



BNA, INC.

HEALTH IT LAW & INDUSTRY



REPORT

Reproduced with permission from Health IT Law & Industry Report, 1 HETR 20, 11/09/2009. Copyright © 2009 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

HITECH's State Health Information Exchange and Health IT Extension Programs: Providing Infrastructure and Support for Meaningful Use of EHRs

BY WILLIAM S. BERNSTEIN, HELEN R. PFISTER, AND
SUSAN R. INGARGIOLA

Few disagree that the quality and efficiency of the U.S. health care system could be improved. The nation's lead federal agency for research on health care quality, costs, outcomes, and patient safety, the Agency for Healthcare Research and Quality has reported on progress and opportunities for improving health care quality each year since 2003, and according to last year's report, "health care quality is suboptimal and continues to improve at a slow pace."¹

Fewer still deny the enormous potential of health information technology ("health IT") to improve patient care and make the health care system more transparent and, by extension, more efficient. More Americans die each year from preventable medical errors than from AIDS or breast cancer.² Further, while substantial in-

vestments have been made in clinical research and development over the last 30 years, resulting in an enormous increase in medical knowledge, a significant lag exists before physicians incorporate this knowledge into their care.³ Use of electronic health records ("EHRs") and other health IT tools can help prevent these medical errors and reduce this lag.

In February 2009, as part of the federal stimulus package, Congress enacted the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which included a number of provisions designed to encourage the adoption and use of health IT tools, including EHRs, and the development of a health information exchange ("HIE") infrastructure. In scoring HITECH, the Congressional Budget Office confirmed the benefits of health IT, finding that "adoption on a nationwide basis would reduce total spending on health care by diminishing the number of inappropriate tests and procedures, reducing paperwork and administrative overhead, and decreasing the number of adverse events resulting from medical errors."⁴

In the months since HITECH's enactment, much has been written about the law's Medicare and Medicaid EHR adoption incentive programs. These programs, which will provide approximately \$46.8 billion in incentive payments for health care providers that adopt and engage in "meaningful use" of EHRs, are designed to eliminate the affordability barrier that has hindered

¹ Agency for Healthcare Research and Quality. U.S. Department of Health and Human Services. National Health Care Quality Report 2008. March 2009.

² Institute of Medicine, To Err Is Human: Building a Safe Health System (1999).

Bernstein is Chair of the Health Care Division at Manatt, Phelps & Phillips LLP. Pfister is a partner at Manatt, Phelps & Phillips LLP and Ingargiola is a manager at Manatt Health Solutions. Bernstein may be contacted at wbernstein@manatt.com; Pfister may be contacted at hpffister@manatt.com; and Ingargiola may be contacted at singargiola@manatt.com.

³ E.A. Balas and S.A. Boren, Managing Clinical Knowledge for Health Care Improvement, in IMIA Yearbook of Medical Informatics 65-70 (2000).

⁴ Congressional Budget Office. Cost Estimate. H.R. 1. American Recovery and Reinvestment Act. As Introduced in the House of Representatives on January 26, 2009. Released January 26, 2009.

EHR adoption.⁵ However, in less widely publicized sections of the law, Congress also allocated \$2 billion to two supporting programs, the State Health Information Exchange Program and the Health IT Extension Program, which will be integral to the ability of health care providers to meet the meaningful use requirement. This article describes these two important programs, reports on their current status, and identifies key issues to be addressed as they move forward.

I. Background on Meaningful Use

As noted above, HITECH ties a health care provider's receipt of Medicare and Medicaid EHR incentive funds to "meaningful use" of a certified EHR system. More specific parameters for "meaningful use" will be established in regulation, but under the HITECH statute, "meaningful use" must encompass at least the following requirements:⁶

- The electronic exchange of health information to improve the quality of health care, such as care coordination.
- Electronic prescribing (does not apply to hospitals).
- Submission of information to the U.S. Department of Health and Human Services ("HHS") on clinical quality measures and such other measures as selected by HHS.⁷

In requiring that providers demonstrate meaningful use, Congress recognized that widespread adoption of EHRs will yield little benefit to patients if providers do not use them in a way that facilitates better care, provided more efficiently. Both the Health IT Extension Program and the State HIE Grant Program are designed to enable health care providers to meet meaningful use requirements.

II. Health IT Extension Program

A. Overview

To address barriers to EHR implementation and use faced by many health care providers, particularly small practices and safety net providers who serve the underserved, HITECH established the Health Information Technology Extension Program (the "Extension Program"), which provides grants for the establishment of Health Information Technology Regional Extension Centers ("Regional Centers") that will offer technical assistance, guidance, and information on best practices to support and accelerate health care providers' efforts to become meaningful users of EHRs. Regional Centers will provide assistance to a minimum of 1,000 priority primary care providers in the first two years of the Program. The Extension Program will also establish a na-

tional Health Information Technology Research Center ("HITRC"), which will gather relevant information on effective practices from a wide variety of sources across the country and help the Regional Centers collaborate with one another and with relevant stakeholders to identify and share best practices. Key facts about the Extension Program are provided below.

- **Grant Award Mechanism:** Cooperative agreements through a competitive process managed by the Office of the National Coordinator for Health IT ("ONC").
- **Regional Center Eligibility Criteria:** Applicants must be a U.S.-based, nonprofit institution or organization or group thereof. ONC anticipates that potential applicants will represent various types of nonprofit organizations and institutions with established support and recognition within the communities they propose to serve.
- **Expected Number of Regional Centers:** 70 or more, each serving a defined geographic area.
- **Funding:** Approximately \$598 million will be made available in the Program's first two years and \$45 million in the Program's last two years. Awards are expected to be between \$1 million and \$30 million per Regional Center. Awardees will be responsible for 10 percent of the annual capital and operating and maintenance funds needed to operate a Regional Center in the first two years of the Program and 90 percent in the final two years.
- **Length of Program:** Four years, after which the Program is expected to be self-sustaining.
- **Priority Providers:** Regional Centers may serve all providers, but must give priority to clinicians providing primary care services in individual and small group practices (fewer than 10 clinicians with prescriptive privileges), public and critical access hospitals, federally qualified health centers, and other settings that predominantly serve uninsured, underinsured, and medically underserved populations. Among other things, Regional Centers will assess the health IT needs of prioritized providers, and assist them in selecting and negotiating contracts with health IT vendors or resellers, including designing group purchasing plans to leverage volume discounts.
- **Services to Be Provided:** In addition, among other things, Regional Centers will provide assistance in:
 - Achieving effective implementation of a certified EHR product;
 - Enhancing clinical and administrative workflows to optimally leverage an EHR system's potential to improve quality and value of care, including patient experience as well as outcome of care; and
 - Observing and complying with applicable legal, regulatory, professional, and ethical requirements to protect the integrity, privacy, and security of patients' health information.
- **Evaluation:** The performance of each Regional Center will be evaluated every two years by an HHS-appointed panel of private experts.

B. Program Status

Program funding will be available in three cycles. ONC released a Funding Opportunity Announcement for the first cycle of Regional Center awards on August 20, 2009. Preliminary applications were due by Septem-

⁵ See estimate released May 2009 by the U.S. Department of Health and Human Services, available at <http://www.hhs.gov/recovery/index.html>. See also the CMS ARRA Implementation Plan, available at http://www.hhs.gov/recovery/reports/plans/hit_implementation.pdf and the ONC Implementation Plan, available at http://www.hhs.gov/recovery/reports/plans/onc_hit.pdf. Note that this estimate is significantly larger than the Congressional Budget Office's official score of the ARRA conference agreement, which was released February 13, 2009.

⁶ According to the statute, state Medicaid agencies "may" base their requirements for provider demonstration of meaningful use on the requirements set out in the statute.

⁷ See Pub. L. No. 111-5, div. B, §§ 4101(a), 4102(a).

ber 8, 2009. Final applications were due by November 3, 2009. Awardees will be selected on December 11, 2009. Preliminary applications for the second cycle will be due by December 22, 2009, with full applications due by March 2, 2010, and awardees selected April 27, 2010. Preliminary applications for the third cycle will be due June 1, 2010, with full applications due by August 3, 2010, and awardees selected by September 28, 2010. ONC expects Regional Centers to be largely self-sustaining by the end of December 2012.⁸

C. Supporting Meaningful Use: Key Questions

While the Extension Program's goals are ambitious, they are integral to the ability of health care providers to demonstrate meaningful use of their EHRs. For this reason, and because of the impact the Program could have on the EHR marketplace, stakeholders will be monitoring the Program's implementation closely, watching for answers to a number of key questions. These include whether and to what degree Regional Centers will facilitate EHR group purchasing arrangements on behalf of the health care providers to whom they are providing support; whether the support provided by Regional Centers will obviate the need for the type of technical support traditionally provided by EHR vendors; how and to what degree implementation of the Program will be coordinated with state Medicaid agencies' administration of the Medicaid EHR incentive payments; and, ultimately, whether the Regional Centers will be able to successfully recruit a critical mass of providers to the Program and enable their meaningful use of EHRs.

III. State HIE Grant Program

A. Overview

As noted above, meaningful use requires that health care providers engage in the "electronic exchange of health information." To spur the development of the infrastructure necessary to allow such exchange, HITECH established the State HIE Grant Program (the "State HIE Program") to provide grants to states and qualified state-designated entities to "facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards." Key facts about the State HIE Program are provided below.

- **Grant Award Mechanism:** Cooperative agreements through a noncompetitive process managed by ONC.
- **Funding:** \$564 million. Awards may be no less than \$4 million and no more than \$40 million.⁹ Increasing match requirements will be required of states beginning in fiscal year 2011 and beyond as follows:

Fiscal Year of Funding	Match Required
2010	None
2011	\$1 for each 10 federal dollars
2012	\$1 for each 7 federal dollars
2013	\$1 for each 3 federal dollars

- **Length of Program:** Four years.
- **Eligible Entities:** States or State Designated Entities or consortia thereof.
- **Expected Number of Awards:** Approximately 50, though this number is dependent on the number of multistate applications submitted.
- **Program Requirements:** States must develop and implement Strategic and Operational Plans outlining a comprehensive set of actions that will facilitate development of statewide HIE. Plans must be approved by ONC and will serve as tools for states and ONC to monitor, communicate, and track progress under the State HIE Program.
 - A Strategic Plan must address a state's vision, goals, objectives, and strategies for statewide HIE development, including any plans to support provider health IT adoption. The Plan must address the five "domains" identified by ONC: 1) governance; 2) finance; 3) technical infrastructure; 4) business and technical operations; and 5) legal and policy. An Operational Plan must explain how a state's Strategic Plan will be executed, including the specific actions and roles of various stakeholders, descriptions of any existing/ongoing HIE implementation activities, and an explanation of how existing activities will fit into the state's future plans for HIE.
 - Participating states will be expected to use their authority and resources to develop and implement up-to-date privacy and security requirements for HIE; develop directories and technical services to enable interoperability within and across states; coordinate with Medicaid and state public health programs to enable information exchange and support monitoring of provider participation in HIE; remove barriers that may hinder effective HIE, particularly those related to interoperability across laboratories, hospitals, clinician offices, health plans, and other health information exchange partners; ensure an effective model for HIE governance and accountability is in place; and convene health care stakeholders to build trust in and support for a statewide approach to HIE.
 - Among others, states are to develop the following HIE services: electronic eligibility and claims transactions; electronic prescribing and refill requests; electronic clinical laboratory ordering and results delivery; electronic public health reporting (i.e., immunizations, notifiable laboratory results); quality reporting; prescription fill status and/or medication fill history; and clinical summary exchange for care coordination and patient engagement.
- **Program Evaluation:** ONC will conduct a national-level program evaluation, working with grant recipients to implement lessons learned and to continuously improve the State HIE Program, as required under HITECH. Grant recipients are required to report on certain performance mea-

⁸ Office of the National Coordinator for Health Information Technology. U.S. Department of Health and Human Services. Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program. Funding Opportunity Announcement and Grant Application Instructions. Released August 20, 2009.

⁹ The State HIE Cooperative Agreement Program Funding Opportunity Announcement states that the \$4 million award floor applies to states, the District of Columbia, and the Commonwealth of Puerto Rico. The amount for remaining Territories will be determined based on population size and needs.

tures and other requirements. ONC has indicated it will provide additional guidance on required reporting in the future.

B. Program Status

ONC released a Funding Opportunity Announcement soliciting applications under the State HIE Program on August 20, 2009. Applications were due on October 16, 2009. ONC is currently in the process of reviewing applications and intends to announce awards in December 2009. ONC anticipates that programs should begin in early 2010.

C. Supporting Meaningful Use: Key Questions

Like the Extension Program, the State HIE Program is integral to health care providers' ability to use their EHRs meaningfully. Designed to build the infrastructure upon which providers may exchange health information at the point of care, the State HIE Program yields a number of questions on which stakeholders will be focused in the coming months. These include questions about the types of technical architectures states will employ to enable HIE and how they will be recon-

ciled into a national health information network; whether ongoing demand for HIE services will materialize and thus provide a sustainable business case for HIE, in support of HITECH's meaningful use requirements and otherwise; what policies states will implement to ensure the privacy and security of patients' health information and how they will relate to any emerging federal standards; and what types of clinical use cases states will employ to demonstrate improvements to clinician workflows.

IV. Conclusion

Health IT has the potential to diminish inappropriate tests and procedures, reduce paperwork and administrative overhead, and decrease medical errors, resulting in improved health outcomes for patients. In buttressing the Medicare and Medicaid EHR incentive programs with the Health IT Extension and State HIE Programs, HITECH has heightened the chances that its investment in health IT will lead to true improvements in the quality and efficiency of the U.S. health care system.