

Health Information Technology for Economic and Clinical Health (HITECH) Act
Assessment of Key Provisions and Funding Allocations

From: Manatt, Phelps & Phillips, LLP
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Subject: Assessment of Health Information Technology for Economic and Clinical Health (HITECH) Act

Background

Last week, House committees began releasing a number of bills (divided along committee jurisdictional lines) as part of the House stimulus package which is also known as the American Recovery and Reinvestment Act (ARRA) of 2009. The ARRA allocates \$20 billion to expand adoption of health information technology (IT) through a combination of grants, loans, technical assistance programs, and Medicare and Medicaid incentives.

The appropriations section of the Bill was marked up in the House Appropriations Committee on Wednesday. It provides for \$2 billion in funding for health IT which is available until expended and \$250 million for the Office of the National Coordinator for Health Information Technology (ONC) for FY09.

On January 16, 2009, the Energy and Commerce and Ways and Means Committees released details of the ARRA which included more than 180 pages on specific health IT provisions (collectively referred to as the Health Information Technology for Economic and Clinical Health Act or "HITECH" Act). The Ways and Means Committee considered the Bill yesterday and did not substantively change the health IT section of the Bill.

The Energy and Commerce Committee marked up and approved the Bill. A few health IT amendments were adopted including technical amendments, a "Buy American" amendment, and an amendment that nothing shall prevent a pharmacist from collecting and sharing information with patients in order to reduce medication errors and improve patient safety, as long as any remuneration received for making such communication is reasonable and cost based.

In sum, the Bills (and related commentary) direct the Secretary of HHS to invest \$2 billion in health IT infrastructure programs for: (1) a health IT architecture that supports nationwide health information exchange (HIE); (2) development and adoption of certified electronic health records (EHRs), (3) training on and dissemination of best practices; (4) tools to promote telemedicine; (5) interoperable clinical data repositories and registries; (6) privacy and security efforts; (7) public health; and (8) regional or sub-national HIE efforts. Funds are to be channeled through the Office of the National Coordinator for Health Information Technology (ONC), Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ), the Centers of Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Indian Health Service.¹ It is anticipated that the remaining \$18 billion will be provided as health IT incentive payments to promote adoption of certified EHRs among practitioners, hospitals, and clinics through Medicare incentives and

¹ HITECH allocates \$250 million in fiscal year 2009 for ONC to support these activities.

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Medicaid programs. Further details on the funding amounts and policy parameters will likely emerge as it is marked up in the various committees and chambers. Funding amounts may change based on CBO scoring, with the possibility that funding for health IT infrastructure may rise from \$2 billion to \$5 billion, and funding for adoption incentives may fall from \$18 billion to \$15 billion. There may be other substantive changes as members are expected to offer health IT amendments and some of those amendments may be adopted.

The House is expected to consider and vote on the stimulus package next week. We expect companion Senate bills to be released shortly and the Senate is hoping to consider the package the week of January 26th.

Below are summaries of the policy parameters, funding details, and implications for stakeholders across the following key areas:

- Authorization and expansion of ONC
- Support mechanisms for health IT adoption
- New grant programs for HIE expansion and workforce development and new loan programs for EHR adoption
- Medicare incentives and Medicaid support for certified EHR adoption and use
- New provisions for privacy and security

ONC Codification and Expansion

HITECH codifies ONC's leadership role and directs ONC to continue maintaining the Federal Health IT Strategic Plan, provide reports and analyses on health IT, and advance the nationwide health information network. The policy framework and funding for the nationwide health information technology infrastructure provided under HITECH is presented as the first step in a multi-phase process. Within 12 months of enactment, the National Coordinator must submit to Congress a report on any additional funding or authority the National Coordinator or other bodies require to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information infrastructure that allows for the electronic use and exchange of health information.

As discussed below, HITECH also specifies new structures and authorities in the areas of policy and standards, privacy, and the ability of the National Coordinator to develop and operate an electronic health record (EHR).

National Health IT Policy and Standards

With respect to national policy coordination, HITECH identifies ONC as a "leading" member in creating and operating an "HIT Policy Committee," a newly created Federal Advisory Committee which will make recommendations to the National Coordinator for the prioritization and harmonization of standards, implementation specifications, and certification criteria needed for health IT use.

HITECH also modifies the existing health IT standards framework. HITECH directs the National Coordinator to lead the establishment and operations of a second, new Federal Advisory Committee, the "HIT Standards Committee." The HIT Standards Committee will recommend standards, implementation specifications, and certification criteria for the electronic exchange and use of health information to the National Coordinator. The HIT Standards Committee would

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also develop a schedule for the assessment of policy recommendations developed by the HIT Policy Committee.

The Act also empowers the National Coordinator to review and determine whether to endorse each standard, implementation specification, and certification criterion that is recommended by the HIT Standards Committee. Once endorsed by the National Coordinator, the Secretary of HHS will have 90 days to adopt or reject the proposed standards, implementation specifications, or certification criteria. Consistent with Executive Order 13410, all federal agencies (and private entities in contract with federal agencies) will be required to utilize health IT systems and products that meet the adopted standards and implementation specifications.²

While the proposed activities and composition of the HIT Policy Committee mirror many of the activities of the recently announced AHIC successor, the National eHealth Collaborative, HITECH clearly establishes a transition of authority back to HHS. HITECH requires the National eHealth Collaborative to transfer all functions, personnel, and assets to the HIT Policy Committee on the day before its enactment. The Bill leaves open the possibility that the National eHealth Collaborative may modify its charter and structure in a manner that permits the Secretary to recognize it as the HIT Policy Committee or the HIT Standards Committee.

HITECH also formulates a more active role for the National Institute of Standards and Technology (NIST) in the health IT standards process. NIST will (1) test standards, (2) create a conformance testing infrastructure, and (3) establish "Health Care Information Enterprise Integration Research" Centers to develop innovative approaches to health IT.³

Potential Implications: The Bill clearly reverses the direction the Bush Administration had taken in establishing the Healthcare Information Technology Standards Panel (HITSP), the Certification Commission for Health Care Information Technology (CCHIT) and the American Health Information Community (AHIC) in a public-private effort. According to the Act, policy development, standard-setting and certification will be done by government controlled advisory committees subject to the Federal Advisory Committee Act (FACA). Two important issues will need to be carefully followed.

First, the devil is in the details as to how the FACA committees are set up and whether, as advisory committees, they are able to link successfully the setting of policy and standards to the actual design and building of new, protocol-based interoperable systems. A legitimate concern is that that the advisory process becomes divorced from implementation realities and lessons.

Second, the Bill is silent on the issue of how the nationwide health information network will be governed, leaving it to the National Coordinator to establish a governance mechanism for the network. Conceivably, the governance mechanism for the nationwide health information network could be set up outside the FACA process.

With respect to NIST's activities, the creation of new Health Care Information Enterprise Integration Research Centers could provide an opportunity for institutions of higher education to work with and/or benefit from research in leading edge health IT fields.

² Signed August 22, 2006, Executive Order 13410, entitled "Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs" is available online at <http://edocket.access.gpo.gov/2006/pdf/06-7220.pdf>.

³ The Appropriations Report directs the Secretary of HHS to transfer \$20 million to NIST to support these activities.

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Health IT Privacy Leadership

In addition to the new privacy provisions outlined below, HITECH requires the HHS Secretary to appoint a Chief Privacy Officer not later than 12 months after its enactment. The ONC Chief Privacy Officer will advise the National Coordinator on privacy, security, and data stewardship of electronic health information and coordinate with privacy officers in other federal agencies, state and regional efforts, and foreign countries.

The Act also directs the newly created HIT Policy Committee to make specific recommendations to the National Coordinator for technologies that protect the privacy of health information and promote security in a qualified EHR, including the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns.

Potential Implications: In direct response to the GAO's and privacy advocates' criticism of ONC's privacy and security efforts, Congress proposes new mechanisms to address these issues. However, without a clear portfolio of projects and delineation of responsibilities with respect to other HHS offices that address privacy, it is unclear how influential and effective the position of ONC Chief Privacy Officer will be, especially without any jurisdiction or preemption authority over the many varied and often conflicting state law privacy and security requirements.

National Coordinators' Electronic Health Record (EHR)

After standards are adopted in 2009, HITECH allows the National Coordinator to make available an EHR "at a nominal fee" if HHS determines that the marketplace isn't substantially and adequately meeting providers' needs.

Potential Implications: Vaguely worded and open to significant interpretation, this provision would allow the Secretary to develop and operate a government-sponsored EHR. For enthusiasts of the EHR system developed by the Veterans Administration, this will be seen as an opportunity to increase support for the adoption of an open-source alternative to commercial software. The threat to commercially-available software is tempered by HITECH's provision that neither private nor government entities will be required to adopt or use the ONC-sponsored EHR.

Support for Health IT Adoption

HITECH calls upon HHS to establish a "Health Information Technology Extension Program" to provide technical assistance to help health care providers adopt, implement, and use certified EHR technology effectively.

The legislation directs the HHS Secretary to create a "Health Information Technology Research Center" that provides technical assistance and develops or identifies best practices to support and accelerate efforts to adopt, implement, and utilize health IT.

The research and findings from the Health IT Research Center will be distributed through a network of non-profit, regional extension centers called "Health IT Regional Extension Centers." Through a combination of HHS grants and local matching funds, each Health IT Regional Extension Center will focus its educational and technical assistance efforts on (1) public and

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non-profit hospitals, (2) federally-qualified health centers, and (3) rural or medically underserved areas.⁴

Potential Implications: Modeled after federal extension programs for agriculture and manufacturing, the Health IT Extension Program will be designed to reduce the barriers and cost of health IT implementation. This provision is likely to lead to a number of issues relating to the type, scope and capacity of the entities charged with developing best practices and providing technical assistance. Many not-for-profit organizations, ranging from QIOs, statewide health IT network policy and/or operations organizations, to health service organizations may elect to compete for funds to administer health IT extension programs. Depending on how structured it is, the extension program could compete with vendors that support the installation and integration of health IT products in practices and hospitals.

The extent to which this provision ties funding to support the implementation of EHRs with the emerging federal and state interoperability standards and networks is unclear. The Bill states that one of the objectives of the regional centers is to enhance and promote the adoption of health information technology through participation – to the extent practicable – in health information exchanges. How strong a tie will be required between adoption efforts and networks will depend on the strategy and funding rules adopted by the HHS Secretary.

New Grant Programs for HIE Expansion, EHR Loans, and Workforce Development

To accelerate the adoption and use of health IT, the legislation creates four new grant programs. Where the Secretary has discretion regarding the creation of a program, the program is noted as “*Optional*.”

State Grants to Promote Health Information Technology (*Required*)

HHS, through ONC, will create a program to offer planning and implementation grants to states or “qualified” state-designated non-profit, multi-stakeholder partnerships to “conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards.” In order to be eligible, states and entities must have a qualified plan and must consult with stakeholders. HITECH directs the HHS Secretary to invest \$300 million to support regional or sub-national efforts towards HIE.

During the first two years, HHS has the discretion to levy a matching requirement on the grants. Following the first two years of implementation, the HITECH *requires* states or the qualified entities to provide matching funds in order to receive a grant.⁵

Potential Implications: Because the Act does not specify the distribution of funding between HIE activities and other permitted grant activities, ONC has considerable discretion in the allocation of funds. Significantly, the Bill provides for both funding of planning activities and implementation activities, and it can be expected that the majority of available funds will support networks ready for implementation. The Bill also allows the Secretary to fund both states and state-designated entities, thereby explicitly recognizing that some states have elected to pursue statewide interoperability strategies through public-private

⁴ The Health IT Regional Extension Centers will receive federal funding for four years and require a 1:1 match.

⁵ Requirements for matching funds gradually scale up each year. In 2011, states or qualified entities must provide \$1 for each \$10 in federal funds. In 2012, the match moves to a ratio of \$1 in state funds for each \$7 in federal funds. Finally, 2013, the match is a ratio of \$1 in state funds for each \$3 in federal funds.

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partnerships, led by multi-stakeholder not-for-profit organizations that work in close collaboration with both state government and the private sector. This provision will mean that some significant projects receive immediate funding and will provide welcome financing for EHR adoption and HIE network projects that are ready for implementation grants. Additionally, there is an indication that Congress is open to providing additional funding for health IT infrastructure. HITECH specifically directs the National Coordinator to make annual recommendations on the federal, state and private investment required to achieve the policy goals.⁶

Competitive Grants to States/Tribes to Develop EHR Loan Programs (*Optional*)

HITECH allows the National Coordinator the option of creating a competitive program that would award grants on a matching basis to eligible states and tribes to create EHR loan programs. The money would be loaned to health care providers to purchase and enhance certified technology, train personnel, and improve the secure exchange of health information. The Act spells out a number of requirements regarding the use, administration, and allowable costs for the entities that manage the funds. The Secretary may not make an award under this program prior to January 1, 2010, apparently because House leadership wants to ensure that money is not spent on helping providers purchase health IT until after ONC has approved a set of standards and certified projects, which is to be completed by the end of 2009. Eligible entities must provide \$1 in matching funds for every \$5 in federal funds. The entity may receive donations from the private sector for the loan fund and may agree to reimburse the donating entity without interest. In accepting the loan, providers must agree to: (1) submit reports on quality measures; (2) improve the quality of health care, such as promoting care coordination; and (3) provide a plan for maintaining and supporting the EHR.

Potential Implications: The EHR loan program, even if the Secretary of HHS decides to create it, may not release funds until January 1, 2010. Apparently, the intention was to ensure that ONC first adopt standards and certify products before lending money to health care providers for the purchase of certified products.

With respect to interoperability, the Act does not specify how EHRs should integrate with health information exchange efforts. The Act requires the certified EHRs to be “connected in a manner that provides, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.” What qualifies as an exchange to improve the quality of care, what constitutes an eligible exchange of health information, and how such criteria would be determined are not defined and could be subject to widely varying interpretations.

Support the Development of Health Care IT Professionals (*Required*)

HITECH directs the HHS Secretary, in consultation with the Director of the National Science Foundation, to provide assistance in the form of matching grants to institutions of higher education to establish or expand medical health informatics education programs, including certification, undergraduate, and masters degree programs. The Act allows the Secretary to support up to 50 percent of a recipient’s total costs. Recipients may request a higher federal proportion of funding on the grounds that national economic conditions are such that they “would render the cost-share requirement detrimental to the program.”

⁶ HITECH authorizes funding through 2013, though the actual amounts will depend on appropriations.

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Demonstration Program to Integrate IT Into Clinical Education (*Optional*)

HITECH allows the HHS Secretary the option of awarding matching grants to academic institutions to develop curricula that integrate certified EHR technology in the clinical education of health professionals. Eligible academic institutions (e.g., school of medicine, graduate school of nursing) must submit to the Secretary a strategic plan for integrating certified EHR technology in the clinical education of health professionals to reduce medical errors and enhance health care quality. The Act allows the Secretary to support up to 50 percent of a recipient's total costs. Recipients may request a higher federal proportion of funding on the grounds that national economic conditions are such that they "would render the cost-share requirement detrimental to the program."

Medicare Incentives and Medicaid Support for Certified EHRs

HITECH provides significant financial incentives to encourage doctors and hospitals to adopt and use certified EHRs through the Medicare fee-for-service program and the Medicaid program.⁷ Healthcare practitioners and community and rural health centers will be eligible for additional payments for demonstrating that they are meaningfully using health information technology. Hospitals will be eligible for several million dollars in the Medicaid and Medicare programs to similarly use health IT.

To be deemed "meaningful" users, practitioners must (1) use a certified EHR, including the electronic prescribing features, (2) connect through HIEs to improve the quality and coordination of care; and (3) submit information on clinical quality measures.

Medicare Incentives

Incentive payments for both practitioners and hospitals continue for several years but are phased out over time. The Act specifies that the first payment year will be 2011. Again, the intention of the drafters may have been to allow the adoption of standards and certification to take place in 2009, purchase of certified products by providers in 2010, and full implementation and Medicare incentive provisions in 2011. The scale for incentives and payment reductions for healthcare practitioners is provided below.

Year	Maximum benefit per provider using certified EHR⁸	Total payment reduction for not using certified EHR
2011	\$15,000	0% reduction
2012	\$12,000	0% reduction
2013	\$8,000	0% reduction
2014	\$4,000	0% reduction
2015	\$2,000	0% reduction
2016	0	1% reduction
2017	0	2% reduction
2018	0	3% reduction

⁷ In addition, Medicare Advantage plans must implement the incentive programs for certain HMO-affiliated practitioners and hospitals.

⁸ These payments reflect the maximum amounts for first year payment for a practitioner who meets the requirements in 2011. Practitioners who elect to postpone adoption will receive their maximum first year allotment in the first year of implementation.

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For hospitals, the Act establishes a complex formula for calculating hospital incentives for certified EHR use. The annual incentive payment would be based on \$2 million plus a sizeable per-discharge amount, but hospitals would be paid only a pro-rated amount contingent on Medicare utilization and payments would be phased out over four years. Medicare payments will then be reduced in the out-years, beginning in 2016, for practitioners and hospitals that do not use certified EHRs, though the legislation does permit the Secretary to grant “significant hardship exceptions” to practitioners or entities, including those in rural areas.

Potential Implications: HITECH marks a significant departure in federal funding strategy. While the federal government to date has relied heavily on market forces for health IT adoption, HITECH offers practitioners and hospitals substantial federal incentives (and penalties) for EHR acquisition and implementation.

Subject to the fixed dollar caps noted above, a Medicare practitioner could earn an additional payment of 75 percent of what he/she would otherwise be paid by Medicare in a year.

Hospitals also stand to benefit greatly. A small community hospital could get several million dollars in incentive payments. Furthermore, the penalty beginning in 2016 is significant -- by 2018, hospitals would lose 75 percent of their market basket update, a painful proposition for hospitals with high Medicare utilization.

As noted above, the Act does not specify how EHRs should integrate with health information exchange efforts. The Act requires the certified EHRs to be “connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.” What qualifies as an exchange to improve the quality of care, what constitutes an eligible exchange of health information, and how such criteria would be determined are not defined and could be subject to widely varying interpretations.

Medicaid Program

HITECH allows state Medicaid programs to support the costs for acquiring, implementing and supporting certified EHRs for certain Medicaid providers, including eligible professionals, federally qualified health centers, rural health clinics, and children’s and acute care hospitals. It provides full federal funding, or a 100 percent matching rate, for state expenditures under this provision.

HITECH defines Medicaid providers eligible for EHR funding as follows:

- eligible professionals (including physicians, nurse mid-wives, and nurse practitioners) who are not hospital-based and have at least 30 percent of the their patient volume attributable to individuals who are receiving medical assistance. To receive Medicaid funding, professionals must waive payment under Medicare for EHR adoption and support;
- children’s hospitals;
- other acute care hospitals that have at least 10 percent patient volume attributable to individuals who are receiving medical assistance; and

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- federally-qualified health centers or rural health clinics that have at least 30 percent of their patient volumes attributable to individuals who are receiving medical assistance.

Medicaid providers and eligible professionals may receive up to 85 percent of allowable costs for EHR technology and support services. Allowable costs for eligible professionals are up to \$25,000 for purchase and initial implementation of a certified EHR and up to \$10,000 annually for up to five years for maintenance and operation. In aggregate, an eligible professional may receive up to 85 percent of \$75,000 over a five year period.

For hospitals, the Act caps Medicaid allowable costs at the product of the overall hospital health IT amount for the hospital computed by the HHS Secretary under the Medicare provisions and the Medicaid share for such hospital.

For clinics, allowable costs will be subject to a cap established by the Secretary, who will also ensure coordination of various EHR funding streams to assure no duplication of funding.

In order to qualify for federal financial participation, a state must demonstrate to the satisfaction of the HHS Secretary that it: (1) tracks Medicaid providers' usage of systems; (2) provides adequate program oversight; and (3) pursues initiatives to encourage the adoption of certified EHRs to promote health quality and exchange of health information.

Privacy and Security of Personal Health Information

HITECH expands current federal privacy and security protections for health information by: (1) extending the reach of HIPAA to a broader range of organizations handling such information; (2) mandating notification to individuals and government agencies in the event of security breaches; (3) expanding individual rights currently afforded under HIPAA; and (4) toughening HIPAA's civil penalties. Key privacy requirements imposed by HITECH include the following:

- Business associates are directly subject to the HIPAA Security Rule and the restrictions on the use and disclosure of protected health information contained in the Privacy Rule. Under existing law, those obligations are imposed on business associates only under contracts with covered entities. Business associates may now be subject to civil or criminal penalties for violating these HIPAA requirements.
- HIPAA covered entities must notify affected individuals and HHS of security breaches involving health information that is not encrypted or otherwise made indecipherable. The definition of a breach, the content of the notice and the method of delivery contained in HITECH are similar to comparable provisions in state breach notification laws. However, HITECH contains an unusual provision requiring covered entities to notify "media outlets" if a breach affects more than 500 individuals. Currently, HIPAA requires covered entities to mitigate the potentially harmful effects of improper disclosures but there is no express obligation to notify affected individuals. The breach notification obligations are also imposed on personal health record vendors, even if they are not covered entities under HIPAA.
- Covered entities are required to honor a request by an individual to withhold protected health information from a health plan if the individual pays for the medical care in full.

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Under existing HIPAA regulations, covered entities must consider such requests but do not have to grant them.

- If a covered entity maintains an electronic health record, it must allow patients to request an audit trail showing all disclosures of their health information made for treatment, payment or health care operations. These disclosures are currently exempt from HIPAA's accounting of disclosures requirement. If a covered entity maintains an electronic health record, individuals must also be given the right to a copy of their information in electronic form.
- Covered entities are prohibited from receiving remuneration for making communications about their products and services without patient authorization, even if these communications fit within an exception to HIPAA's exception to the prohibition on marketing. This provision could affect, for example, communications about drugs that are made by or on behalf of physicians or pharmacies but are financially supported by pharmaceutical companies.
- Employees of covered entities or other individuals who knowingly access, use or disclose protected health information for improper purposes will be subject to criminal penalties. The authority of prosecutors to criminally charge such individuals (who are not covered entities themselves) has been the subject of debate since HIPAA was enacted.
- Civil penalties under HIPAA are increased on a tiered scale based on the nature of the covered entity's conduct. The maximum penalty for an offense is up sharply to \$50,000 per occurrence and \$1.5 million per year. The federal government must impose penalties if the violation was the result of willful neglect. State attorneys general are authorized to seek civil penalties. The GAO is directed to develop recommendations for permitting affected individuals to share in penalties that are collected by government agencies.
- HHS is directed to study whether and how HIPAA should be expanded to organizations handling protected health information that are not currently covered entities.

Potential Implications: A wide range of vendors will be directly subject to HIPAA for the first time, raising their risk of non-compliance and necessitating heightened privacy compliance initiatives. The prospect of substantially heightened civil penalties and reduced HHS discretion to settle violations without payment raise the stakes of non-compliance for covered entities and business associates, especially when there is willful neglect. Security breaches are more likely to become public and generate greater financial and reputational risks. EHR vendors and their customers will have to evaluate whether their systems are capable of generating the audit trails required by HITECH.