

Stimulus Bill Implementation: Expanding Meaningful Use of Health IT

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ROB CUNNINGHAM, Consultant

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OVERVIEW — The American Recovery and Reinvestment Act authorizes an estimated \$38 billion in incentives and supports for health information technology (IT) from 2009 to 2019. After years of sluggish HIT adoption, this crisis-driven investment of public funds creates a unique opportunity for rapid diffusion of a technology that is widely expected to improve care, save money, and facilitate transformation of the troubled U.S. health system. Achieving maximal effect from the stimulus funds is nevertheless a difficult challenge. The Recovery Act strengthens the federal government's leadership role in promoting HIT. But successful adoption and utilization across the health system will also require development of a supportive infrastructure and broad-based efforts by providers, vendors, state-based agencies, and other health system stakeholders. Optimal use of IT for health care may require extensive reengineering of medical practice and of existing systems of payment. The future course of HIT adoption will also be subject to the effects of any health care reform legislation and of technological innovation in the fast-changing world of electronic communications.

National Health Policy Forum

2131 K Street, NW Suite 500 Washington, DC 20037

T 202/872-1390 **F** 202/862-9837 **E** nhpf@gwu.edu www.nhpf.org

Judith Miller Jones Director Sally Coberly, PhD Deputy Director Monique Martineau Publications Director A sis of 2008 brought years of cautious policy-making on health information technology to a sudden end with passage of the American Recovery and Reinvestment Act (ARRA, or the Recovery Act) early in 2009. Treating health IT as an infrastructure investment in future economic productivity, the Recovery Act authorized more than \$36 billion in incentives from 2009 to 2019 for doctors and hospitals to acquire and use electronic health record systems, and an additional \$2 billion to support them with loans, grants, training, and technical assistance. After much less ambitious IT bills had languished in Congress for years, the economic crisis precipitated a swift leap into uncharted territory.

For two decades, business, government, and clinical leaders have argued that greater use of information technology in health care could improve quality and reduce costs just as it has in other sectors of the economy. Even as computer speed and capacity have accelerated and use of the Internet has extended into almost all aspects of everyday life, adoption of clinical IT in the health sector has lagged behind hopes, expectations, and possibilities. In a 2007–2008 survey, only 4 percent of physicians in office-based practice reported having a comprehensive electronic records system, while another 13 percent reported having a basic system only.¹

Throughout these past two decades, champions of health IT have called for stronger government leadership in promoting and supporting adoption.² While some physicians have reported rapid improvements in efficiency and a positive return from their IT investments, other providers and policy analysts argue that the economic benefits of IT accrue largely to payers and consumers, while most of the costs are borne by providers, resulting in a cost-benefit imbalance that has discouraged private market support of IT use. Also, health IT implementation would have a widespread impact on society, making it appropriate for government to promote. Individuals would likely enjoy improved health care quality, public health goals would be supported, and the economic burden of excessive costs

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and cost growth would be eased—although estimates of expected savings from health IT are subject to debate.

On such grounds, President George W. Bush issued an executive order in 2004 creating the Office of the National Coordinator for Health Information Technology and setting a 10-year goal of putting an electronic health record (EHR) system in every hospital and doctor's office and providing an EHR for every patient. But the Bush administration eschewed major subsidies or mandates. Since then, voluntary public-private efforts to promote standardization and interoperability of IT products have intensified, but the rate of adoption has remained sluggish, especially in smaller physician practices. Most doctors reported financial concerns as the biggest roadblock, including both acquisition costs and ongoing technical support expenses and revenue lost to workflow disruptions.³

Democratic leaders in Congress had proposed larger subsidies for health IT prior to the 2008 elections, and the election of a Democrat to the presidency made such subsidies more likely. But the financial crisis of 2008 and the huge public spending legislation that ensued, the Recovery Act, upped the ante by an order of magnitude. Two titles of the ARRA, known together as the Health Information Technology for

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Economic and Clinical Health Act, or HITECH, created a 10-year, \$38-billion program of incentives and supports. The focus on health IT in ARRA was justified by the important role it is expected to play in reform of the health care system, and by the Act's larger purpose of investing in a technological infrastructure that will make the nation's economy more productive and competitive in the future. In fact, many health reform proposals being debated in 2009 envision that IT would play an important role in monitoring and improving health care quality, in laying a foundation for better payment systems, and improving on the poor coordination of care that is characteristic of the current delivery system.

This issue brief outlines the basic provisions of HITECH, its goals, and initial steps toward its implementation. It describes the process for defining criteria on which incentive payments will be awarded—the "meaningful use" of qualified health IT—and for developing common technical standards for insuring that patients,' payers,' and providers' information systems can "talk to each other." The brief also outlines plans to create a supportive infrastructure to provide

technical assistance and facilitate connectivity among IT users. In order to focus efficiently on HITECH implementation, this paper does not include detailed discussion of privacy and security, health system reform, or emerging innovations such as personal health records.

HITECH: THE BASICS

The HITECH provisions of the Recovery Act strengthen the government's leadership role in health IT in several ways. The Act brings the Office of the National Coordinator (ONC) into the Department of Health and Human Services (HHS) as a statutory office, rather than a discretionary agency as it was under the previous executive order. Similarly, new advisory committees that counsel ONC and the HHS Secretary on IT policy and standards are established in statute. The Recovery Act also requires ONC to define technical standards for approved IT systems and establish a process for certifying compliance with those standards. The process for setting technical standards for interoperable data exchange will conform to HHS rule-making procedures and have the force of regulation. Compliance with standards is still technically voluntary, as before, but is required in order to receive Medicare and Medicaid incentive payments to providers. The statute calls for ONC, in consultation with the Centers for Medicare & Medicaid Services (CMS) and the National Committee on Vital and Health Statistics (NCVHS), to define the criteria for "meaningful use" of health IT, which providers must meet to qualify for incentives. It also strengthens the IT privacy and security standards established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).⁵

Most notably, the Recovery Act authorizes an estimated \$36.5 billion in incentive payments to doctors and hospitals through Medicare and Medicaid between 2011 and 2019, as well as penalties for non-adopters. The Congressional Budget Office (CBO) estimates that these outlays will be offset by about \$17.1 billion as a result of provider penalties (\$3.9 billion) and savings from the use of IT (\$13.2 billion). Net spending, including \$2 billion for support programs operated by ONC, will total an estimated \$21.4 billion. However, maximum outlays depend on the amount of incentives that providers qualify for, which is uncertain. National Coordinator David Blumenthal has projected an upper bound for these outlays at \$45 billion. Individual physicians may receive a maximum of \$44,000

in incentives over five years.⁸ Hospitals are eligible for much larger payments, which depend on bed size and Medicare, Medicaid, and charity care volume. According to one estimate, a 500-bed hospital with average inpatient composition could receive \$6.1 million over the life of the HITECH program, and could be subject to up to \$3.2 million in penalties for non-adoption.⁹

The Recovery Act authorizes an additional \$2 billion for the Office of the National Coordinator. These funds are to be used to meet the

ONC's operating expenses, establish state loan and grant funds, support local and regional information exchanges, finance regional extension centers to provide technical assistance to smaller provider organizations, and support research and training of IT professionals. CBO estimates that the legislation will more than double the projected rate of health IT

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adoption from 2009 to 2014. Without ARRA, 40 percent of physicians and 25 percent of hospitals were expected to be using IT in the next five years. With it, those projected rates increase to 85 percent and 55 percent, respectively.¹⁰

The deadlines in the Recovery Act put CMS and the ONC under considerable time pressure. An interim final rule on the definition of meaningful use is due by December 31, 2009, to give vendors and providers time to develop and install systems that will qualify for incentive payments that begin in 2011. While some standards approved by HHS through the previous voluntary process are likely to be carried forward, they will have to be modified to fit HITECH requirements. Vendors are concerned about having enough time to develop products that meet new criteria for meaningful use. The end of 2009 is also the deadline for HHS to approve a basic set of technical standards incorporating specifications developed prior to HITECH. But National Coordinator Blumenthal has already suggested publicly that Congress may have underestimated the time it will take to implement the full scope of HITECH's requirements.¹¹

A TRANSFORMATIONAL TECHNOLOGY

Deliberations over the definition of meaningful use began soon after Blumenthal's appointment as national coordinator in March 2009. A two-day hearing of the National Committee on Vital and Health Statistics in April reflected both high expectations for health IT's

potential as a transformative influence in system reform and concerns about the difficulty of fostering adoption and connectivity.

The maximum potential of IT has been described in a variety of reports by the Institute of Medicine and others, and is based on the experience of integrated delivery systems and the Veterans Health Administration.¹² Comprehensive and standardized IT provides clinicians with clinical decision support systems including alerts and guidelines based on clinical research applicable to an individual patient. Lab and imaging results are readily accessible to doctors and patients. Automated order entry systems transmit physician orders to hospitals, clinical labs, imaging facilities, or pharmacies with minimal delay and reduced risk of human error. Automated reporting of quality measures enables systematic performance improvement and performance-based payment strategies. Compilation of disease registries allows providers to keep track of patient needs, issue alerts and reminders, and feed real-time disease surveillance data to public health agencies. An EHR system with a patient interface, or personal health record (PHR), may promote self-management, facilitate scheduling and prescribing, and serve as a two-way communications channel that can significantly reduce the need for office visits.¹³ Provider-to-provider interoperability supports care coordination between primary care providers, specialists, hospitals, and others. Taken together, these capabilities result in more appropriate, coordinated, and efficient care and better patient outcomes, according to a growing body of medical literature.14 Additionally, automated billing and claims processing, facilitated by HIPAA in 1996, promises to improve the efficiency of financial administration.¹⁵

But outside the world of integrated delivery systems where physicians and hospitals are part of a single organization, achieving this multiplicity of functions and interactions will present many difficult challenges. As stated earlier, health IT systems are expensive to buy and maintain, but the savings they achieve frequently appear to accrue to payers rather than the providers who must acquire them. Similarly, the benefits of improved care accrue to patients, while the burden of implementation, which entails the reengineering of clinical workflow, also falls on providers' shoulders. Linkages among the diverse parties involved in provision of care are beyond the power of individual providers to control. Some providers fear that detailed data about their clinical practices may be used against them in adversarial business relationships with insurers; and services avoided

by improved quality may mean loss of revenue for providers until payment systems begin to reward better patient outcomes. Efforts to establish local and regional health information exchanges have frequently been impeded by a reluctance to collaborate among stake-

holders who are more accustomed to competing than cooperating. All these factors help explain why adoption has been slow.

On the other hand, providers benefit too. If health IT can demonstrably improve the safety, quality, and affordability of care, it is difficult to justify a failure to adopt it, just as it would be difficult to justify con-

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tinued use of a discredited treatment. While difficult to measure, medication errors prevented and inappropriate treatment avoided represent high value for patients and clinicians alike. Successful adopters report decreased clerical costs, reduced office space needs, and higher revenues through improved "charge capture." Patient satisfaction and loyalty may be increased by more convenient scheduling, ready access to family medical records, and fewer redundant interviews and forms to fill out. Some experts report that patient portals or PHRs are becoming a competitive necessity in some markets, and that consumer demand will ultimately become the strongest force driving IT adoption.¹⁷

The difficulty of establishing robust health information exchanges (HIEs) represents a more tangible barrier than providers' cost-benefit calculations. The costs of launching and sustaining an HIE are too great for individual providers to bear, and yet the full benefit of their own IT investments cannot be realized without community-wide, and eventually nationwide, interoperability. Funding for support of HIEs in HITECH is limited. Yet these enterprises, like public utilities or the interstate highway system, might repay public investment many times over in the long run and justify further public support in the future.

DEFINING MEANINGFUL USE

Recognizing that all these capabilities can't be achieved at once, and that HITECH incentives cannot cover the full costs of adoption, witnesses at the NCVHS hearing shared the view that the definition of meaningful use should at first allow providers to be rewarded for use of a limited set of basic IT tools and functions. But the sense of the hearing was also that the criteria for meaningful use should become

increasingly comprehensive over time, so that IT does not fail to develop to its full potential. HITECH includes minimum specifications: some use of basic EHR technology including electronic prescribing; some form of information exchange with another data source or user; and some reporting on measures of clinical quality approved by the HHS Secretary.¹⁸ The ONC is charged with elaborating these.

To reconcile achievable short-term goals with the larger goal of transformation, the NCVHS report on its hearing emphasizes the need for a meaningful use definition that allows for multiple pathways from basic EHRs to "the ultimate goal of quality outcomes, health status improvement, and value/control of costs." The strategy of defining meaningful use in progressive phases and allowing multiple pathways from basic to complex systems was subsequently endorsed and adopted in principle by the ONC's Health IT Policy Committee. This committee, created by the Recovery Act, is charged with advising the national coordinator and the HHS Secretary on privacy and security, HIEs and other features of the IT infrastructure, workforce and training needs, and meaningful use. It is also charged with working in tandem with the Standards Committee, a sister group also created by ARRA, and helping to set its goals and priorities. The substitute of the standards committee, a sister group also created by ARRA, and helping to set its goals and priorities.

The Policy Committee's implementation scenario emphasizes capture of basic data in a coded format as an objective for 2011, including maintenance of a patient problems list, medication and allergies lists, vital signs, lab results, and demographic characteristics. Also expected in the first year of incentives are use of e-prescribing and ability to generate lists of patients by condition. Public comments on the Policy Committee's initial recommendations resulted in deliberations about the right balance between an aggressive timetable and requirements and the need to make meaningful use achievable. In response to the comments, for example, data exchange requirements were modified to recognize that providers could not achieve exchange where data-sharing partners lack IT capabilities. Thus qualifications were added to objectives for computerized order entry (CPOE), care coordination, and public health reporting.²²

By 2013, providers should be capable of computerized order entry, decision support at the point of care, and reports to external disease registries; and should be able to provide secure patient-provider messaging and produce care summaries during transitions, such as from hospital to post-acute or ambulatory care. By 2015, proposed

objectives include achieving target scores on selected quality measures, patient access to PHRs, and comprehensive data exchange among providers. But committee members acknowledged that aggressive patient outcome goals may not be achievable for providers who began the adoption process at low readiness levels or with limited resources.²³

Measurement strategies outlined by the Policy Committee in June and July of 2009 were straightforward. They were generally based on percentages of patients and procedures for whom electronic data were collected and used, as well as percentages of patients achieving recommended outcomes, such as patients with blood pressure, diabetes, or cholesterol under control or receiving recommended screening or preventive care. Again, balancing ambitious goals with realistic expectations was expected to be an ongoing challenge for policymakers. NCVHS witnesses also recommended that documentation of patient use of IT tools and provider participation in local or regional health information exchanges, where they exist, should also be considered among the indicators of meaningful use.

STANDARDS AND CERTIFICATION

The Recovery Act also requires the use of "qualified EHR technology" as a condition of receiving incentive payments. Defining "qualified" thus became a priority task for the Office of the National Coordinator, of equal urgency to the task of defining meaningful use. The ONC had an extensive body of experience in the pre-HITECH era in dealing with the processes underlying such qualification. In fact, since the creation of the ONC in 2004, a central emphasis had been placed on the development of technical standards for interoperable IT products and the certification of those products' conformity with the standards. In the absence of legislative mandates or significant government subsidies—that is, where IT policy was based on the assumption that market forces would drive adoption—the standards and certification procedures established under the Bush administration were thought to be the most efficient way to inspire providers' trust that certified products on the market would be of good quality and be able to "talk to each other" in common digital languages and formats that would enable automated communication.

The ONC and HHS Secretary contracted with two private groups to perform these functions. One was the Health Information Technology Standards Panel, or HITSP, which reviewed and harmonized existing nomenclatures and protocols for exchange of data between hospitals, doctors, pharmacies, clinical labs, and imaging centers. The Certification Commission for Health Information Technology (CCHIT) received a contract to test commercial products and vouch for their conformity with HITSP's recommended standards.

The HITSP/CCHIT process had its strengths and weaknesses, its critics and defenders. But with the government's stake raised dramatically by the size of the HITECH incentives, the Recovery Act restructured the framework for standards and certification, bringing both functions inside HHS and giving the standard-setting process the force of regulation. While not ruling out the possibility that HITSP—a large, multi-stakeholder collaborative—would continue to play an advisory role, the Recovery Act created the Health IT Standards Committee under the ONC to supervise the process. The committee began its work with a review of the strengths and shortcomings of the previous structure and a redefinition of the objectives of the process to maximize its usefulness to the HITECH agenda.

The pre-HITECH standards and certification process was credited with laying a foundation for product reliability. But it was faulted for not achieving the desired rate of accelerated adoption. More specifically, critics alleged that the process focused too much on products and not enough on functions.²⁴ The standards process was slow and cumbersome, they said, and certified products were often sold but not used and not user-friendly.²⁵ However, because of the tight implementation deadlines needed to put stimulus dollars to work without undue delay, Congress allows the ONC to make use of standards approved previously by the HHS Secretary. Pending recommendations from the Policy Committee, the Standards Committee established its priorities around a set of functionalities that mirror to a large extent the starter set of meaningful use functions identified in the NCVHS hearing. Existing standards for these functions will be the first that the committee seeks to revamp by its December 31 deadline. Public comments underscored the importance for many IT users of retaining previously established standards when possible for products already in use.

Committee members and the national coordinator are concerned about striking the right balance between standards that are consistent enough to be stable and predictable for vendors and providers, and yet not so rigid that they inhibit innovation and evolution. Critics of the Recovery Act warned of the effect the cumbersome HHS regulatory process might have on product development, and members of the Standards Committee also called for creating a process that is flexible enough to accommodate feedback from users that moves "faster than the full regulatory loop."²⁶ However, the ONC thus far has shown an ability to move quickly to meet HITECH deadlines; and observers note that the regulatory process does not necessarily entail delays, as in the CMS's timely annual updates of Medicare provider payment rates.

The committee also recognized the environmental pressures that might affect the adoption process, and the complexities of incorporating sophisticated electronic tools into clinical care. For example, beginning in 2011, providers submitting electronic reimbursement claims under HIPAA's administrative simplification rules will be required to begin using the new diagnostic codes from the World Health Organization's International Classification of Diseases, or ICD-10. The previous version of the system, ICD-9, is about 30 years old and has about 17,000 diagnostic codes. ICD-10 has 155,000. The changeover will require a new and expanded set of technical standards for automated transmission, to be implemented at the same time that CMS and the ONC are seeking to establish and verify providers' meaningful use of qualified EHR technology.²⁷

EXTENSION CENTERS

Analysis of the slow rate of IT adoption, especially in smaller provider organizations, has generally shown that in addition to financial obstacles, the technical capacity to adapt and maintain new systems is often lacking.²⁸ State- and foundation-supported programs have had some success in helping smaller physician groups overcome these challenges.²⁹ The HITECH legislation responded to the suggestions of "geek squad" advocates by authorizing the creation of a national network of regional extension centers to provide technical assistance and share best practices. The extension center concept is modeled on agricultural extension centers at state universities that have for many decades provided information and guidance to farmers on agricultural science and best practices. Funding for the IT centers will come from the ONC's \$2-billion discretionary budget and could amount to several hundred million in federal funds, to be

supplemented by matching funds from extension center sponsors and fee revenues.

Further details about program plans were spelled out in the Federal Register in May 2009. Groups that are organized as nonprofit, multi-stakeholder collaboratives with the capacity to leverage local resources will be preferred applicants for extension center contracts. Likely candidates include universities with informatics and health professions programs; professional societies; primary care coalitions; hospital, health center, and provider networks; Medicare quality improvement organizations; state and tribal agencies; public health agencies; libraries; consumer/patient groups; and local or regional health information exchanges.

The centers are meant to provide services for all areas of the United States, with one organization per defined geographical area, although the Federal Register notice acknowledges that intensive services will probably not be available everywhere. In some areas, the centers will serve merely as providers of information on health information exchange. Priority will be given to assisting groups serving uninsured, underserved, disadvantaged, and special-needs populations and to small provider organizations. Notably, the services of new extension centers supporting Medicaid providers may be eligible for reimbursement through Medicaid. HITECH also calls for the creation of a national research center to disseminate best practices through the extension program.³⁰

HEALTH INFORMATION EXCHANGES

The ONC's budget includes \$300 million to support the further expansion of local and regional health information exchanges, which were also a focal point of federal IT policy before HITECH. There were, in mid-2008, an estimated 55 to 60 HIEs in operation around the country, up from 20 a year and a half earlier. Another 42 were in the planning stages, according to a 2008 survey, and 34 HIE projects had ceased operations.³¹ While the level of activity has been impressive, financial sustainability has been a question mark for many projects. Moreover, the types of data that are being shared are in most cases limited, and sponsors have often been disappointed that initially narrow functionalities have not been expanded. Test results are the most frequently exchanged data type, followed by inpatient data and medication histories.

The new subsidies for HIEs and the opportunity for them to expand their scope by becoming extension centers may shore up these enterprises. Participating in HIEs, where they exist, will be a helpful path-

way to meaningful use for providers, creating an additional incentive that should help stimulate further HIE participation.

One constraint that the developing support infrastructure may face, according to some observers, is a technology workforce shortage. The ONC's discretionary budget under HITECH includes funds for training and workforce development, but the Although the level of activity in planning and operating health information exchanges has been robust, financial sustainability has been a question mark for many projects.

funds are limited and the lead time required to grow the workforce precludes instantaneous transformation. Technical support costs and workforce concerns underscore the need for technological innovations that might reduce the cost and complexity of next-generation EHRs. Web-based "software-as-a-service" applications are cited by some informaticians as a potentially cost-reducing framework for HIE that won't place insupportable technical demands on small organizations.³² In some scenarios, Web-based patient health record systems sponsored by Internet service providers like Microsoft and Google may also represent an opportunity for reducing future data management burdens on providers.

CONCLUSION

The ONC is gearing up swiftly to meet the policy and administrative challenges of implementing the HITECH provisions of the Recovery Act. Vendors and providers face many daunting tasks as they pursue the opportunity to qualify for incentive payments in 2011 and after. The ultimate success of HITECH in promoting IT adoption and use, however, may depend on factors outside the reach of the legislation. These include the provisions of any major health reform legislation that may come out of the 111th Congress.

The most salient of these environmental factors will be efforts to change payment strategies in both public and private insurance. Among the expected benefits of health IT are improved efficiency and reduction of unnecessary and inappropriate services. Fee-for-service payment rewards providers for service volume. Alternative payment strategies that reward providers for quality and efficiency

would strengthen incentives for IT adoption and contribute to meeting ongoing costs.

Technological change and health reform are the biggest wildcards in the environment. Internet service providers may be able to reduce costs and enhance connectivity as they have in many commercial applications. Personal health records may become an additional channel for connectivity between patients and providers and help generate demand for EHRs above and beyond the effects of financial incentives, driving the system to a point where electronic data exchange becomes a universally expected norm. Thus the ultimate goal of the incentives program is to make itself unnecessary. Reform measures could increase funding for IT adoption, and could also entail payment and delivery system changes that would make IT an indispensible part of 21st century medical practice.

ENDNOTES

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(endnote 5, continued)

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