

**Testimony before the Senate Health, Education, Labor
and Pensions Committee
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Statement of

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**Continuing America's Leadership: Realizing the Promise of Precision
Medicine for Patients
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Chairman Alexander, Ranking Member Murray, and distinguished Committee members, thank you for the opportunity to appear today. My name is Dr. Karen DeSalvo and I am the National Coordinator for Health Information Technology. I appreciate the invitation to be here to discuss how health information technology plays a necessary role in our Nation's precision medicine efforts.

For far too many diseases, there is no proven means of prevention or effective treatment. We must gain better insights into the biology of these diseases to make a difference for the millions of Americans who suffer from them. Precision medicine is an emerging approach for disease treatment and prevention that takes into account variability in genes, environment, and lifestyle for each person instead of a "one-size-fits-all-approach." While significant advances in precision medicine have been made for select cancers, the practice is not currently in use for most diseases. Many efforts are underway to help make precision medicine the norm rather than the exception. To accelerate the pace, President Obama has unveiled the Precision Medicine Initiative — a bold new enterprise to pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select the treatments that will work best for individual patients. Working with our colleagues at the NIH and FDA, our mission is to improve the lives of all Americans by empowering patients, research participants, scientists, and providers to work together and turn new knowledge into individualized treatment and prevention strategies for a new era of precision care.

To turn the promise of precision medicine into the reality of better health, we require robust and useful information tools, systems and practices for participants, providers, and more. As President Obama stated when he unveiled this initiative, "This helps us find new cures but also helps us create a genuine health care system as opposed to a disease care system. We want each of us to have sufficient information about our individual differences so that we can make better life decisions." This goal cannot be realized without unlocking the data stored in various health information technology tools to ensure consumers have access to their own health data – and to the applications and services that can safely and accurately analyze it – so that in addition to treating disease, we can empower individuals and families to invest in and manage their health in partnership with their clinicians.

Health information technology is the foundation required to bring precision medicine to operational life. Genomics helps to define us as individuals, and is one kind of important data for precision medicine. Other data of emerging importance to our health include microbiomes or bacteria and other microbes that share our bodies, environmental exposures or “exposome,” social determinants of health, and personal lifestyle choices – all of which provide us with more detailed knowledge about ourselves.

We at the Department of Health and Human Services have recognized the importance of this data to advance better health and a healthier Nation, and have been working over the years to further refine our information infrastructure through health information technology adoption, policy development, and innovation by both the public and private sector. The Office of the National Coordinator for Health Information Technology (ONC) was established by Executive Order in 2004, charged with the mission of giving every American access to their electronic health information when and where they need it most. In 2009, ONC was statutorily established in the Health Information Technology for Economic and Clinical Health Act (HITECH), enacted as part of the American Reinvestment and Recovery Act of 2009 (ARRA). HITECH also provided the resources and infrastructure needed to stimulate the rapid, nationwide adoption and use of health IT, especially electronic health records (EHRs). In the six years since the HITECH Act was enacted, we have seen dramatic advancement in the use and adoption of health information technology. The combined efforts of initiatives like the Regional Extension Centers, the ONC Health IT Certification Program, use of standard terminologies, and the CMS Medicare and Medicaid EHR Incentives Programs have brought us past a tipping point in the use of health information technology. Today, we are irreversibly on the path to a digital health care system.

Since I became the National Coordinator in January of last year, HHS has been working intensely to harness both the health care industry’s energy and consumer demands for interoperability to drive improvement in health—we feel the strong sense of urgency and have acted on it quickly. The Nation asked for a clear strategy to get to interoperability and a learning health system, and we delivered that plan in *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0*. We received broad feedback and have heard agreement from critical stakeholders like developers, consumers, providers, technologists, and others that this plan is the right path forward, and that they would like to work with us to advance interoperability. The roadmap explains that to get to interoperability as

quickly and safely as possible we need to build upon the current infrastructure and we need to pursue three immediate goals.

First, we need to focus on ensuring that applicable standards are consistently used, including standards for application programming interfaces, health care terminology, implementation, and security. Second, we need to foster an environment of trust where individuals can access their data, and where that data is kept private and secure. Third, we need to incent, through consumer demand and delivery system reform, interoperable movement and use of electronic health information that endures and is self-sustaining. These three goals will ultimately advance health care and health.

Our work in interoperability matters because it is what the Nation expects, but also because, in order for physicians, scientists, researchers, individuals and other partners to provide care tailored to the specific needs and characteristics of individuals, they will need to be able to access individual level information to learn more about how to treat patients, and ultimately improve the diagnosis, treatment, and prevention of diseases. This information cannot flow in the form of mail or fax to partners across the country—it must be quickly, efficiently and appropriately available electronically, and with patient consent when required by law, we must be able to apply the incredible speed and computing power available in the 21st century to help us analyze the data.

To advance this work in precision medicine, ONC will build on our strong foundation through our standards advancement authorities, our regulatory authorities, our policy expertise and our deep connection with the private sector and consumers, in close coordination with our Federal partners. As proposed in the President's Fiscal Year 2016 Budget, ONC would fund standards-coordination and -development to advance the basis on which precision-based medicine can be practiced. ONC's \$5.0 million funding proposal will lay the groundwork to achieve many of the milestones included in the Interoperability Roadmap's milestones for how health IT can support a learning health system. ONC will engage industry stakeholders to identify the standards, technology, and policy necessary to support big data analyses and precision medicine with appropriate privacy protections. Working closely with our many partners, ONC will aggressively pursue a portfolio of standards and technology initiatives that support precision medicine and protect user privacy, such as the standardization and use with consent of patient-generated health data from non-clinical settings; the incorporation of genomic

data into health IT with appropriate protections; patient identity management and matching with consent to permit linked analyses; a patient's ability to access their data and contribute it to research projects, and new platforms for clinical trial recruitment through the use of health IT.

Health information technology and information sharing plays a fundamental role in the President's Precision Medicine Initiative to improve care and speed the development of new treatments. We look forward to building on our current foundation and reaching for the future of better health for all Americans. Thank you again for inviting me today.