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Implementation of the Health Information Technology for Economic and Clinical Health (HITECH) Act

Statement of

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Chairman Pallone, Ranking Member Shimkus, distinguished Subcommittee members, thank you for the opportunity to submit testimony on behalf of the Department of Health and Human Services (HHS) regarding the implementation of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) passed as part of the American Recovery and Reinvestment Act of 2009 (ARRA).

The passage of the HITECH Act represents an historic and unparalleled investment in health information technology (HIT). This investment lays the groundwork necessary to pursue the President's goals related to improved health care quality and efficiency and will help transform the way health care is both practiced and delivered. Broad use of HIT has the potential to improve health care quality, prevent medical errors, increase the efficiency of care provision and reduce unnecessary health care costs, increase administrative efficiencies, decrease paperwork, expand access to affordable care, and improve population health.

Implementing the HITECH Act

The provisions of the HITECH Act are best understood not as investments in technology *per se*, but as efforts to improve the health of Americans and the performance of their health care system. They are specifically designed to work together to provide the necessary assistance and technical support to providers, enable coordination and alignment within and among states, establish connectivity to the public health community in case of emergencies, and assure that the workforce is properly trained and equipped to be meaningful users of certified electronic health records (EHRs). Combined, these programs build the foundation for every American to benefit from an EHR, as part of a modernized, interconnected, and vastly improved system of care delivery.

The HITECH Act essentially laid out four objectives for HHS: 1) to define the meaningful use of certified EHR technology; 2) to encourage and support the attainment of meaningful use through incentive payments and grant programs; 3) to bolster trust in electronic IT systems through ensuring privacy and security; and 4) to foster continued HIT innovation.

The HIT Policy and Standards Committees

The HITECH Act established two new Federal Advisory Committees, the HIT Policy Committee and the HIT Standards Committee, from which I regularly seek advice and recommendations in implementing the provisions of the HITECH Act. Formed a little over one year ago, these two committees have already contributed a great deal to our activities. The HIT Policy Committee played a critical role in the process of defining meaningful use Stage 1. The HIT Standards Committee played an equally important role in recommending an initial set of HIT standards and implementation specifications for adoption by HHS and in support of meaningful use.

Both Committees have created several workgroups to tackle the many challenging issues for which we seek expertise, wisdom, and advice. These workgroups focus on making recommendations to the two full committees related to: meaningful use; certification and adoption; health information exchange; strategic planning; privacy and security; enrollment; and standards for clinical operations as well as clinical quality activities.

As we pursue the ambitious agenda set forth by the HITECH Act, we are acutely aware that it is paramount to implement appropriate policies to keep electronic health information private and secure. Privacy and security form the bedrock necessary to build trust, which is essential to achieve the vision outlined. Patients and providers must feel confident in the processes and policies in place related to HIT and the electronic exchange of health information.

Thus, to ensure that we have timely privacy and security recommendations related to the HITECH programs for which we are responsible, the HIT Policy Committee formed an interdisciplinary "Tiger Team" of experts comprised of members from both the HIT Policy and Standards Committees as well as members from the National Committee on Vital and Health Statistics (NCVHS). The Tiger Team is currently focused on addressing the priority privacy and security issues identified by the State Health Information Exchange Cooperative Agreement Program, the Regional Extension Centers (RECs), and Nationwide Health Information Network programs.

The Tiger Team is expected to make recommendations to the HIT Policy Committee shortly on: 1) consent, in particular, whether individuals should be allowed to choose whether to participate in the exchange of data through health information organizations; 2) data segmentation technologies that protect information an individual may deem sensitive from disclosure; and 3) the privacy and security requirements for participants in health information exchange activities who are not subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. Once the Policy Committee receives the Tiger Team's input and issues its recommendations, we anticipate finding ways to incorporate, where appropriate, such recommendations into our programs. For example, the RECs may be able to incorporate new training information on best practices for health care providers they support.

The Office of the National Coordinator for Health Information Technology (ONC) is further working with the President's Cybersecurity Coordinator, Mr. Howard Schmidt, as well as the President's Chief Technology Officer, Mr. Aneesh Chopra, and Chief Information Officer, Mr. Vivek Kundra, to identify best practices for improving the security of EHRs. Our

meaningful use rule requires that users of certified EHRs perform a security risk assessment and correct any deficiencies detected.

Meaningful Use of Certified EHR Technology

Three interdependent rulemakings were required to implement the Medicare and Medicaid EHR Incentive Programs. The first rulemaking establishes the requirements that eligible health care providers will need to satisfy in order to qualify for incentive payments. The second specifies the technical capabilities and standards that certified EHR technology will need to include to support these health care providers. And the third creates the processes for EHR technology to be tested and certified, thus providing confidence and assurance to eligible health care providers that the certified EHR technology they adopt will perform as expected.

On July 13th, with the issuance of the Medicare and Medicaid EHR Incentive Programs final rule and the Initial Set of Standards, Implementation Specifications, and Certification Criteria final rule, a 17-month effort was capped to publish the three rulemakings necessary to implement meaningful use Stage 1. These rules, cumulatively, reflect the over 2,000 public comments from stakeholders across the health care system, and illuminate the initial pathway to achieving an integrated and electronically connected health care system.

During this time, and in response to public comments, ONC and the Centers for Medicare & Medicaid Services (CMS) worked collaboratively to strike a balance between acknowledging the urgency of adopting EHRs to improve our health care system and recognizing the challenges that adoption will pose to health care providers. Our approach to meaningful use must be both ambitious and achievable. Like an escalator, HITECH attempts to move the health system upward toward improved quality and effectiveness in health care. But the speed of ascent must

be calibrated to reflect both the capacities of providers who face a multitude of real-world challenges and the maturity of the technology itself.

The Initial Set of Standards, Implementation Specifications, and Certification Criteria Final Rule

In this final rule, the Secretary completes the adoption of an initial set of standards, implementation specifications, and certification criteria, to align such standards, implementation specifications, and certification criteria with final meaningful use Stage 1 objectives and measures. The adopted certification criteria establish the required capabilities and specify the related standards and implementation specifications that certified EHR technology will need to include to, at a minimum, support the achievement of meaningful use Stage 1 by health care providers under the Medicare and Medicaid EHR Incentive Programs. EHR technology must be tested and certified according to the adopted certification criteria to ensure proper incorporation and usage of the adopted standards and implementation specifications, and thus compliance with the adopted certification criteria. The standards, implementation specifications, and certification criteria adopted in this final rule will help ensure that certified EHR technology on the market can maintain data confidentiality, share information securely, and perform a well-defined set of functions to help health care providers realize the full potential of EHRs and electronic health information exchange.

With the adoption of the initial set of standards, implementation specifications, and certification criteria completed, we are now ramping up the development of other processes that will need to be in place to enhance interoperability. Many of these processes will be components of a comprehensive standards and interoperability framework under development by ONC to expedite standards harmonization as well as their adoption and use. We anticipate that this framework will: assist in managing the standards lifecycle; enable the reuse of standards

components to expedite standards development for new business scenarios; provide a way for semantic discipline (i.e., to ensure computability and traceability); and allow for greater coordination among stakeholders. Over time, we anticipate that the standards and interoperability framework will assist the HIT Standards Committee as it considers standards and implementation specifications for adoption by HHS.

We are also continuing to coordinate within the Executive branch on complementary activities where the use of adopted standards and implementation specifications may be appropriate. In this regard, on February 19, 2010, Director Orzag and Secretary Sebelius co-signed an Office of Management and Budget (OMB) Memorandum 10-10 entitled "Federal Agency Coordination on HIT" which created an interagency HIT Task Force to facilitate implementation of the President's HIT agenda through better coordination among Federal agencies. As noted, under the aegis of this HIT Task Force, we are working with Mr. Howard Schmidt, to leverage security lessons learned from other Federal programs, supporting our colleagues at the Department of Defense and the Department of Veterans Affairs on their implementation of the Virtual Lifetime Electronic Record (VLER) project, and have continued our work with the Federal Health Architecture (FHA). ONC has also maintained a close working relationship with HHS' Office for Civil Rights (OCR) and consulted with OCR as they developed the proposed modifications to the HIPAA Privacy, Security, and Enforcement Rules required by the HITECH Act to strengthen the privacy and security protections for health information and to improve the workability and effectiveness of the HIPAA Rules. The proposed regulation provisions would, among other things, expand individuals' rights to access their information and restrict certain disclosures of protected health information to health plans; extend the applicability of certain of the Privacy and Security Rules' requirements to the

business associates of covered entities; establish new limitations on the use and disclosure of protected health information for marketing and fundraising purposes; and prohibit the sale of protected health information without patient authorization. This proposed rulemaking will strengthen the privacy and security of health information, and is an integral piece of the Administration's efforts to broaden the use of HIT in health care today.

The Temporary Certification Program Final Rule

As previously mentioned, in order to provide assurance to eligible health care providers that the EHR technology they adopt will assist their achievement of meaningful use under the Medicare and Medicaid EHR Incentive Programs, HHS issued at the end of June a final rule establishing the Temporary Certification Program for health information technology. The Temporary Certification Program final rule outlines how organizations can become ONC-Authorized Testing and Certification Bodies (ONC-ATCBs). Once authorized by the National Coordinator, ONC-ATCBs will test and certify that EHR technology is compliant with the standards, implementation specifications, and certification criteria adopted by the Secretary.

We strove to balance speed with rigor in our proposals for the establishment of the certification programs. In order to reduce market uncertainty and the potential for delay with respect to the adoption and implementation of certified EHR technology, we determined that it was necessary to implement in the very near term, a strong, but temporary certification program, while in parallel working to establish a more rigorous permanent certification program that would be able to achieve greater incorporation of international standards and best practices for third-party conformance assessment, including requirements such as accreditation and surveillance. We intend to publish a final rule for a Permanent Certification Program this fall. We expect the permanent certification program will be fully operational sometime in early 2012.

Additionally, in accordance with the HITECH Act, ONC consulted extensively with our colleagues from the National Institute of Standards and Technology (NIST) in the development of our proposals for both the temporary and permanent certification programs. We received valuable input from the experts at NIST and will continue to work with them as the certification programs mature.

In approximately four weeks since the Temporary Certification Program rule was finalized, ONC has already distributed 32 applications to organizations seeking to become ONC-ATCBs to test and certify EHR technology. Of these, 26 requested authorization to test and certify Complete EHRs, or "all-in-one" EHR technologies that meet all applicable certification criteria adopted by the Secretary, while another 6 have requested authorization to test and certify EHR Modules, specialized EHR technologies that meet at least one, but not all, of the certification criteria adopted by the Secretary. I am highly encouraged by the strong interest shown thus far, and I am optimistic that multiple organizations will be granted ONC-ATCB status, and thus authorization to test and certify Complete EHRs and/or EHR Modules under the Temporary Certification Program. Such a result should create a competitive market, would provide EHR technology developers with multiple options (relieving a concern we heard about regarding the possibility of long lines for EHR technology developers to have their products tested and certified), and could lower the costs to EHR technology developers that are associated with testing and certification.

HITECH Programs

ONC is engaged in a number of crosscutting activities related to administering the provisions of the HITECH Act. The major program investments established to date with the $2 billion appropriated to ONC under ARRA include: the Health Information Technology

Extension Program; the State Health Information Exchange Cooperative Agreement Program; the Beacon Community Cooperative Agreement Program; the HIT Workforce Program; and the Strategic Health IT Advanced Research Projects Program.

The Health Information Technology Extension Program

The Health Information Technology Extension Program includes the establishment of a national Health IT Research Center (HITRC) and a nationwide network of RECs. RECs will be dedicated to ensuring that providers have all the necessary resources to meet the challenges ahead to adopting and becoming meaningful users of certified EHR technology. They will place a special emphasis on providing technical assistance to clinicians furnishing primary-care services from an individual or small group practice. Clinicians in such practices deliver the majority of primary care services, but have the lowest rates of EHR adoption and the least access to resources to help them implement, use and maintain such systems.

The goal of the RECs is to provide outreach and support services to at least 100,000 priority primary care providers within two years. Presently, ONC has awarded grants to 60 RECs located throughout the United States. Over $700 million has been devoted to the RECs, with an additional $50 million invested in establishing the HITRC. The HITRC will be assembling and disseminating materials to support and address the needs of all prioritized providers and working with special needs patient populations.

The State Health Information Exchange Cooperative Agreement Program

The State Health Information Exchange Cooperative Agreement Program has the overall aim to advance appropriate, secure, and sustainable HIE within and across states and other jurisdictions. Over $500 million has been obligated to 56 states, eligible territories, and qualified State Designated Entities (SDE) to support health care providers, demonstrate the meaningful

use of certified EHR technology and to leverage the additional efficiencies and quality improvements gained from HIE. The state cooperative agreements are designed to be flexible enough to support states and providers at multiple levels of HIE adoption, recognizing the important investments already made at the regional and state levels.

Participating states are expected to develop and implement strategic and operational plans to ensure that there is measurable progress within states toward meeting the meaningful use measures that require the exchange of electronic health information. They are also encouraged to use their authority and resources to coordinate with Medicaid and state public health programs, convene stakeholders, and develop technical services to enable interoperability.

The Beacon Community Cooperative Agreement Program

The Beacon Community Cooperative Agreement Program provides certain communities with funding to build and strengthen their HIT infrastructure and HIE capabilities. These communities will demonstrate the vision of a future where hospitals, clinicians, and patients are meaningful users of HIT, and together the community achieves measurable improvements in health care quality, safety, efficiency, and population health. Using HIT as a tool to enable other delivery system changes, each Beacon Community is setting specific performance improvement targets for cost, quality, and population health. We anticipate that this program will demonstrate how HIT can help stakeholders develop innovative ways of delivering care leading to sustainable and measurable health and efficiency improvements. The Beacon Community Cooperative Agreement Program has obligated $220 million to 15 communities and is in the process of awarding an additional $45 million to support two more communities, technical assistance and program evaluation. The Beacon Communities are required to coordinate their activities with the RECs and State Health Information Exchange Cooperative Agreement Program.

The HIT Workforce Program

The HIT Workforce Program is a multi-pronged approach designed to support the education of HIT professionals, including curriculum development, competency examinations, and training. An increased workforce of skilled HIT specialists will be essential to supporting providers as they transition to certified HIT technologies. To date, ONC has obligated over $80 million in total funding to achieve the overall goal of training up to 45,000 new HIT workers to assist health care providers in becoming meaningful users of certified EHR technology. Training will focus on core HIT professional roles, and standardized competency examinations will be used for credentialing.

The Strategic Health IT Advanced Research Projects (SHARP) Program

To implement the provisions of the HITECH Act that focused on innovation, we have obligated approximately $60 million to support the SHARP program. The SHARP program funds research projects across four universities focused on achieving breakthrough advances to address well-documented problems that have impeded adoption. These projects are guided by a two-part ONC strategy: to implement a collaborative, interdisciplinary program of research addressing short and long-term challenges in their respective focus area; and to develop and implement a cooperative program between HIT stakeholders – researchers, industry, health care providers, and others – to transition the research findings into practice. The research projects will focus on security of health information technology; patient-centered cognitive support; healthcare application and network platform architectures; and secondary use of EHR data.

Conclusion

The HITECH Act provides for an unprecedented level of funding to improve the quality and efficiency of health care through HIT, and its historic investment will undoubtedly help

transition our current antiquated, paper-dominated health care system into a high-performing 21st century health care system. It was my privilege to testify before you today and I look forward to continuing to work together and answering any questions you might have.