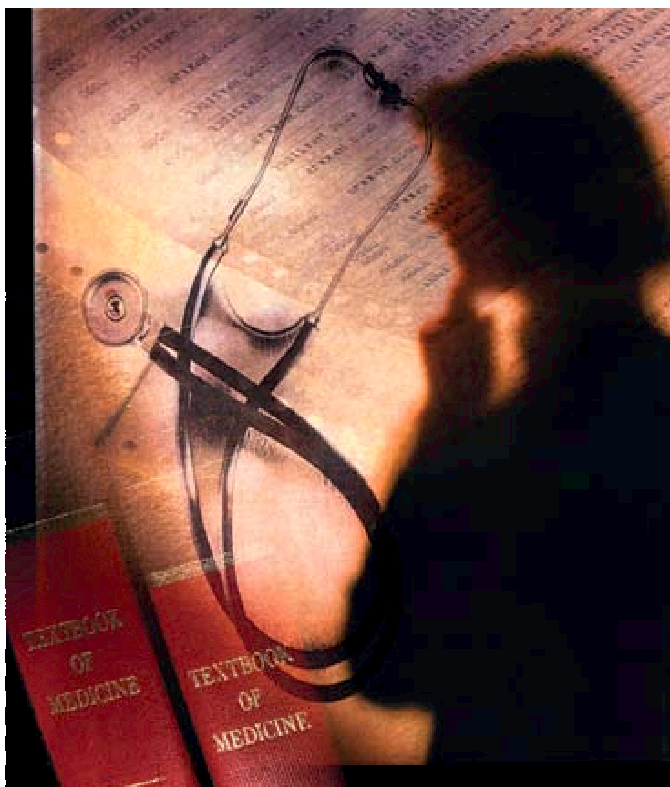


and, thereby, effectively highlights three areas that it currently is unable to address, but that are essential to a successful VBP program.³⁰ These unsolved issues are discussed next.

B. VBP Measures Focused on Provider Activity Rather Than Patient Need. Patients define quality care as care that makes them better, reduces their chances of death or disability, does not result in hospital-acquired complications, reduces the likelihood of readmissions, and does not jeopardize their safety. That is to say, patients (along with many quality experts) focus on outcomes of care. Healthcare providers typically prefer process of care measures: where they can assign their own staff to achieve and document the measured result; where patient characteristics, physician behaviors, and other external variables are not as critical to success; and where scoring and payment calculation do not require risk adjustment or other complex adjustments. Process measures, however, may not necessarily produce good outcomes for patients (or produce good outcomes only for certain sub-categories of patients), may divert provider focus from other important processes, and unintentionally may deter innovation and experimentation with better processes.³¹ Also, hospitals are finding RHQDAPU's data infrastructure and management requirements to be burdensome and costly—and question whether even the increased bonus incentive (up to 2%) will cover the costs of participation.³² Finally, providers may begin to reconsider their support of government-prescribed treatment protocols if the number of these protocols grows from dozens to potentially hundreds, which could resemble the “cookbook medicine” utilization review methods providers found so objectionable in the managed care era.

CMS advocates increased VBP focus on outcome and other patient-focused measures, while also noting the current obstacles to their implementation. CMS acknowledges the complexities and risks of outcome measures, which require risk adjustment to control for differences in patient illness levels across hospitals and measures to prevent hospital avoidance of patients with greater outcome risks. CMS, however, lists the values of outcome measures: direct focus on patient rather than provider needs; promotion of hospital coordination of care with other providers; decrease in fragmentation of care; encouragement of process improvement by not mandating processes; and more stability over time as desirable outcomes are less likely to change than processes.³³

C. VBP Overly Focused on Hospitals and Under Focused on Other Providers. The Congress, CMS, and many of the major quality organizations have focused their VBP efforts primarily on hospital inpatient care. There has been far less attention on ambulatory care, rehabilitation, long term care, and—most importantly—physician care. There are obvious and good reasons for focusing on hospitals (they do treat the sickest and most expensive patients). But the lack of physician-focused quality measurement methods significantly limits fair and accurate measurement of hospital performance because the physician (rather than the hospital) determines whether the patient will be admitted, orders and oversees the services the patient will receive, and directs when and to where they will be discharged. As quality measurement systems phase into P4P systems, hospitals may be unfairly



penalized (or rewarded) for activities or results over which it has limited control—unless physician and hospital incentives are properly aligned.

Although hospitals have extensive and growing legal obligations for oversight of the quality of care provided within their facilities (see Section VII of this article), hospital staff have varying degrees of control in influencing performance under the different categories of quality indicators. Hospitals typically prefer process of care measures that they can incorporate into their care plans, assign specific staff to assure compliance, document compliance or non-compliance, and correct as necessary to strive for 100% compliance. In contrast, clinical outcome measures (e.g., reduction of specific preventable complication or preventable readmissions) likely will require extensive coordination among many hospital departments and several medical physician specialties, along with community home health and nursing facilities.

Hospitals should be expected to lead in improving such patient outcomes, given the scope of their corporate responsibilities for quality oversight. CMS expects that its imposition of clinical outcome and patient safety measures on hospitals will motivate hospitals to drive other providers to decrease the fragmentation and discontinuities in the overall care delivery systems.³⁴ But physicians and other provider groups will need to be motivated to work with hospitals to establish services that are coordinated and continuous. Also, when CMS and other payors expand P4P to track episodes of patient care involving multiple providers across multiple organizations, these complex issues of responsibility allocation, incentive alignment and apportionment, and care coordination will need to be addressed seriously by both payers and providers.³⁵

D. Minimal Financial Commitment to Value-Based Purchasing.

As noted, CMS intends to transform itself into a rational purchaser: one who buys maximum quality services with a minimum of unnecessary or counter-productive costs. CMS is committed to a budget-neutral VBP program; therefore, VBP should not add dollars to the system but should reallocate existing dollars towards valuable services and away from poor quality services. The proposed VBP Plan design initially provides small dollar awards to hospitals for complying with CMS data reporting requirements and subsequently for conforming to a small number of CMS-defined best processes. Incentive bonuses are estimated at 2% to 5% of total payments, which would not provide the incentive for hospitals to make the clinical, operational, and information technology investments necessary to improve performance. Hospitals already have expressed concerns about the financial and administrative burdens that have resulted from tracking the relatively small number of current process indicators.³⁶ Also, CMS' plan to target only a certain number of processes creates potential problems: hospitals may be motivated to only focus resources on the selected care processes and re-direct resources from other patients and conditions.³⁷

VI. Current Quality of Care and Value-Based Purchasing Law

A. Federal and State Mandates. CMS' initiatives in quality reporting and VBP impose a sizable and growing body of legal requirements upon hospitals (e.g., RHQDAPU, POA, and HAC). In addition, more than thirty states have established their own hospital public reporting laws, including twenty-six states that require infection reporting and twenty-four states that require reporting of never events.³⁸ The validity of infection reporting will be improved significantly where states implement state-wide collection of present-on-admission data.³⁹ Thirty-four state Medicaid agencies have established some kind of P4P program, typically directed towards physician and/or health plan best practices.⁴⁰ Only Massachusetts has mandated Medicaid P4P for hospitals, as part of its comprehensive healthcare reform act.⁴¹

B. Federal Enforcement Actions Targeting Quality Problems.

The federal government's increased focus on quality has been accompanied by increased civil and criminal enforcement actions against healthcare providers who deliver low quality and/or medically unnecessary services. Government prosecutors are employing a variety of theories primarily under the False Claims Act, including express false certification on claims for government payment, implied false certification, medically unnecessary services, worthless services, criminal enforcement for fraud, false statements, or kickbacks.⁴² Also, the Office of Inspector General (OIG) has announced that it will target never events and other serious medical errors on the individual hospital level (incidence, corrective action, and payment), on CMS' ability to detect and deny and recoup payment, and on the value of state and voluntary incidence reporting systems.⁴³

CMS has stated its intention to expand the use of the electronic data it gathers for payment and performance management purposes to "more efficiently detect improper payment and program

vulnerabilities.⁴⁴ CMS has multiple sources of data from which to draw in its data mining, such as RHQDAPU, the PEPPER electronic data report, the CERT and PERM payment error monitoring programs, and the RAC recovery audit program.⁴⁵ Although certain state and federal laws offer privilege or discovery protection for some of the healthcare quality information provided by hospitals, the public quality and cost data used by CMS in data mining are not subject to these protections.⁴⁶ The federal government's increased focus on hospital quality problems will require hospital risk management, quality, financial, and information systems to work together in an increasingly proactive and sophisticated manner (see Section VII).

C. Medical Malpractice System and VBP

American medical malpractice law is based on historical assumptions about healthcare providers and quality of care that conflict with current principles that form the foundations of the quality, transparency, and VBP movements. The traditional malpractice paradigm is premised on the concepts of individual professional judgment and local standards of care. In contrast, the quality/transparency movement is slowly but surely building national treatment standards based on evidence-based medicine and the application of objective performance data. CMS' leadership in this quality development process, as the nation's most powerful healthcare payor and regulator, assures the increasing nationalization of standards of care. In the traditional malpractice model, the performance data contained in the medical record is guarded by the provider and made available only as required in an adversarial legal proceeding. The quality/transparency model is designed to make detailed comparative provider performance data available to all interested stakeholders (e.g., patients, payors, researchers, and other providers). Quality improvement programs require the identification of important problems, collection of benchmark data, design of explicit corrective actions, and objective documentation of the results of correction efforts. As CMS (and other regulators, payors, and quality advocates) motivates hospitals to operate under transparent quality improvement principles, hospitals still need to protect and defend themselves under fault-based state medical malpractice laws.

Certainly, medical malpractice laws and proceedings will be strongly affected as CMS, other federal agencies, and national organizations lead the development of quality and VBP programs—but hard to predict when and how. Many questions arise. What role will NQF and other CMS-endorsed national care standards play? How will publicly reported hospital performance scores be used against (or for) hospitals? Will occurrences of preventable hospital conditions as defined in federal or state reporting or VBP programs be viewed as negligence per se? How will the expert medical witness role change in malpractice proceedings given the growing body of evidence-based and/or national standards?⁴⁷



D. Apology Laws. Patient apology programs and associated legal protections are another example of changing hospital approaches to medical errors. The Leapfrog Never Events Hospital Policy includes disclosure of medical errors to the patient and an apology—and represents an increasingly popular component of preventable injury risk management (and patient communication). Twenty-nine states have passed laws protecting a healthcare provider's apology from being used as evidence or as an admission of liability in a lawsuit.⁴⁸

E. Health Information Technology

Law. Federal and state advocates of VBP simultaneously promote development of interoperable health information technology, viewing interoperability as essential to an effective, full-scale VBP program.

CMS' strong promotion of its value-driven healthcare agenda to state Medicaid directors is an example.⁴⁹ At the same time, interoperability will pose additional challenges for providers with respect to protection of the privacy and security of patient information and the security and confidentiality of their proprietary information.

VII. Hospital Corporate Fiduciary Duties in a VBP World

Responding to trends in healthcare quality and patient safety law, hospital boards increasingly recognize that oversight of quality of care provided within their organizations is a core fiduciary duty—a duty that encompasses the hospital's development and/or maintenance of effective quality assessment and performance improvement programs along with medical staff credentialing. The American Health Lawyers Association and OIG's *Resource on Corporate Responsibility and Healthcare Quality for Healthcare Boards* clearly delineates the legal bases of these quality oversight responsibilities and identifies board actions necessary for their fulfillment.⁵⁰ The Resource emphasizes that the hospital's corporate quality oversight is required as a condition for participation in Medicare and Medicaid. How then will CMS' growing focus on Medicare VBP affect the hospital's corporate fiduciary responsibilities and associated management functions?

A. Quality Reporting/Transparency. CMS' commitment to transparent public reporting of increasing types and numbers of quality indicators requires hospital boards and management to place even greater focus on their quality improvement programs for legal compliance as well as reputation protection reasons. Federal and state officials have access to increasing amounts of detailed information about hospital performance (e.g. never events, conformance to care processes, and soon outcomes) and will not hesitate to use it in enforcement actions for serious failures in care and/or fraudulent care. Hospitals will need to

ensure the accuracy and timeliness in collection and reporting of required data because they do not want to raise compliance issues—and because they want to understand their public performance scores and manage to improve them. Hospitals will need to invest in the human and IT resources necessary to generate the high quality documentation and coding that is the basis of accurate quality data—and obtain the equally essential cooperation of their medical staff in these activities.

B. Transition from P4R to P4P. CMS' commitment to VBP programs of increasing complexity and financial significance will require increased attention of the hospital board and senior management—for financial as well as legal compliance reasons. Timely and accurate data collection and reporting become even more important where the result is payment adjustment. The OIG already has announced that it will closely monitor implementation of the HAC/POA Initiative. Hospitals will need to clearly understand and closely manage these serious preventable events. The OIG certainly will audit hospital reimbursement payment, and seek recoupment where they deem necessary, under the new VBP Initiatives.

C. Partnership with Physicians/Other Providers. Hospitals need physician cooperation to improve performance under the HAC/POA Initiative and also under any VBP Plan. Assuming that CMS begins as promised to introduce new outcome measures (e.g., potentially preventable readmissions), hospitals will need to form effective partnerships—where the incentives of both parties are aligned to achieve the target outcome(s). P4P models that seek to encourage such aligned hospital-physician relationships will need to conform to among other things: restrictions of hospital profit-sharing relationships with physicians (gain-sharing); regulations on capitation arrangements; and Stark and anti-kickback laws. Complex contracting arrangements among physicians, hospitals, and other provider organizations will need to be carefully structured.

D. Targeted Investment in Information Technology and Management. Hospitals will require more sophisticated information systems to flourish in a VBP environment. Hospital management information system departments, however, are typically under-resourced. Neither the current RHQDAPU program nor the proposed VBP Plan provides sufficient bonuses to fund such information technology investment. Also, these CMS programs rely heavily on process measures—which increasingly burden the hospital data infrastructure and quality programs. Outcome measures are based on computerized clinical and demographic data and also will require significant, but slightly different, investments in information technology and quality management. It is true that many hospitals outsource aspects of their quality program to specialized vendors. But the hospital's quality functions are ultimately non-delegable; vendor contracts must contain strong and specific performance commitments, HIPAA protections, and robust audit rights.

E. Risk Management Upgrade. The CMS HAC initiative and related state/commercial payor “never event” programs will require hospitals to report and adjust payment on a growing number of serious, preventable, and potentially actionable events. Hospital risk management programs will need the tools and commitment from all levels of the organization to identify, document,

analyze, and respond to these events—and to establish programs to prevent re-occurrences. Given CMS' and also the OIG's focus on hospital-acquired, preventable conditions, hospital senior management and boards of directors should establish and oversee an enterprise-wide risk management program to address serious preventable events.⁵¹

F. Participation in VBP Development/Lobbying. CMS acknowledges that its VBP Plan is a work in progress—and has carefully and systematically involved hospitals in VBP Plan design. In fact, hospitals have been invited to collaborate in each of CMS' building blocks for VBP (NQF measures Hospital Compare/HQA reporting and Premier Demonstration). CMS' cautious and consensus-oriented approach to VBP presents a striking (and welcome) contrast to the adversarial positions assumed by payors and providers in the managed care era. Hospitals obviously will need to vigorously and creatively participate in VBP development, given its critical potential importance to their clinical operations and financial stability. As payors and regulators experiment with an increasing diversity of P4P programs (with different measures, scoring systems, provider target, and payment adjustments), hospitals will need to advocate for consistency, practicality, and clinical soundness in VBP program design and implementation. They will need to weigh the respective advantages and disadvantages of both process and outcome measurement systems. Finally, they will need to demand the productive and aligned involvement of physicians and other providers in more comprehensive P4P programs.

In summary then, the CMS VBP initiatives represent a modest, but definite, start to a major transformation of hospital payment and performance accountability. CMS' further implementation of its stated VBP objectives will impact significantly hospital financing, management, and service delivery—and many aspects of health law.

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- 1 The views expressed in this article are that of Mr. Tracy, and do not necessarily reflect those of 3M Health Information Systems.
 - 2 Centers for Medicare and Medicaid Services: *Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program*, November 21, 2007, p. 2.
 - 3 U.S. Department of Health and Human Services, Medicare Hospital Value Based Purchasing Plan Development, 1st Public Listening Session, January 17, 2007, p.1.
 - 4 The Institute of Medicine's seminal 1999 study *To Err is Human* was followed in 2003 by *Crossing the Quality Chasm*, followed by a stream of targeted quality studies commissioned by Congress under the MMA. All available at www.iom.edu.
 - 5 Medicare Prescription Drug, Improvement and Modernization Act of 2003, Section 501(b).
 - 6 Deficit Reduction Act of 2005, Public Law 109-171. The RHQDAPU and VBP Plan provisions each are found in Section 5001(b). The HAC /POA provisions are found in Section 5001(c).
 - 7 Deficit Reduction Act of 2005, Public Law 109-171, Section 5001(c).
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 - 10 The Leapfrog Group. Never Events Position Paper Sample Hospital Policy, December 2006, available at www.leapfroggroup.org.
 - 11 Fuhrmans, Vanessa. “Insurers Stop Paying for Care Linked to Errors.” *Wall Street Journal*, Jan. 15, 2008.
 - 12 Carroll, Roberta. *Heading to Never Never Land: The CMS Proposal to Halt Reimbursement for “Never” Events Teleconference*, American Health Lawyers Association, 9/20/07.

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- 14 Fuhrmans, *Insurers Stop Paying for Care Linked to Errors*, WSJ, 1/15/08.
- 15 CMS Inpatient Prospective Payment System FY2008 Final Rule, 72 Fed. Reg. 47130 (August 22, 2007). Comments on HAC/POA sections of Final Rule.
- 16 Deficit Reduction Act of 2005, Section 5001(b).
- 17 U.S. Department of Health and Human Services Medicare Hospital VBP Plan Development, 1st Public Listening Session 1/17/07, p.4.
- 18 *Id.*, pp.5-6.
- 19 CMS Report to Congress, Medicare Hospital VBP Plan, p.11.
- 20 *Id.* pp. 9-10.
- 21 *Id.* p. 72.
- 22 *Id.* pp. 12-14.
- 23 *Id.* pp. 15-19.
- 24 *Id.* pp. 3-5.
- 25 *Id.* pp. 5-8.
- 26 *Id.* p. 8.
- 27 *Id.* p. 20.
- 28 *Id.* pp. 12-14.
- 29 *Id.* pp. 28-29. Covers CMS' review of the scant and inconclusive P4P research literature.
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- 31 *Id.* pp. 25-26.
- 32 CMS Report to Congress, Medicare Hospital VBP Plan, p. 33.
- 33 *Id.* p. 72.
- 34 *Id.*
- 35 Miller, p. 25 and 28.
- 36 CMS Report to Congress, Medicare Hospital VBP Plan, p. 33.
- 37 Miller, p. 25-26.
- 38 For state infection reporting: Maruca, William. *New CMS Policy on Preventable Injuries Teleconference*, Health Law Week, Hospital Litigation Reporter, and New York Health Law Update, 1/9/2008. For never events: Carroll, *CMS Proposal to Halt Payment for Never Events Teleconference*, American Health Lawyers Association, 9/20/07.
- 39 Hughes, John S., et al. "Identifying Potentially Preventable Complications Using a Present on Admission Indicator," *Healthcare Financing Review*. Vol. 27, No. 3, p. 64.
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- 41 Massachusetts General Statutes, Chapter 58 of Acts of 2006, Section 25-58.
- 42 Wagonhurst, Cheryl, and Janice Anderson, "Compliance and the Quality of Care Revolution," *Health Lawyers News*, Vol. 11, No. 9, September 2007, American Health Lawyers Association, pp. 20-21.
- 43 Maruca, William. *New CMS Policy on Preventable Injuries Teleconference*, Health Law Week, Hospital Litigation Reporter, and New York Health Law Update, 1/9/08.
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- 45 Wagonhurst, Cheryl, and Janice Anderson, "Compliance and the Quality of Care Revolution," *Health Lawyers News*, American Health Lawyers Association, Vol. 11., No. 9, p. 22.
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- 48 Dwyer, Sean. *New CMS Policy on Preventable Injuries Teleconference*, Health Law Week, Hospital Litigation Reporter, and New York Health Law Update, 1/9/08.
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- 51 The Rozovsky Group, *Risk Management Services Newsletter*, Vol. 3, No. 8, August 2007, www.therozovskygroup.com, p. 5-7.

PRACTICE GROUPS

Chair's Corner

Edward F. Shay, Esquire

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In my salad days as a young lawyer, I worked on legislative analysis during the 1971-1972 debate on national health insurance. National health reform has come and gone a few more times since then and, again, it seems to be a part of the current health policy discussion. Each time America has broached the question of comprehensive national health reform, a lesser formulation has emerged. Following the 1971-1972 debate, the Nixon Administration passed the Health Maintenance Organization Act of 1973, which became the beta for what we now call managed care. After the Clinton health reform initiative foundered in 1994, Congress enacted HIPAA in 1996, giving us portability, advisory opinions and, the oxymoron of the age, administrative simplification. I no longer attempt to predict the fate of national health reform, universal coverage, or its permutations; I believe, however, that as part of, or apart from, the upcoming national health reform dialogue, health information technology (HIT) will get a major push in the next legislative session.

HIT will transcend the fate of national health reform for two reasons. First, there is broad consensus across the political spectrum that HIT can add efficiency to the healthcare system. Whether HIT improves healthcare through fewer medication errors (e-prescribing) or through an envisioned public/private database to support development of provider performance measurement, it will be at the heart of developing a reformed healthcare system. HIT has become essential because it has become strategic. HIT is no longer just about a novel technology in healthcare; it is also about knowledge, and specifically, very strategic knowledge.

The HIT Practice Group is moving abreast of this industry trend. It has developed an affinity group on HIT's emerging uses. Our Emerging and Secondary Uses Affinity Group is on the bleeding edge of the leading edge of strategic health information solutions. I urge you to join this Affinity Group, contribute your insights and ideas, and help us keep the HIT Practice Group at the forefront of developments in healthcare.

For more information on how to join the Emerging and Secondary Uses Affinity Group, please see page 9.

Staying Safe in the Internet's Wild Wild West

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As more people search for health information online, having an effective Internet presence is becoming more important for healthcare providers and insurers alike. Although thorny questions are best left to intellectual property specialists, here are some general concepts health lawyers should think about as we advise our clients on the content of their websites.

I. What's in a [Domain] Name?

A company's domain name is its "front door" on the Internet, consisting of the second-level domain (the distinctive name), a "dot," and a top-level domain (TLD) such as org, com, or edu.¹ Although various U.S. government agencies initially played a role in organizing Internet names,² domain names are not registered with a government agency. The National Telecommunications & Information Administration has entered into agreements with the Internet Corporation for Assigned Names and Numbers (ICANN) to administer the domain name system.

The first step in setting up a website is to check availability of the desired domain name through a registration company dealing with ICANN. What if a registered trademark that your client has used for generations is unavailable for registration as a domain name? The Anticybersquatting Consumer Protection Act³ provides that a party that has registered a domain name that is identical or confusingly similar to a distinctive or famous mark can be liable to the trademark holder, but only if the registrant had a bad faith intent to profit from the name.⁴ Also, ICANN has adopted a Uniform Domain-Name Dispute Resolution Policy (UDRP). Under the UDRP, the complainant must show that (a) the domain name it complains of is identical or confusingly similar to a trademark or service mark in which the complainant has rights; (b) the domain name holder does not have legitimate interests in the domain name; and (c) the name was registered and is being used in bad faith.⁵

After your client has registered a domain name with ICANN, can it also register the domain name as a trademark? Yes—but as with any other trademark or servicemark, the applicant must show that the mark is associated with the owner's goods and services and is not merely descriptive. The Patent and Trademark Office has published an Examination Guide to assist

examining attorneys in applying these concepts to marks composed of domain names.⁶ In particular, the Examination Guide notes that the essence of the mark is created by the second-level domain name, not the TLD, and adding a TLD to a mark that is merely descriptive does not make it registrable.

II. Liability for Website Content

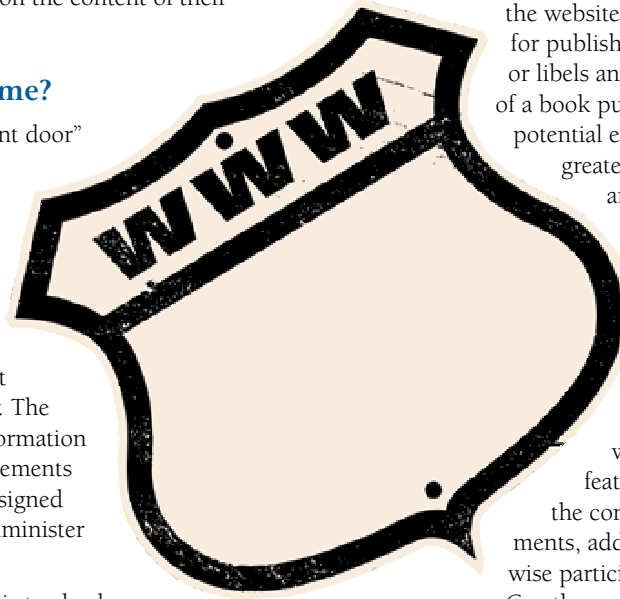
The owner of a website, like any other publisher, may be liable for false or misleading advertising, defamation or libel, or copyright or trademark infringement. In assessing risks in operating a website, it is important to understand the types of content that may be displayed, and how it is generated.

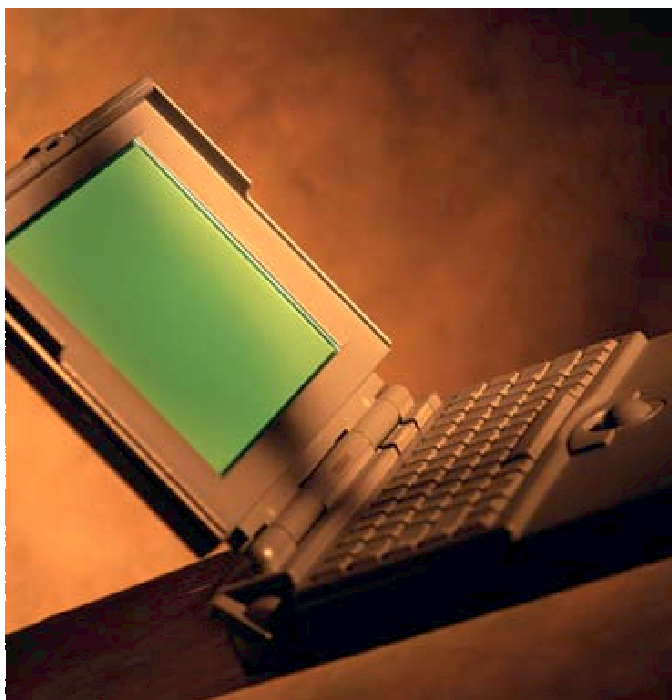
In a traditional website, all the content originates with the website owner. The site owner can be liable for publishing content that infringes copyright or libels another person, just like the author of a book published in Dead Tree Media. The potential exposure for web publishers is vastly greater because the Internet's ease of access and ability to link content on one site to another⁷ may lead to broader dissemination of offending content.

It is not very likely that our clients knowingly will publish content that infringes copyright or is defamatory. Many modern websites, however, contain "Web 2.0" features that allow users to interact with the content and publish their own comments, add links, upload pictures, and otherwise participate in the website "community."

Can the website owner be responsible for content contributed by an unrelated user? If the website owner does not allow users to self-publish items without review, but instead moderates comments and other user-supplied content, does the undertaking of that editorial function expose the website owner to liability?

Congress has recognized the value of the vibrant intellectual marketplace provided by the Internet and enacted laws to protect freedom of discussion in that forum. The Digital Millennium Copyright Act (DMCA)⁸ limits the liability of a "service provider" for infringing material placed by users on its system. The term "service provider" can include not only Internet service providers and hosting companies, but also companies that operate websites.⁹ Under the DMCA, a service provider is not liable for copyright infringement by a user who stores infringing material on a system controlled by the service provider as long as the service provider was unaware of the infringement and promptly removes the infringing material after notice of claimed infringement.¹⁰ The limitation on liability, however, applies only if the service provider has designated an agent to receive notices of claimed infringement, by filing the designation with the U.S. Copyright Office.¹¹





A website owner cannot be held liable for libel or defamation based on content posted to the website by a user. The Communications Decency Act of 1996 (CDA)¹² provides that a provider of an interactive computer service may not be treated as the publisher of any information provided by another information content provider.¹³ Many courts have held that this section affords immunity against suits seeking to hold a website owner liable for third-party content,¹⁴ while some take the more limited view that it merely bars claims for which publication is an essential element.¹⁵

Blogs, forums, wikis, and other interactive features frequently have administrative tools that allow the webmaster to either hold items submitted by site users for review or permit users to immediately self-publish. If the webmaster chooses to moderate comments and posts, does the assumption of this editorial function increase potential liability? To allay concerns that self-policing could increase liability exposure, the CDA included an immunity provision stating that no provider or user of an interactive computer service may be held liable for action taken to restrict access to material that the provider considers objectionable.¹⁶

III. Protection of User Information

Obviously, under the Health Insurance Portability and Accountability Act (HIPAA),¹⁷ a healthcare provider or health plan whose website contains any patient information (e.g., by allowing persons to register for appointments or displaying claims information) must protect the privacy and security of patient information. What about email addresses and other information submitted by persons who are merely subscribing to a newsletter or signing up for a class?

If the website has any section devoted to children, special procedures are required. The Children's Online Privacy Protection Act of 1998 (COPPA)¹⁸ prohibits a website that is "directed to children" thirteen years of age or younger from collecting personal information from a child without obtaining verifiable parental consent. In determining whether a website, or part of a website, is "directed to children," the Federal Trade Commission will consider its subject matter, visual or audio content, age of models, language or other characteristics, empirical evidence regarding audience composition, and whether the site uses animated characters or child-oriented activities and incentives.¹⁹ Websites subject to COPPA must: provide an online notice describing its website privacy practices; obtain parental consent before any collection, use, or disclosure of a child's personal information; provide reasonable means for a parent to review personal information collected from the child; not condition a child's participation in an activity on the child disclosing more personal information than is needed to participate in the activity; and establish reasonable procedures to protect the confidentiality, security, and integrity of personal information collected from children.²⁰ The Federal Trade Commission (FTC) enforces COPPA and reported in 2007 that it has brought eleven actions for violations of COPPA and collected more than \$1.8 million in civil penalties.²¹

In May 2000, the FTC presented testimony before the Senate Committee on Commerce, Science and Transportation urging adoption of legislation requiring privacy protection for websites, but no overall Internet privacy law has been adopted in the United States.²² When COPPA does not apply, website owners are not required under federal law²³ to post a privacy notice on their websites, although the practice is becoming increasingly common. This is due not only to industry self-regulation, but also to the international nature of the Internet. The European Union has adopted a directive protecting privacy of individual information,²⁴ and Canada has adopted the Personal Information Protection and Electronic Documents Act.²⁵

The electronic frontier presents a potpourri of legal issues involving intellectual property and individual privacy rights. It behooves us all to stay tuned as our historical legal frameworks are adapted to apply to new means of instantaneous communication.

1 By custom, the TDL *edu* is used by educational organizations (including many teaching hospitals), *org* is used by nonprofit organizations, *gov* for governmental entities, and *com* for businesses. There are now several other TDLs available, such as *info* and *mobi*.

2 The origins of the Internet's domain name system are described in a 1998 Statement of Policy issued by the U.S. Department of Commerce, available at www.ntia.doc.gov/ntiahome/domainname/6_5_98dns.htm.

3 Title III of P.L. 106-113, 113 Stat. 1501A-545 et seq.

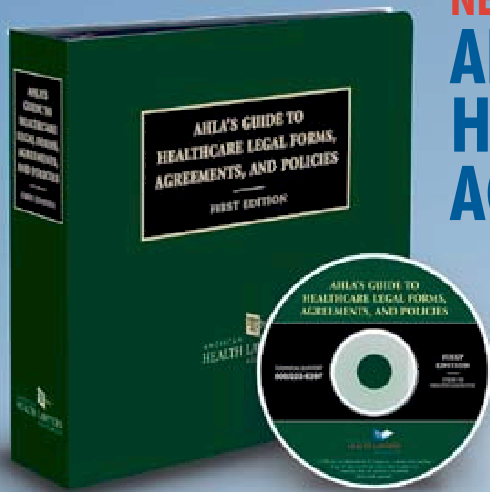
4 15 U.S.C. § 1125(d)(1)(A).

5 Uniform Domain Name Dispute Resolution Policy, available at www.icann.org/dndr/udrp/policy.htm.

6 U.S. Dept. of Commerce, Patent and Trademark Office, Examination Guide No. 2-99, (available at www.uspto.gov/web/offices/tac/notices/guide299.htm).

7 While the ability of one website to link to another is an inherent quality of the Internet, "deep linking" (i.e., linking to a page within a website rather than the home page) can be controversial. See, e.g., *Ticketmaster Corp. v. Tickets.com, Inc.*,

- 2003 U.S. Dist. LEXIS 6483 (C.D. Ca. 2003) (deep linking did not constitute trespass to chattels or violate display rights of copyright holder).
- 8 P.L. 105-304, 112 Stat. 2860 (Oct. 28, 1998).
- 9 *Corbis Corp. v. Amazon.com, Inc.*, 351 F. Supp. 2d 1090 (W.D. Wash. 2004).
- 10 17 U.S.C. § 512(c)(1).
- 11 17 U.S.C. § 512(c)(2). The Copyright Office has published a summary of the DMCA that describes its procedures for maintaining lists of agents (*available at* www.copyright.gov/legislation/dmca.pdf).
- 12 P.L. 104-104, 110 Stat. 56 (1996).
- 13 47 U.S.C. § 230(c)(1).
- 14 *See, e.g., Zeran v. America Online, Inc.*, 129 F.3d 327 (4th Cir. 1997).
- 15 *Chicago Lawyers' Committee for Civil Rights Under the Law, Inc., v. Craigslist, Inc.*, 461 F. Supp. 2d 681 (N.D. Ill. 2006). This opinion notes that the "near-unanimous" view appears to favor a broader grant of immunity as recognized in *Zeran* (461 F. Supp. 2d 681, 688-690).
- 16 47 U.S.C. § 230(c)(2).
- 17 P.L. 104-191.
- 18 P.L. 105-277, 112 Stat. 2681.
- 19 16 C.F.R. § 312.2.
- 20 16 C.F.R. § 312.3.
- 21 The FTC's report is *available at* www.ftc.gov/reports/coppa/07COPPA_Report_to_Congress.pdf. The enforcement actions included a \$100,000 settlement with Mrs. Fields Famous Brands, Inc. related to the cookie manufacturer's "birthday club."
- 22 The FTC's statement is *available at* www.ftc.gov/os/2000/05/testimonyprivacy.htm.
- 23 This article does not address whether there are circumstances in which HIPAA or the Gramm-Leach-Bliley Act (15 U.S.C. §§ 6801 et seq.) may require that the privacy notices required under those laws must be posted on an organization's website.
- 24 *Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data*, *available at* www.cdt.org/privacy/eudirective/EU_Directive_.html.
- 25 *Available at* <http://laws.justice.gc.ca/en/P-8.6/index.html>.



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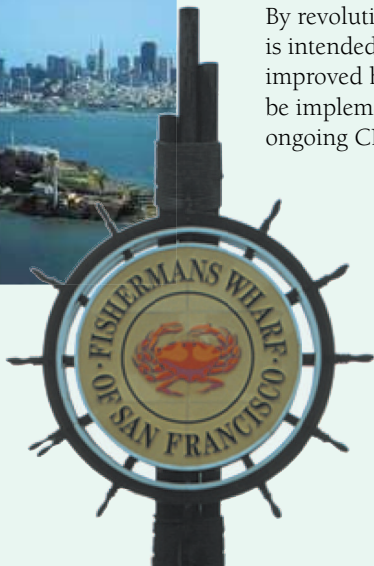


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Health Information and Technology *and* Teaching Hospitals and Academic Medical Centers Practice Groups Joint Annual Luncheon

On Monday, June 30, 2008, the Health Information and Technology *and* Teaching Hospitals and Academic Medical Centers Practice Groups will co-sponsor a luncheon at the 2008 AHLA Annual Meeting to be highlighted by a cutting edge presentation by David Sayen, Regional Administrator of the Centers for Medicare & Medicaid Services, Region IX.

Title: "Medicare 3.0"

In August 2006, President Bush signed an Executive Order to help make America's healthcare system more transparent. The President's Order has four cornerstones: advancing interoperable health information technology (HIT); measuring and publishing quality information to enable consumers to make better decisions about their care; measuring and publishing price information to give consumers information they need to make decisions on purchasing healthcare; and promoting incentives for quality and efficiency of care.

CMS is working with the Health and Human Services Department to identify and encourage standards that lower barriers to HIT adoption and interoperability. At Secretary Leavitt's direction, CMS is implementing a five-year demonstration project that will provide financial incentives to small- and medium-sized physician primary care practices that use electronic health records (EHRs) to improve the quality of care. By revolutionizing the way healthcare data is stored and managed, the EHR project is intended to help transform the way medicine is practiced and delivered, leading to improved health outcomes and greater patient satisfaction. This demonstration will be implemented in 12 communities across the country that are not already part of an ongoing CMS demonstration.

Presenter:

David Sayen

Regional Administrator of the
Centers for Medicare & Medicaid Services, Region IX
San Francisco, CA

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