

Digital Health Care Reform

Under the HITECH Act

By John Hazewinkel



Fast Facts:

Less than \$38 million of the approximately \$32 billion in electronic health record (EHR) incentives was distributed nationally by the first quarter of 2011.

In the same period, 32 Michigan hospitals and 1,581 eligible professionals applied for incentives from Medicare and Medicaid worth a potential \$71,233,000 in payments.¹

According to 2010 estimates by the Centers for Disease Control and Prevention, 24.7 percent of office-based physicians in Michigan use an EHR with basic features.²

Beneath the raging torrent of debate over the health reform goals of the Accountable Care Act, steady legal and policy currents are pushing the health care industry in new, information-technology-driven directions. Much of the change is due to the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009.³ Although HITECH is already more than two years old, its effects are just starting to ripple through the information technology and health care industries. The act accelerates bipartisan goals to promote adoption of electronic health records (EHRs) and other health information technology (HIT) tools to wring extra costs savings, efficiencies, and quality improvements out of the industry. Even if the goals are only partially realized, waves of change in health care will be felt in the economy and throughout the legal community in a sector that already exceeds 17 percent of the country's gross domestic product and continues to grow.

Chaos in the Paper Environment

The health care industry lags behind others in its use of information technology for its core business (clinical care), although it is used extensively for functions such as processing claims for payment. Paper charts are still the dominant media used for storing patient information. When HIT is used, it is often dedicated to specialized functions or has limited connections to outside data sources. It is not unusual, for example, for a hospital to have separate systems in its emergency, pharmacy, and orthopedic departments that are unable to communicate with each other or store patient information in a single location. Unrelated organizations often lack the means (and the will, for competitive reasons) to exchange data with each other even when they use the same HIT products. Patient information sometimes makes the journey to and from electronic form as it moves downstream. Laboratory test results may be stored in one system, faxed to the ordering physician whose staff may re-key the results into an EHR system, and later printed in a report to a referenced specialist, public health agency, or other entity.

As patient care increasingly becomes a team enterprise, especially for the chronically ill, the flow of information is just as critical as its form. Fragmentation of treatment and patient medical records results in unnecessarily repeated tests and procedures, adverse reactions to conflicting medications and allergies, emergency personnel who have little or no knowledge of the health histories of patients they're treating, and other costly and dangerous omissions. Knowledge gaps also apply to the science of medicine and the business of health care. The industry produces wide ranges in expenses and treatment outcomes—trends that do not necessarily correspond. To capitalize on HIT adoption for better care coordination, data must move between points of care (known as health information exchange or HIE) and between practitioners and researchers to discover the best, evidence-based medicine.

Meaningful Use

A major thrust of HITECH—and its largest economic impact—is the promotion of the “meaningful use” of EHR systems through financial incentives payable by Medicare (over a period of four years ending by 2014) and Medicaid (over a period of six years ending in 2021). The U.S. Department of Health and Human Services (HHS) released the final rules for the EHR Incentive Program on July 28, 2010.⁴ Eligible hospitals may receive a combination of payments from both programs with a potential value of up to \$11 million depending on complicated formulas. Eligible professionals under Medicaid, including physicians, dentists, certified nurse midwives, nurse practitioners, and physician assistants (PAs) practicing in a PA-led federally qualified health center or rural health clinic, may receive a maximum of \$63,750. Eligible professionals under Medicare, including physicians, dentists, podiatrists, optometrists, and chiropractors, may receive a maximum of \$44,000 (plus 10 percent if they practice in a designated professional shortage area). Medicare participants that do not meet the meaningful-use criteria by 2015 face statutory reductions in reimbursements. HHS estimates that the amount spent on Medicare and Medicaid incentives will range between \$10.9 and \$22.3 billion, although earlier Congressional Budget Office estimates put the figure as high as \$32.7 billion. Near the end of the first quarter of 2011, only slightly more than \$37.5 million had been spent. The swell of stimulus money will add to existing streams of public and private HIT funding, multiplying the investment.

To receive payments, eligible hospitals and professionals must meet specific meaningful-use requirements using EHR products that have been certified by federal government contractors. The meaningful-use requirements are rolling out in three stages with such gradually increasing requirements as capturing clinical data, reporting quality measures, and using automated clinical decision support tools. Eligible professionals must achieve a total of 25 meaningful-use objectives in the first stage, including 15 core requirements and 10 menu options, 5 of which must be selected. Eligible hospitals in the first stage have a total of 24 meaningful-use objectives. To qualify for an incentive payment, they must achieve 19 (including 5 of 10 menu requirements). Each objective has a measurement attached. For example, for e-prescribing in stage 1, more than 40 percent of all permissible prescriptions written by an eligible professional must be through e-prescribing. This increases to 50 percent in stage 2. Measures and mandatory objectives will ratchet up in future stages.



The final certification rule,⁵ issued on the same day, establishes a process for verifying that EHR products are capable of meeting meaningful-use criteria. Certification gives purchasers assurance about a basic level of performance while also creating a basis for comparing products. By default, the rule also cuts through the fog of incompatibility by steering vendors toward common technical standards. Syntactic, semantic, and security standards are especially important in developing software applications for an industry steeped in complicated medical vocabularies and heightened confidentiality concerns. The certification regulations specify which standards may be used for functions such as sending public health and quality reports, communicating medications and laboratory results, and encrypting data. Use of common standards still does not ensure interoperability, so HIT technology vendors continue to develop and demonstrate workable integration between products through efforts like “Integrating the Healthcare Enterprise” (see www.ihe.net). While the financial incentives will eventually recede, the program’s certification and standardization legacies will have worn away at least some of the barriers to HIT adoption and HIE.

Public Infrastructure Investments

The Office of the National Coordinator for Health Information Technology (ONC) was formally established by HITECH to serve as the focal point for the federal government HIT initiatives. In addition to managing committees that develop meaningful-use criteria, standards adoption, and policy recommendations, the ONC acts as a grant maker, dispensing funds from the \$2 billion authorized by HITECH for state HIE projects, regional extension centers designed to deliver EHR adoption and meaningful-use assistance to small primary-care providers, research grants for breakthrough HIT applications, demonstration projects, HIT training programs for community colleges, and curriculum development at universities and other projects. The ONC has even sponsored the creation of open-source software for basic HIE applications, trusted point-to-point exchange, and practice-level population analysis. HITECH funds have also been funneled through other departments to bolster public-health HIT capabilities, Medicaid systems, and other public-sector capabilities.

Administrative Standards

On top of the race to install clinical applications that meet meaningful-use standards, IT departments of health providers and insurers are facing another set of mandates from HHS. The administrative simplification provisions of the Health Insurance Portability and Accessibility Act of 1996 (HIPAA) are better known for their privacy and security rules. They also promulgated regulations governing transaction and code sets that govern the business and financial sides of health care. Transactions cover such items as claims, eligibility determination, and payments of insurance premiums. Medical data code sets help classify diagnoses

Syntactic, semantic, and security standards are especially important in developing software applications for an industry steeped in complicated medical vocabularies and heightened confidentiality concerns.

and inpatient hospital procedures, for example. In a rule published on January 16, 2009,⁶ HHS requires adoption of X12 Version 5010 and corresponding prescription standards for HIPAA transactions by January 1, 2012 (small health plans have until January 1, 2013). In a separate rule, HHS stipulates that covered entities adopt the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedural Coding System (ICD-10-PCS) for inpatient hospital procedure coding. The industry shorthand for these requirements is HIPAA 5010 and ICD-10.

Privacy and Security Concerns

At the same time HITECH promotes HIT use, it also raises consequences for HIT misuse, forcing health-industry participants to navigate a careful course. Since many lawmakers felt that HIPAA’s privacy rules had been too lightly enforced and that consumers needed more reassurance during the great HIT expansion, they significantly increased penalties and reporting requirements by amending HIPAA. Business associates—contractors with secondary access to protected health information—are currently governed by their agreements with covered entities (health care providers, health plans, and data clearinghouses). Under proposed regulations, they will be directly subject to most of HIPAA’s privacy and security rules.⁷ New breach notification rules⁸ in effect since September 2009 require that major breaches of confidentiality (involving 500 or more individuals) must be reported to the media. Breaches of fewer than 500 must be recorded in a log and annually reported to HHS. Current HIPAA rules require covered entities to provide patients a list (upon request) of all protected health information disclosures, but exempt information sent for routine payment, treatment, and health care operations. HITECH removed this exemption for disclosures made from EHRs. The act requires an accounting for the previous three years,⁹ challenging software developers to create communication logs for each patient. It also adds and amends several other rules in the HIPAA portfolio and extends enforcement beyond the HHS Office of Civil Rights by allowing state attorneys general to bring civil actions.

Secondary Use of Data

Despite these changes, several legal unknowns remain largely outside the sphere of HIPAA influence. The “secondary use of data” is one such frontier. This term applies to everything beyond the primary business use of delivering and receiving payment for patient services, including such diverse activities as biomedical research, public-health reporting, and proprietary marketing. Currently, analysts interested in medical content often contend with the laborious process of extracting information from paper charts or they make the most of electronic data from limited data sets or proxies such as payment claims. These sources frequently lack the sufficient granularity or breadth for intended purposes. EHRs enable data to be structured in discreet, common formats and create longitudinal profiles on patients. Researchers, quality improvement experts, and companies that market to medical providers are resisting legal efforts to restrain secondary use and argue for open access while privacy advocates and consumers (including many doctors) are pushing for greater restraints.

The United States Supreme Court will have a chance to wade into this controversy as it hears arguments concerning a case from the U.S. Court of Appeals for the Second Circuit.¹⁰ At issue is a 2007 Vermont law¹¹ banning the sale, transmission, and use of “prescriber-identifiable data” for the marketing of prescription drugs. Data-mining and aggregation companies, such as the original plaintiffs, purchase information from pharmacies that include the name and address of the prescribing physicians; the name, dosage, and quantity of the drug; and the patient’s age and gender. The companies compile and sort the information, then sell reports to pharmaceutical companies for targeted marketing to the prescribers, including personal-sales visits. The appeals court struck down the statute, overturning a lower court decision, on First Amendment grounds (as an unwarranted restriction on commercial speech). The decision sets up a conflict with the U.S. Court of Appeals for the First Circuit, which upheld similar laws in New Hampshire¹² and Maine.¹³

Courts and legislative bodies will likely revisit similar issues in coming years as the steady progress of HIT continues to push against boundaries of private and public interests. Consumers, who are largely unaware of how far their records currently travel outside their doctors’ offices, even in the paper system, will want reassurances that their most private and personal details will not end up in the wrong place on the Internet. Fears of embarrassment, job discrimination, and denial of health insurance will continue, as will the need to constantly seek systematic improvements in a health care industry that is just beginning its digital evolution. HITECH, on its own, may not deliver IT-led health reform, but it plots the course. ■



John Hazewinkel is a staff member with the Institute of Health Care Studies at Michigan State University. He focuses on health information technology policy, health information exchange, and IT-related health reform issues. He is a member of the SBM Health Care Law Section’s Substantive Law Committee and chairs its Technology Subcommittee. John is also an adjunct instructor in the MSU Master of Public Health program, teaching “Legal and Ethical Issues in Public Health Informatics.”

FOOTNOTES

1. Michigan Department of Community Health, Medical Services Administration.
2. Hsiao, Ph.D., Hing, M.P.H., Socey & Cai, M.A.Sci., Centers for Disease and Control and Prevention, *Electronic Medical Record/Electronic Health Record Systems of Office-based Physicians: United States, 2009 and Preliminary 2010 State Estimates* <http://www.cdc.gov/nchs/data/hestat/emr_ehr_09/emr_ehr_09.htm> [accessed June 11, 2011].
3. American Recovery and Reinvestment Act of 2009, PL 111-5, 123 Stat 115 (2009).
4. U.S. Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services, 75 Fed Reg 44314-44588 (July 28, 2010) (amending 42 CFR pts 412, 413, 422, and 495).
5. HHS, Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed Reg 44590-44654 (July 28, 2010).
6. HHS, Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standard, 74 Fed Reg 3296 (January 16, 2009) (amending 45 CFR pt 142).
7. HHS, Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act, 75 Fed Reg 40912 (July 14, 2010).
8. HHS, Breach Notification for Unsecured Protected Health Information, 74 Fed Reg 42740-42770 (August 24, 2009).
9. 42 USC 17935(c)(1).
10. *IMS Health v Sorrell*, 630 F3d 263 (CA 2, 2010).
11. *Vt Stat Ann tit 18 §4631* (2011).
12. *IMS Health Inc v Ayotte*, 550 F3d 42 (CA 1, 2008).
13. *IMS Health Inc v Mills*, 616 F3d 7 (CA 1, 2010).