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Health Information Technology: Key Committees and Agencies Race Forward with Implementation of Stimulus Mandates Relating to Health IT

This alert discusses important developments in the implementation of the health information technology (HIT) provisions of the American Reinvestment and Recovery Act of 2009 (ARRA), including inaugural meetings of the HIT Policy and Standards Committees, as well as the release of HIT implementation plans by the Office of the National Coordinator for Health Information Technology (ONCHIT) and the Centers for Medicare and Medicaid Services (CMS). These developments have implications for a wide range of health care stakeholders—including pharmaceutical and device manufacturers, physicians and hospitals—and present numerous upcoming opportunities for public comment and stakeholder input.

Implementation of the HIT provisions of ARRA is underway and proceeding rapidly, in large part because of ambitious deadlines Congress set when drafting the legislation. As has been widely reported, the portion of the ARRA known as the Health Information Technology for Economic and Clinical Health Act (HITECH Act) provided \$19 billion to support HIT adoption efforts over the next five years.¹ While the legislation demonstrates a clear commitment from both Congress and the Obama Administration to implement national HIT initiatives, it left many of the specifics to be determined through regulations promulgated by the U.S. Department of Health and Human Services (HHS). To facilitate and coordinate these efforts—and to do so within the aggressive timelines mandated in the statute—Title XIII of the ARRA established within HHS the ONCHIT, as well as two advisory committees, the HIT Policy Committee and the HIT Standards Committee.

¹ For more information on the HITECH Act, see the Sidley Healthcare Privacy Update issued on February 19, 2009: “Congress Significantly Expands Federal Laws Regarding Privacy of Health Information and Electronic Medical Records and Adds Substantial Medicare/Medicaid Incentives Tied to Electronic Health Records,” available at http://www.sidley.com/healthcare_privacy_update021909/.

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HIT Policy and Standards Committees

In April 2009, the Obama Administration appointed David Blumenthal to head ONCHIT as the National Coordinator for HIT. A few weeks thereafter, Blumenthal announced the appointed membership of the HIT Policy and Standards Committees established in the HITECH Act and the dates of each committee's first meeting. The Policy Committee conducted its first meeting on May 11; the inaugural meeting of the Standards Committee followed on May 15.

HIT Policy Committee

The Policy Committee will recommend high-level policies for developing a national infrastructure for exchanging health information via interoperable systems. It must provide the Standards Committee with recommendations for the areas in which standards, implementation specifications, and certification criteria are necessary for advancing HIT efforts; in doing so, the Policy Committee also must recommend an order of priority for the Standards Committee to follow when developing, harmonizing, and issuing standards.

At its first meeting on May 11, the Policy Committee identified four key challenges inherent in the effort to implement the HITECH Act:

- Defining the term “meaningful use” of electronic health records (EHRs) by December 31, 2009, as required by ARRA;
- Developing certification standards;
- Establishing effective governance, workforce training, and education for health care providers and consumers; and
- Ensuring patient privacy and data security.

To facilitate work on these issues, Blumenthal established three HIT Policy Committee workgroups that will make policy recommendations to the full committee at future meetings on the first three issues, respectively. All of the workgroups will be responsible for incorporating privacy and security issues into

their considerations. The work of these groups will have a significant impact on the direction of HIT policy and implementation, and health care providers and manufacturers should make themselves aware of these developments as they occur.

HIT Standards Committee

The HIT Standards Committee is responsible for making recommendations to the National Coordinator on specific standards, implementation specifications, and certification criteria for the electronic exchange and use of health information within 90 days of receiving an endorsement of a particular policy area from the Policy Committee. Consistent with that requirement, ONCHIT published a Notice in the Federal Register on May 26, 2009, setting forth the Standards Committee's schedule for assessing the recommendations it receives from the Policy Committee.

At its first meeting on May 15, the Standards Committee focused on both substantive and administrative issues, including: (1) determining the elements and types of information that HIT systems should include; (2) maintaining a patient-centered focus; (3) developing working groups to discuss specific issues; and (4) creating a timeline for action.

Committee members generally agreed that they should develop specific standards for the following four types of information: (1) e-prescribing, (2) quality measurements, (3) clinical summaries, and (4) laboratory work. They noted that previous work done by the National Institute of Standards and Technology (NIST) and the Health Information Technology Standards Panel in these, and other, areas can—and should—be used by the Standards Committee in making its recommendations, particularly given the tight timeframe under which the committee is operating. The committee also discussed the development of a standard vocabulary or set of codes for physicians to use in order to foster efficiency and ensure that the different systems can “talk” to one another.

The Standards Committee formed three working groups during its first meeting: (1) a clinical standards group; (2) a quality standards group; and (3) (unlike its Policy Committee counterpart) a separate privacy and security standards group. The members also left open the possibility of forming additional working groups at a later time to cover administrative issues and methods of communicating information from the Standards Committee to relevant parties and provider groups.

CMS and ONCHIT Implementation Plans

On May 18, 2009, shortly after the inaugural meetings of the HIT Policy and Standards Committees, ONCHIT and CMS released their respective plans for implementing the HIT provisions of the ARRA. The implementation plans include important information regarding anticipated timelines for the release of regulatory proposals and guidance, as well as opportunities for public comment.

ONCHIT Implementation Plan

The ONCHIT implementation plan focuses on the \$2 billion in discretionary funding that is available to HHS for HIT initiatives as a result of the stimulus legislation. First, the plan devotes just under \$24.3 million to privacy and security. This includes \$9.5 million for audits by the HHS Office of Civil Rights (OCR) and CMS. The privacy and security provisions of the ARRA will be implemented through “fully competitive contract rewards” that will aim to achieve the “time-sensitive, mandatory regulatory and enforcement requirements in Subtitle D.” The implementation plan also includes a detailed timeline for the release of guidance, regulations, and reports regarding privacy and security issues. The timeline features roughly 20 regulatory actions between April 2009 and February 2012. Highlights include guidance or regulations about the following:

- Technologies and methodologies that impact breach notification requirements;
- Breach notification standards for HIPAA covered entities and business associates;

- Modifications to the HIPAA Enforcement Rule to implement statutory revisions to the Privacy Rule, implement the willful neglect provisions, implement provisions for sharing civil money penalties or settlements with harmed individuals, and extend certain HIPAA Enforcement rules to business associates; and
- Modifications to the HIPAA Privacy Rule regarding the accounting of disclosures provisions, what constitutes the “minimum necessary,” and generally prohibiting the exchange of health information for remuneration without individual authorization.

Of the \$2 billion allocated to discretionary funding, the ONCHIT implementation plan allocates \$300 million to develop regional HIT exchanges and \$20 million to NIST to continue its work on advancing health care information integration through activities such as analyzing technical standards and establishing conformance testing infrastructure. The remaining \$1.5 billion is left “Unspecified” at this time.

The ONCHIT plan sets forth a timeline for HHS’s adoption and publication of an initial set of standards, implementation specifications, and certification criteria. The plan also discusses the ways in which HIT programs will be monitored and evaluated, including performance metrics, reporting requirements, and coordinated efforts between ONCHIT and the HHS Office of the Inspector General to conduct risk assessments, internally test management controls, and externally perform any audits necessary to ensure that grant recipients and contract awardees are financially stable and have auditable financial systems.

Finally, the implementation plan commits to involving stakeholders at all stages of the process, and it lists current opportunities for stakeholder participation. These include:

- Listening to and participating during public comment periods at the HIT Policy and Standards Committee meetings;
- Commenting on draft program descriptions; and

- Providing expert input and information to inform a report.

CMS Implementation Plan

The CMS implementation plan focuses on the administrative funding that this agency received to establish the Medicare and Medicaid incentive program created in the ARRA to spur the adoption of certified EHRs by providers and hospitals. The HITECH Act provided CMS with just over \$1 billion in administrative funding (\$745 million for Medicare and \$300 million for Medicaid) for fiscal years 2009 to 2019 to modify and/or develop, implement, operate, and maintain all systems necessary to support the payment of incentives to hospitals and eligible professionals as set forth in the statutes.

The CMS implementation plan provides a “Delivery Schedule” with general target dates of completion for various “milestones” relating to the incentive program. In 2009, CMS will:

- Coordinate with ONCHIT to develop policies such as the definition of meaningful use;
- Develop proposed rules to allow public input to the incentive program policies;
- Plan systems and other requirements needed to support the incentives programs; and
- Plan national outreach programs.

In 2010, CMS will:

- Conduct outreach to eligible professionals and providers and to State Medicaid Agencies;
- Develop systems to support the payment of incentives;
- Develop final rules to establish policies needed to pay incentives; and
- Develop systems to monitor and evaluate incentive payments.

Incentive payments to hospitals will be determined through a statutory formula that multiplies a specified dollar amount (based on the hospital’s number of discharges in a given payment year) by the percentage of Medicare-eligible inpatient bed days a hospital has during the payment year. (For example, if a hospital discharges up to 23,000 patients in a payment year, the multiplier is \$6,370,200.) Medicare payments to hospitals will begin no sooner than October 2010. Medicare payments to eligible professionals will begin no sooner than January 2011, and eligible professionals may receive up to \$44,000 (per provider) over the five-year period from 2011 to 2016. Both eligible professionals and hospitals may start receiving Medicaid incentives no sooner than January 2011. Medicare payments to hospitals and providers can continue through 2016; Medicaid incentives can continue through 2021. However, a provider is not eligible to receive both Medicare and Medicaid incentive payments at the same time. Payment reductions to Medicare hospitals and eligible professionals that fail to adopt EHRs will begin in 2015 and continue in subsequent years.

If you have any questions about the HIT Policy Committee, the HIT Standards Committee, the implementation plans of ONCHIT and CMS, or any other aspects of the HITECH Act and related HIT developments, please contact any of the attorneys listed on this alert or the Sidley attorney with whom you usually work. As this implementation effort speeds forward, we will be happy to answer any questions that you and your organization may have, or to assist with the preparation of comments or other feedback.

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