Office of the National Coordinator for Health Information Technology (ONC)

Federal Health Information Technology Strategic Plan

2011 – 2015

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Putting the **I** in Health**IT** ℠

Introduction

The technologies collectively known as health information technology (health IT) share a common attribute: they enable the secure collection and exchange of vast amounts of health data about individuals. The collection and movement of this data will power the health care of the future. Health IT has the potential to empower individuals and increase transparency; enhance the ability to study care delivery and payment systems; and ultimately achieve improvements in care, efficiency, and population health.

However, these technologies – including electronic health records (EHRs), personal health records (PHRs), telehealth devices, remote monitoring technologies, and mobile health applications – are remarkably underutilized today. In 2010, only 25 percent of physician offices and 15 percent of acute care hospitals took advantage of EHRs.[i] Even fewer used remote monitoring and telehealth technologies. While many consumers access their banking information online daily, only 7 percent have used the web to access their personal health information.[ii]

Recent legislation has established an agenda and committed significant resources for health IT. The Health Information Technology for Economic and Clinical Health (HITECH) Act, passed as part of the American Recovery and Reinvestment Act of 2009, allocated billions of dollars for the health care system to adopt and meaningfully use health IT to improve health. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, (referred to collectively as the Affordable Care Act) builds on the HITECH Act and recognizes health IT as a critical enabler to broad transformations in health care. This document is the Federal Health IT Strategic Plan, developed under the leadership of the Office of the National Coordinator for Health Information Technology (ONC) and in close collaboration with other federal partners, for working with the private and public sectors to realize Congress and the Administration's health IT agenda.

The first Federal Health IT Strategic Plan was published in June 2008. Section 3001(c)(3) of the Public Health Service Act, as added by the HITECH Act, requires the National Coordinator to update and republish the Plan. This Plan updates the previous version to take into account the rapidly changing landscape of health IT and health IT policy. In order to update the Plan, ONC leveraged the strategic framework put forth by the HIT Policy Committee and obtained additional input by conducting interviews with representatives from federal agencies/offices and the private sector. ONC also engaged its federal partners, the private sector and members of the public to provide comments on multiple versions of the Plan.

Goal I, "Achieve Adoption and Information Exchange through Meaningful Use of Health IT" discusses the centerpiece of the government's health IT strategy over the next five years. "Meaningful use" is aimed at widespread adoption and information exchange in its first two stages, and will then build to improve health outcomes in the third stage. Activities are focused on two areas: defining the meaningful use of certified EHR technology; and encouraging the achievement of meaningful use through the CMS administered Medicare and Medicaid EHR Incentive Programs and the support of meaningful use through grant programs, including information exchange with public health departments and laboratories.

G*oal II*, "Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT," discusses the specific ways health IT is contributing to the goals of health care reform: improved care, improved population health, and reduced per capita costs of health care. Widespread adoption of EHRs, information exchange, quality improvement initiatives, and health care reform pilots are required to implement the Affordable Care Act. As part of each of these activities, the government is investing in and leveraging health IT to transform the health care system.

Goal III, "Inspire Confidence and Trust in Health IT," focuses on government efforts to update its approach to privacy and security issues related to health IT, and build greater confidence and trust in

EHRs and health information exchange among providers and the public. The digitization of health records will create a new set of challenges for protecting the privacy and security of health information, but it will also open new opportunities for improving safeguards.

Goal IV, "Empower Individuals with Health IT to Improve their Health and the Health Care System," discusses how the government is designing health IT policies and programs to meet individual needs and expectations, provide individuals with access to their information, help facilitate a strong consumer health IT market, and better integrate individuals' and clinicians' communications through health IT. A public that has a voice in designing national health IT policies and programs and is empowered with access to its health information through useful tools can be a powerful driver in moving toward patient-centered health care.

Goal V, "Achieve Rapid Learning and Technological Advancement," focuses on demonstrating ways health IT and meaningful use can enable innovation and appropriate use of health information to improve knowledge about health care across populations. In the long run, the government is pursuing a vision of a learning health system, in which a vast array of health care data can be appropriately aggregated, analyzed, and leveraged using real-time algorithms and functions.[iii] This future will require technical innovation to build on the foundation of meaningful use, as well as finding new ways to use that foundation in the practice of health care.

ONC will track national progress towards achieving the goals laid out in this Plan. Ongoing collaboration with federal agencies, states and providers will be necessary in order to realize these goals. The Plan is meant to be a living document that will be updated based on experience with stage one meaningful use and the implementation of a robust evaluation program.
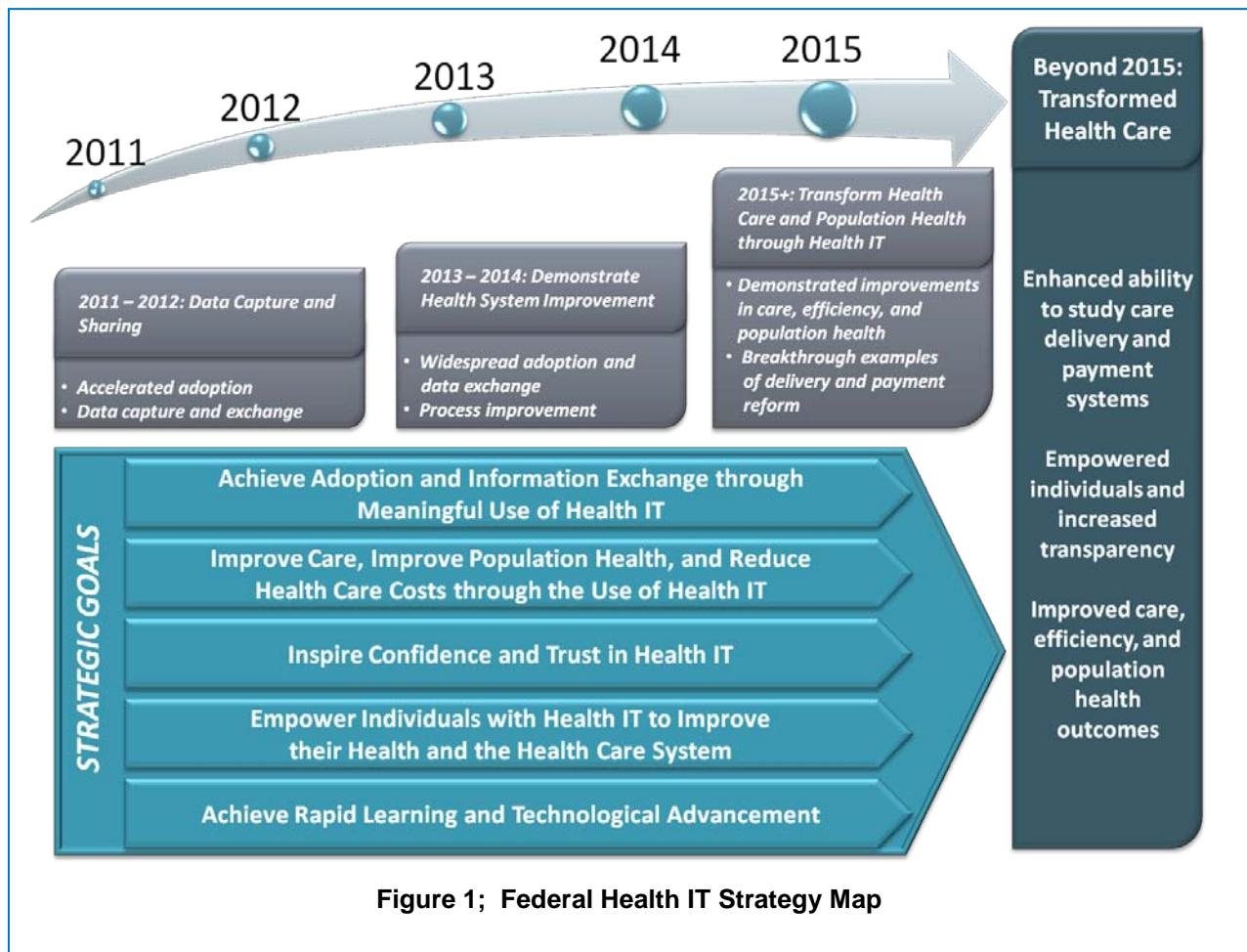

Figure 1; Federal Health IT Strategy Map

Federal Health IT Vision and Mission

Vision

A health system that uses information to empower individuals and to improve the health of the population.

Mission

To improve health and health care for all Americans through the use of information and technology.

Federal Health IT Principles

In developing and executing the federal health IT strategy, the government strives to

- **Put individuals and their interests first.** In order to enhance the health and well-being of all Americans, the government must meet the needs and protect the rights of each individual.

- **Be a worthy steward of the country's money and trust.** The government seeks to use its resources judiciously. This means relying to the extent possible on private markets to accomplish important societal objectives, and acting to correct market failures when necessary. It also means developing governmental policies through open and transparent processes.

- **Support health IT benefits for all.** All Americans should have equal access to quality health care. This includes the benefits conferred by health IT. The government will endeavor to assure that underserved and at-risk individuals enjoy these benefits to the same extent as all other citizens.

- **Focus on outcomes.** Federal health IT policy will constantly focus on improving the outcomes of care, so as to advance the health of Americans and the performance of their health care system.

- **Build boldly on what works.** The government will set ambitious goals and then work methodically to achieve them, monitoring health IT successes, and looking for ways to expand upon programs that work. It will seek to be nimble and action-oriented: evaluating existing government activities, learning from experience, and changing course if necessary.

- **Encourage innovation.** The government is working to create an environment of testing, learning, and improving, thereby fostering breakthroughs that quickly and radically transform health care. The government will support innovation in health IT.

Goal I: Achieve Adoption and Information Exchange through Meaningful Use of Health IT

The first priority in realizing the benefits of health IT is to achieve nationwide adoption of EHRs and widespread information exchange. As patients and providers experience the benefits of EHRs, they will demand nothing less from their health care practices. The Medicare and Medicaid EHR Incentive Programs accelerate the realization of this future by offering financial incentives to hundreds of thousands of eligible professionals, eligible hospitals and critical access hospitals for incorporating certified EHR technology into their practices. "Meaningful use" is much more than just adoption – these providers will also be required to maintain data confidentiality, share information securely with each other, engage patients with their electronic health information, and improve care.

There are a few well-defined barriers that have slowed acceptance of EHRs and widespread information exchange. Small- and medium-sized providers often do not have sufficient capital to implement EHR systems. There is a lack of skilled health IT professionals to support providers as they transition from paper records to EHRs. Using EHRs may alter current provider workflows, and many providers struggle to select systems, use them in ways that will improve care, and make the necessary changes to their processes. Finally, information exchange, which is central to realizing the benefits of EHRs, is not fully possible today – there is no interoperable infrastructure to securely exchange health information nationwide among providers, between providers and patients, and between providers and public health agencies (see Objectives I.B and I.C).

Through the HITECH Act, the Department of Health and Human Services (HHS) created a set of far-reaching programs to help providers overcome such barriers. For the Medicare and Medicaid EHR Incentive Programs, the three progressive stages of meaningful use will define what eligible professionals and hospitals can and should accomplish through the adoption and use of EHRs over the next five years. Stage one objectives focus on adopting EHRs and beginning to take advantage of basic electronic data capture, medication ordering, and decision-support tools. We expect future stages to become more rigorous, for example, by requiring providers not only to adopt the technology but to use it to exchange health information and – ultimately – to achieve improvements in care, efficiency, and population health (*see Goal II*). We anticipate that future stages of meaningful use will be aligned to support advancing nationwide-wide health goals, as defined in the HHS Strategic Plan, and the priority areas identified in the National Quality Strategy.

In addition to incentive payments, the HITECH Act programs provide significant support for providers to achieve adoption and meaningful use, including implementation support, workforce training, and information exchange support. Programs are focused on the providers that need the most help – solo and small group practices, community health centers, critical access hospitals, and providers located in rural and underserved areas. In 2010, HHS issued rules establishing the requirements of the first stage of meaningful use. HHS expects to articulate two further stages through rulemaking over the next five years. Participation in the Medicare and Medicaid EHR Incentive Programs is voluntary, but beginning in 2015, eligible professionals and hospitals under the Medicare EHR Incentive Programs will face payment reductions if they do not meet the meaningful use requirements.

In implementing the Medicare and Medicaid EHR Incentive Programs, the government is taking advantage of the experience of federal agencies that deliver health care (Department of Veterans Affairs, Department of Defense, and Indian Health Service) that have already-developed EHR systems which have been in place for over a decade. These agencies' experiences in using EHRs can offer important insights and best practices for the nationwide adoption of EHRs.

It is the government's goal that such a large-scale movement will create a tipping point – that the adoption and meaningful use of EHRs will become ubiquitous across the nation. To this end, the government is seeking to encourage meaningful use through other mechanisms in addition to HITECH Act programs. This includes supporting the above-mentioned federal agencies that deliver health care and federal grant recipients (critical access hospitals, community health centers, etc.) in meeting meaningful use requirements. We expect that medical societies and professional licensing and certifying bodies will also help to encourage meaningful use among their members. Some private insurers are already mirroring the Medicare and Medicaid EHR Incentive Programs and providing incentives for the achievement of meaningful use among their provider communities. For providers ineligible for incentive payments under the

Medicare and Medicaid EHR Incentive Programs (for example, long-term and post-acute care facilities, community mental health centers, and some behavioral health providers), the government is developing technology and policy solutions that will build on the Department's meaningful use efforts and fit their unique needs (*see Strategy I.C.3*).

The government's objectives to "Achieve Adoption and Information Exchange through Meaningful Use of Health IT" are:

A. Accelerate adoption of electronic health records

B. Facilitate information exchange to support meaningful use of electronic health records

C. Support health IT adoption and information exchange for public health and populations with unique needs

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Spotlight on Health Outcomes

Use of health IT can improve health outcomes and enhance care coordination

George is a 62-year-old man with diabetes, hypertension, and heart failure who smokes one pack of cigarettes every day. George's primary care provider (PCP) is reviewing an EHR-generated listing of patients with an HbA1c test result over 9. She notices that George is on her list with an HbA1c of 11.2 and that he missed his last appointment and has not yet rescheduled. George's PCP emails him via secure messaging to request he make an appointment and get the following tests in advance of the visit: HbA1c and cholesterol panel. She orders these tests via computerized provider order entry (CPOE). George goes online to schedule his appointment. Prior to his appointment, George's PCP checks his lab results which are sent electronically to the EHR and sees that his HbA1c and cholesterol are still elevated. A nurse uses clinical decision support to determine that George would benefit from diabetes self-management and smoking cessation counseling, which she gives before his appointment. During his appointment, George's PCP talks to him about adding a new medication to better control his diabetes and increasing the dose of his cholesterol medicine. She sends the new prescriptions electronically to George's pharmacy so that they will be ready for pick-up when he leaves the office visit. Clinical decision support also reminds the PCP that George is due for eye and foot exams. She performs a foot exam and sends an electronic referral to the ophthalmologist's office, who will contact George via secure messaging to schedule an appointment. The ophthalmologist has access to George's record and can input data and recommendations that are viewable by his PCP, thus creating a "seamless care" model. To help him with his multiple conditions, George is set up with a case manager who will work with George to develop strategies to quit smoking and eat healthier/exercise more. The case manager has access to the full EHR and can communicate directly with the rest of the team to update them on George's progress.

Jane is an 83-year-old woman with COPD, hypertension, and peripheral vascular disease who is admitted to the hospital with pneumonia. As the admitting physician is ordering an antibiotic for pneumonia, a drug-allergy warning pops up on the screen alerting the physician that Jane had an anaphylactic reaction to penicillin in the past and another antibiotic is preferred – saving Jane from an adverse drug event. Jane is at high-risk for developing a clot in her legs, which can lead to a pulmonary embolism. As part of the admissions order set, the physician is prompted to choose a type of prophylaxis for clots, which reduces her risk of developing this complication and a prolonged hospital stay. The nurse who admits Jane notices a small decubitus ulcer present on admission. She documents the ulcer on her mobile device and monitors and treats it with the aid of clinical decision support

These "Spotlight on Health Outcomes" are intended to highlight exemplary ways that widespread adoption and use of health IT and electronic health information exchange could help transform and improve health care. Some of these examples are only aspirational today or only exist in select communities or health systems. However, these examples illustrate the type of transformed health care that could be possible with the achievement of the goals of this Plan.

OBJECTIVE A
Accelerate adoption of electronic health records

Strategy I.A.1: Provide financial incentive payments for the adoption and meaningful use of certified EHR technology.

Central to the HITECH Act is the establishment of the Medicare and Medicaid EHR Incentive Programs, which makes available incentive payments that could total an estimated $27 billion over 10 years, to encourage eligible professionals and hospitals to adopt and meaningfully use certified EHR technology.[iv] The programs generally require providers to do the following:adopt EHRs that are certified according to standards, implementation specifications, and certification criteria adopted by the Secretary, and meet certain objectives and measures using certified EHR technology established for progressive stages of meaningful use as defined in CMS rules. CMS' final rule for stage one meaningful use was published in July 2010. Stage one meaningful use objectives include:

- Recording patient information into EHRs, such as gender, race, preferred language, height, weight, smoking status, and blood pressure

- Using a software application to inform clinical decisions

- Entering medical prescriptions electronically

- Providing patients with a timely electronic copy of their health information

- Securing EHRs to protect the privacy of patient data

Future stages of meaningful use are likely to include a combination of new objectives, some of which may require new EHR functionality, changes to existing objectives, such as an increase in the threshold or broadening of the definition. In the future stages of the Medicare and Medicaid EHR Incentive Programs, the government expects to reward improvement against predetermined thresholds that are associated with the adoption and use of EHRs. Stages two and three are anticipated to transition gradually away from further process requirements like those included in stage one, to requirements for improvement in outcomes and quality of care. Any such improvement measures will be in line with nationwide health goals as laid out in the HHS Strategic Plan and with the national priorities identified in the National Quality Strategy.[v] In order to receive incentive payments, eligible providers must demonstrate that they can use certified EHR technology to incorporate more sophisticated uses of health IT, such as clinical decision support (CDS), patient registries, reminder systems, and changes to workflow and clinical care redesign into their practices (see *Goal II)*.

Strategy I.A.2: Provide implementation support to health care providers to help them adopt, implement, and use certified EHR technology.

The Regional Extension Center (REC) Program, established through the HITECH Act with more than $720 million in grants over a four-year project period, has set up 62 centers across the nation with staff and resources dedicated to helping providers implement and become meaningful users of certified EHR technology. Additionally, HRSA's Health Center Controlled Network (HCCN) Program provides resources to community health centers to implement health IT, including EHRs. Further support is provided by the Health Information Technology Research Center (HITRC), which will work to gather relevant information on effective practices and help the RECs collaborate with one another and with relevant stakeholders to identify and share best practices in EHR adoption, meaningful use, and provider support. Through its regional offices and other outlets, CMS offers support to states to encourage adoption of EHR technology.

Strategy I.A.3: Support the development of a trained workforce to implement and use health IT technologies.

To meet the anticipated growth in demand for health IT professionals, HITECH made available $118 million to support the training and development of more than 50,000 new health IT

professionals. Four grant programs will prepare qualified individuals to serve in 12 high priority roles related to the implementation and maintenance of EHR systems.

Three grant programs work together to prepare a workforce in six of these priority roles for which community colleges are the natural home for training: Community College Consortia to Educate Health Information Technology Professionals; Curriculum Development Centers; and Competency Examination for Individuals Completing Non-Degree Training. A fourth program, Assistance for University-Based Training, will prepare students for six different roles, for which universities are the natural home for training.[vi]

Strategy I.A.4: Encourage the inclusion of meaningful use in professional certification and medical education.

The federal government will encourage meaningful use to be incorporated into the U.S. medical education and accreditation processes. To this end, ONC and CMS are collaborating with various professional certification and medical education organizations to assist providers in adopting and becoming meaningful users and to incorporate meaningful use into the professional certification and medical education organizations' professional requirements. The American Board of Medical Specialties, a professional certification body, has taken steps to assist and encourage physicians in the adoption and meaningful use of EHRs, with the ultimate goal that such EHR use and competencies should become an element of professional certification.

Strategy I.A.5: Establish criteria and a process to certify EHR technology that can support meaningful use criteria.

In order for eligible providers, eligible hospitals, and critical access hospitals to qualify for the Medicare and Medicaid EHR Incentive Programs, they must first adopt certified EHR technology that meets established criteria, which are aligned with the Medicare and Medicaid EHR Incentive Programs meaningful use requirements. The HHS Secretary has adopted EHR standards, implementation specifications and certification criteria, as well as a process for EHR technology to gain certification. These programs aid providers in selecting certified EHR technologies that support them in becoming meaningful users. ONC collaborated extensively with the National Institute of Standards and Technology (NIST) to establish the certification processes.

Established through rulemaking in 2010 and 2011, ONC's certification programs specify how organizations can become authorized by the National Coordinator to certify EHR technology as being compliant with the standards, implementation specifications, and certification criteria adopted by the HHS Secretary.

ONC published the Initial Set of Standards, Implementation Specifications, and Certification Criteria interim final rule in January 2010 and a final rule in July 2010. The certification criteria establish the required capabilities, standards, and implementation specifications in EHR technology that supports the achievement of meaningful use stage one. The certification criteria will continue to evolve with future rulemakings, as further stages of meaningful use are established.

ONC, with its federal partners, will consider whether to adopt certification criteria for health IT that is used by non-eligible providers (such as long-term and post-acute care facilities), and whether the availability of certification for specific types of health IT would be beneficial.

Strategy I.A.6: Communicate the value of EHRs and the benefits of achieving meaningful use.

HHS is conducting outreach to providers to increase awareness of the HITECH Act programs that are available to support efforts to attain meaningful use and to share evidence and best practices on the use of health IT to improve health. Primary care providers are a primary audience for this strategy (see Strategies III.B.1 and IV.A.2 for outreach directed at individuals). The strategy will have four aims:

- Raise awareness among providers about the availability and benefits of EHRs and other health IT

- Educate providers about privacy and security protections as they relate to EHRs and other health IT

- Encourage providers to participate in HITECH Act programs and other federal initiatives (e.g., Medicare and Medicaid EHR Incentive Programs, grants, contracts) in order to take full advantage of EHRs and other health IT

- Increase provider understanding of health IT products and services, so that they may make informed decisions and take full advantage of the technologies' benefits

The education and outreach strategy is being developed by ONC, CMS, and the Office for Civil Rights (OCR), and will be implemented over the next two years.

Strategy I.A.7: Align federal programs and services with the adoption and meaningful use of certified EHR technology.

HHS is committed to encouraging providers that are not eligible for the Medicare and Medicaid EHR Incentive Programs to use EHR technologies to improve the care they provide to patients. For future stages of meaningful use, HHS plans to propose more rigorous health information exchange requirements which may encourage providers that are not eligible for the incentive programs (e.g., long-term and post-acute care facilities, community mental health centers or substance use disorder treatment providers) to adopt health IT and participate in health information exchange. The Federal Health IT Taskforce,[vii] consisting of the National Coordinator for Health IT, administration officials, and other federal agency leads for health IT, is the key federal committee responsible for coordinating federal health IT investments and aligning programs to support meaningful use of certified EHR technology.

Specifically, the Department of Defense (DoD), Department of Veterans Affairs (VA), and Indian Health Service (IHS) are developing plans for their health care systems to align with meaningful use. Similarly, the Health Resources and Services Administration (HRSA) and the Federal Communications Commission (FCC) are developing plans to encourage their grantees and subsidy recipients, respectively, to become meaningful users. The Substance Abuse and Mental Health Services Administration (SAMHSA) is working to foster adoption and implementation of certified EHRs among its providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs, including community mental health centers and substance use disorder treatment facilities. Finally, the Office of Personnel Management (OPM) is developing a strategy to encourage health plans that provide coverage through the Federal Employee Health Benefits (FEHB) Program to support EHR adoption and meaningful use among their networks of providers.

Strategy I.A.8: Work with private sector payers and provider groups to encourage providers to achieve meaningful use.

The federal government will support the efforts of private payers and private provider groups to encourage their networks of providers to achieve meaningful use. Some major payers have begun to implement incentive programs that will work in parallel with the Medicare and Medicaid EHR Incentive Programs and utilize meaningful use objectives. These programs have the potential to play a role in expanding the number of providers who achieve meaningful use, and may also provide incentives for providers who are not eligible for the Medicare and Medicaid EHR Incentive Programs. In addition, some private sector payers are implementing new payment models that increasingly rely on collaboration among health care providers to coordinate patient care and achieve efficiencies. These new payment models are helping to create a business case for providers not eligible for incentives under the Medicare and Medicaid EHR Incentive Programs to adopt health IT and participate in health information exchange.

Strategy I.A.9: Encourage and facilitate improved usability of EHR technology.

The government is collaborating with industry and researchers to improve the usability of EHRs. The usability of EHRs is considered a key barrier to adopting health IT and achieving meaningful use. NIST is conducting ongoing research and advancing the development of standards and test methods that can be used to evaluate and improve the usability of EHRs. It has released a Common Industry Format (CIF), a standard for developers to report usability test findings and demonstrate evidence of usability in their products in a format that allows for independent evaluation of a single product and comparison across multiple products. NIST is also developing guidance and tools for RECs and professional societies on available tools and resources to incorporate concepts of usability in selecting and implementing EHR systems. The Food and Drug Administration (FDA), in collaboration with NIST and the Agency for Healthcare Research and Quality (AHRQ), will develop best practices to address systematic evaluation of usability with regard to patient safety to ultimately improve patient care. AHRQ is developing toolkits that medical practices can use to assess the usability of EHR systems and assess the redesign workflow. In addition, AHRQ is conducting research and convening industry workgroups that provide perspectives on what constitutes usability and how to systematically improve the usability of EHRs.

ONC will explore ways to improve the ability of providers to select or change EHR products by improving data portability. Reducing the cost associated with switching products while increasing data fluidity and choice can help drive market competition to improve the usability of EHR products.

ONC has directed one of its four Strategic Health IT Advanced Research Projects (SHARP) (see Strategy V.B.2) to further EHR usability through the identification and development of better cognitive and user-centered design. In addition, ONC is working with private sector groups to encourage the collection of usability information and its dissemination to vendors and consumers through mechanisms they can trust.

OBJECTIVE B
Facilitate information exchange to support meaningful use of electronic health records

For future stages of meaningful use, the plan is to propose health information exchange and interoperability requirements that are more rigorous, so that patient information follows patients to the point of care and informs critical health decisions. This will require overcoming barriers across geographies and stakeholders (i.e. providers, laboratories, hospitals, pharmacies, behavioral health clinics, and patients), including insufficient demand for electronic health information, lack of a business model for facilitating exchange, and disparate federal, state, and local policies that hinder exchange. It will also require more rigorous standards to support interoperability so that the data that is exchanged can be used for multiple purposes.

Historically there have been significant barriers to the adoption and use of EHRs to exchange information, including their cost, low provider demand, the perceived lack of financial return for investing in them, and the technical and logistical challenges involved in installing, maintaining and updating them.[viii] But the Medicare and Medicaid EHR Incentive Programs and the Affordable Care Act payment reforms are sparking a paradigm shift in the collection and use of health care data that addresses some of these challenges head on. First, the Medicare and Medicaid EHR Incentive Programs reward eligible professionals and hospitals who digitize health care information. We anticipate that the requirements for sharing information electronically across provider settings will grow stronger in future stages. Second, ongoing payment reforms initiated by the Affordable Care Act – including accountable care organizations, medical home models, and bundled payments – are an even more important potential driver of provider motivation to exchange information. Private sector payers may also adopt similar payment reforms to align with Medicare and Medicaid. To prepare for such reforms, hospitals are already reaching out to their surrounding community providers to share

information and EHR systems. Eventually, as digital health information becomes more widely available, exchanging it will be more natural and incentives will become less relevant. Several challenges also exist to creating a national infrastructure whereby business networks can connect to one another, including but not limited to the development of consistent standards to ensure interoperability and privacy and security protocols to ensure trust that the network will handle information appropriately. Health information exchanges (HIEs) must be designed to address legal, organizational, and technical challenges that might otherwise impede their sustainability.

With demand increasing, the government is helping to ensure that exchange standards and infrastructure are in place to meet it. This does not mean constructing significant new national infrastructure from scratch. Rather, the federal government, in close collaboration with state governments, is helping evolve the various current exchange models, so that – taken together – they may serve every health care provider and meet a broader set of health care needs. There are many examples of information sharing that are already occurring in the health care system, and the government will foster the growth and development of these models. Where there are gaps in exchange options, the government will identify the specific barriers to exchange and develop plans to address them. Finally, so that communication and information sharing can take place across various information exchange models – both public and private – the government will advance national adoption of key exchange standards.

Strategy I.B.1: Foster business models that create health information exchange.

Many sustainable exchange options already exist for certain providers and certain types of health information. Some hospital networks and group provider practices have found a business case for investing in information exchange within their networks. Vendors of EHR systems are developing "information networks" for their customers. Communities are creating health information networks to facilitate information sharing among providers. Diagnostic lab companies and electronic

prescription companies are offering services that enable exchange of specific pieces of health information for providers able to pay for them. The Nationwide Health Information Network standards, services, and policies – including the Nationwide Health Information Exchange and Direct protocols – are being used by many health care organizations as the preferred solution to exchanging information across organizational and geographic boundaries. Protocols such as Blue Button (*see Strategy IV.B.2)* provide a method to electronically exchange health information between providers and consumers. The Blue Button is an initiative at DoD, VA, and CMS that enables individuals to access a web-based portal to download their personal health information and share this information with health care providers, caregivers, and others they trust.

For as many providers as possible, the first priority is finding the right combination of already-available exchange models that will enable them to electronically exchange lab results, patient care summaries, and medication histories. State-level grantees in the State HIE Cooperative Agreement Program are identifying, articulating, and promoting adoption pathways that will help providers do just that. RECs will work with individual providers to identify and implement the right pathway.

ONC is also making it easier, faster, more secure, and less expensive to transport health information. The Direct project at ONC enables a simple, secure, scalable, standards-based way to send authenticated, encrypted information directly to known, trusted recipients over the Internet. Direct helps some providers satisfy the stage one meaningful use requirements by allowing a secure method of pushing content from a sender to a receiver. For example, by leveraging Direct, a primary care physician can send a secure email with a clinical summary of a patient to a referring specialist. Direct is a national solution to health information exchange that can rapidly lower the cost and complexity of local interfaces between providers, laboratories, hospitals, pharmacies, and patients, in turn substantially lowering the cost of providing information exchange services. In some cases this could make it possible for a small provider to

connect to a lab company or a health information exchange organization, where it may have been cost prohibitive for them to do so otherwise. Federal partners that provide health care services, including the VA, are implementing Direct as a consistent, national solution for directed exchange in local communities. The RECs will promote EHRs that already have the Nationwide Health Information Network Direct interfaces built in, lowering the cost of exchange for small providers. Continuing work to simplify and extend the Nationwide Health Information Network will continue to focus on lowering the cost of exchange and improving the interoperability of EHR systems.

ONC continues to work with the private sector and federal health care organizations to further refine the standards, services, and policies for securely exchanging authorized health information between providers through the Nationwide Health Information Network Exchange protocols. For example, the query/response protocols provide a method of exchanging information, when authorized, between a provider and another authenticated entity that may have information on a patient that is necessary for care. In this case, a query is sent to providers with an authorization and responses are sent with the needed information. This model provides a high level of information exchange potential and capability. It also requires a robust electronic health record system and investment. Currently, the Nationwide Health Information Network Exchange is primarily used by a group of federal agencies and private organizations that have come together to securely exchange electronic health information and are demonstrating the capabilities of information exchange. Today, select participants in the Nationwide Health Information Network Exchange are: exchanging summary patient records for Social Security Administration (SSA) disability determination purposes; exchanging summary patient records for the Virtual Lifetime Electronic Health Record (VLER); and participating in bio-surveillance and case reporting with CDC. The Exchange protocols and the pilot programs that are using them will help pave the way for broader adoption of query/response exchanges as envisioned by the authors of the President's Council of Advisors on Science and Technology (PCAST) December 8, 2010 report, *Realizing the Full Potential of Health Information Technology To Improve Healthcare for Americans: The Path Forward* and many health information thought leaders.

In addition to the exchange of health information between providers, the exchange of information that engages individuals and gives them access to their health data is a top priority of the Medicare and Medicaid EHR Incentive Programs. The best way to empower individuals and reorient the health care system to be more patient-centered is to give patients access to their personal health information. Information exchange protocols such as the Blue Button format that was developed and adopted by the VA, DoD, and CMS, is one way to put patients at the center and give them control of their information. ONC supports the exchange of information with consumers and the re-use of such information for themselves and with providers.

This portfolio of exchange mechanisms is part of a broad national strategy to have an interconnected health system through the Nationwide Health Information Network. The Nationwide Health Information Network is being developed by ONC to provide the building blocks for a secure, nationwide, interoperable health information infrastructure that can connect providers, consumers, and others involved in the health care system. Exchange, Direct and evolving methods of health information exchange create an infrastructure that is critical to enabling health information to follow a patient and be available for clinical decision making and uses beyond patient care, such as measuring quality.

Finally, the government will also seek to remove unnecessary regulatory barriers to sustainable exchange options, helping them to develop. In collaboration with the State HIE Cooperative Agreement Program, for instance, state governments will look for ways to align Medicaid policies to health information exchange requirements.

Strategy I.B.2: Monitor health information exchange options and fill the gaps for providers that do not have viable options.

Many providers – particularly those in areas with low hospital and provider density – are not currently supported by sustainable information exchange models. A main focus of the State HIE Cooperative Agreement Program is expanding existing networks to help these providers. The program is investing over $500 million in supporting state-level initiatives to expand capacity for exchanging health information both within and across states. It encourages states to develop statewide HIE plans which will align with the nationally recognized standards and services and state Medicaid initiatives. States will support providers by building on existing exchange activities, providing critical shared services and infrastructure such as provider directories, record locator services, and master patient indices, increasing the use of standards, services, and policies needed for widespread information sharing, and enhancing the information exchange capabilities of key trading partners including clinical laboratories, pharmacies, and public health agencies.

In order to exchange health information electronically, providers must have broadband Internet access. The FCC's Rural Healthcare Program subsidizes broadband access for health care providers that are disadvantaged in meeting this requirement. The program is authorized to spend up to $400 million per year to ease the burden of costly telecommunications services for rural health care providers. The program is divided into two different components: one that subsidizes ongoing monthly costs, and one that helps providers build new infrastructure where the existing infrastructure is insufficient. In addition, the U.S. Department of Agriculture (USDA)'s Broadband Technologies Opportunities Program (BTOP) and Department of Commerce's Broadband Initiatives Program (BIP) were collectively funded by over $4 billion through the Recovery Act to support broadband grants around the country. Health care was one of the strategic priorities of these grant programs.

The government will also encourage consumers to gather and exchange their own individual health information. Informed and engaged consumers who have access to their own interoperable health records can be a powerful force for bringing that information with them to the point of care. See Goal IV for more detail on how the government will accelerate consumers' and caregivers' access to their electronic health information in a format they can use and reuse.

Strategy I.B.3: Ensure that health information exchange takes place across individual exchange models, and advance health systems and data interoperability.

Electronic health information can be a critical element in the implementation of business models, such as bundled payments and accountable care organizations being implemented through the Affordable Care Act. These delivery system reform models will rely on richer and more timely information to better align payments with the actual costs of providing efficient care. These efforts, as well as future proposals for subsequent stages of meaningful use, will rely on these emerging models for sustainable information exchange and will likely require greater capacity for connecting the various models – so that providers may securely send health information to any other authorized provider through the Internet. HHS recognizes that the government has a duty to help ensure that health information can flow where needed and follow patients where they go, consistent with patient preferences. CMS recently reinforced this policy in its proposed regulations on accountable care organizations[ix]. ONC is putting in place the standards, services, and policies to support the infrastructure needed to connect these emerging models for exchange.

Nationally, the government is developing a standards and interoperability framework (S&I framework) to harmonize existing standards and improve sharing of standards across different organizations and federal agencies, making it easier to broaden interoperability through shared standards for data and services. In order to support exchange and advance interoperability, there are three types of standards that the S&I framework will support.

First, the S&I framework will focus on identifying transport standards. These standards enable one provider to exchange data with another provider, or

one system to another system, securely. A second type of standards is necessary for the data to be interoperable between different providers, or systems. These are known as content standards, which allow data to be packaged or "read" in a way that is useful for the provider. For example, the Medicare and Medicaid Incentive Programs' stage one criteria require that an eligible professional generate and transmit prescriptions electronically. The S&I framework ensures that standards are available that enable certified EHR technology to view data in a way that is usable to the provider in ordering the prescription and usable to the pharmacist receiving the prescription. Lastly, the S&I framework will identify vocabulary and terminology standards and value sets in order to achieve semantic interoperability at the level of individual data elements. ONC will work to reduce variability in vocabulary and terminology standards which will help to reduce costs and to move toward more semantically interoperable health information exchange. ONC will work with its federal partners and standards development organizations to harmonize the existing standards and vocabularies they produce to create the building blocks and implementation packages in support of national priorities, including meaningful use.

The S&I framework is intended to be flexible, so that it can be used to establish meta-data standards, or "data about data," that include additional information about the context in which the data has been collected. The S&I framework will provide tools, data and meta-data standards, value sets, and service descriptions in an integrated and harmonized way to support meaningful use and interoperability, and focus these efforts on the highest priority kinds of information exchange. ONC is leading this effort in close collaboration with other federal agencies. The S&I framework will support not only existing specifications for the Nationwide Health Information Network, but also support new meta-data tagged approaches recommended by the President's Council of Advisors on Science and Technology (PCAST) December 8, 2010 report, *Realizing the Full Potential of Health Information Technology To Improve Healthcare for Americans: The Path Forward*.

ONC, and its federal partners, will continue to use the HIT Policy and HIT Standards Committees (ONC's federal advisory committees) to provide recommendations on priorities for standards. ONC, and its partners, will promote the adoption of standards through the Medicare and Medicaid Incentive Programs and other federal programs.

In establishing and maintaining the S&I framework, ONC will leverage the National Information Exchange Model (NIEM) processes. NIEM is a government collaborative of the U.S. Department of Justice, the U.S. Department of Homeland Security, and HHS designed to develop, disseminate, and support enterprise-wide information exchange standards and processes to enable jurisdictions to effectively share critical information. NIEM processes will help ensure that existing applicable standards are re-used when possible, creating efficiencies in the government standards work. ONC will work with its federal partners to leverage the NIEM processes where possible and add to it as necessary.

This strategy recognizes the experience and leadership of federal agencies and offices – including National Institutes of Health/National Library of Medicine (NIH/NLM), Centers for Disease Control and Prevention (CDC), CMS, AHRQ, FDA, and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) – and private sector standards development organizations and aims to leverage existing standards and standards development processes where possible. The federal government has a role in ensuring that standards designated for U.S. health information exchange are readily available and are regularly maintained and enhanced in response to feedback from implementers and users. Federal agencies encourage the adoption and use of standards, participate and coordinate actively in standards development organizations, and direct and support specific standards development projects to address implementation problems and fill gaps. In the case of some terminologies and code sets, federal agencies, including NIH, CDC, CMS, and FDA, support the development and ongoing maintenance and free dissemination of designated standards and

promote their use across the spectrum of health care, public health, and research.

Using the integrated set of specifications developed in the S&I framework and shared services and infrastructure (e.g., provider directories, record locator services, and master patient indices), the Nationwide Health Information Network will be the preferred solution to securely exchange information nationwide to support meaningful use. Health care organizations using the Nationwide Health Information Network to share health information can serve as innovators, creating a pathway to more advanced health information exchange and interoperability.

In order to engender trust and interoperability and facilitate broad participation in the Nationwide Health Information Network, ONC will establish a governance mechanism through rulemaking that seeks to include accountability and oversight of nationwide information exchange. The Nationwide Health Information Network governance rules will be established as a voluntary solution to health information exchange. The government will pursue various options to encourage participation in this preferred solution to nationwide information exchange.

In carrying out its assigned duties, ONC is tracking standards activities in other countries and learning from their experiences with health IT and health information exchange. Currently, ONC is working to identify whether there are internationally recognized standards that should be endorsed for use in the United States. To further this effort, ONC intends to participate in international efforts to identify interoperability standards and implementation specifications for EHR technologies that will facilitate data and systems integration. ONC's input into these international standards activities should ensure that U.S. standards will work with the international community in the event of global public health emergencies.

OBJECTIVE C
Support health IT adoption and information exchange for public health and populations with unique needs

Strategy I.C.1: **Ensure public health agencies are able to receive and share information with providers using certified EHR technology.**

CDC, CMS, FDA, NIH, HRSA, the Assistant Secretary for Preparedness and Response (ASPR), and ONC are working together to ensure that meaningful use of certified EHR technology supports the needs of public health agencies. Meaningful use stage one currently includes an objective on the menu set to submit electronic syndromic surveillance data, immunization registries, and electronic lab reporting to public health agencies. This will pave the way for EHRs to exchange information with local, state, and federal public health agencies and will set the stage for two-way communication between providers and these public health agencies prior to, during, and after an incident. Eventually, information exchange between providers and public health entities can be expanded. It can include routine and emergency public health preparedness and response, and many-ways exchange of information (i.e., between different providers, public health agencies at different jurisdictions, and public health reference laboratories) for immunizations, public health case reports, and situational awareness reports. CDC is helping local and state public health agencies prepare their systems and processes for such changes. Through the State HIE Cooperative Agreement Program, state governments and state Medicaid agencies will play a key role in building the public health infrastructure to support meaningful use. As with clinical data, public health departments require public health standards to effectively exchange information. CDC's Public Health Informatics and Technology Program Office (PHITPO) at the Office of Surveillance, Epidemiology and Laboratory Services (OSELS) is leading the development of public health standards in coordination with FDA, NIH and other agencies, that align with certified EHR technology.

Strategy I.C.2: **Track health disparities and promote health IT that reduces them.**

In order to achieve nationwide adoption and meaningful use of certified EHRs, it is critical that providers who face unequal challenges in adopting and using EHRs be included in the government's initiatives. The RECs are providing outreach and technical assistance to support providers who serve underserved communities and resource-poor settings, including small practice settings, rural hospitals/clinics, community health centers, and Critical Access Hospitals. The RECs will work through community-based organizations and will develop tailored solutions and best practices to reach these providers. RECs will also collaborate with groups representing underserved and minority providers on the national and local levels.

ONC is also investing in better ways to monitor and identify disparities in health IT adoption. This effort can enable ONC to measure health IT adoption disparities and focus resources on areas of greatest need to mitigate disparities.

HHS is evaluating approaches for using health IT to collect and analyze data about disparities (on the bases of race, ethnicity, gender, primary language, and disability status) in health and health care provision, and using this data to improve the care of underserved populations. Beacon Community grantees are acting as test sites for using health IT for this purpose. RECs will disseminate best practices identified by Beacon Communities to providers and other organizations serving underserved communities. NIST will provide technical guidance for EHR design and development, in order to help prevent the creation or exacerbation of health care disparities with the adoption and utilization of EHRs.

Through efforts underway related to the Medicare and Medicaid EHR Incentive Programs, the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009, and other initiatives authorized by the Affordable Care Act, HHS is developing electronic clinical quality measures that enable providers and hospitals to gauge the health status of their communities. Also,

standards developed to support meaningful use will strengthen data collection and quality measurement, enabling quality improvement efforts that reduce health disparities.

Existing health IT applications such as telehealth can be used to address gaps in access and quality of health care services. Telehealth uses electronic information and telecommunications technologies such as videoconferencing and wireless communication to support long-distance care. The HRSA Health Disparities Collaboratives (HDC) were created to assist in the transformation of primary health care practices in order to improve the care provided to everyone and to eliminate health disparities. HDC now continues as a private endeavor. HRSA's Telehealth Network Grant Program supports established telehealth networks that are looking to expand the number of sites that are receiving clinical services. HRSA's Telehealth Resource Program funds Centers of Excellence, which provide technical assistance on telehealth to any HRSA grantee in the country. In addition, IHS, VA, CMS, and USDA all take advantage of telehealth technologies to meet the needs of disparate populations. In order to improve access to quality health care services through telehealth, ONC is working with states to increase medical licensure portability by streamlining licensure application and credentials verification processes so providers can more easily apply for a license in multiple states. ONC is also working with HRSA on developing a report to Congress for the use of health information technology in underserved communities.

Strategy I.C.3: **Support health IT adoption and information exchange in long-term/ post-acute, behavioral health, and emergency care settings.**

Providers working in long-term and post-acute care (LTPAC) and behavioral health settings are essential partners in patient care coordination. ONC, CMS, and ASPE will collaborate to address quality measures and evolving clinical decision support opportunities that will promote appropriate exchange of health information in LTPAC and behavioral health care settings for optimal coordination of care.

HHS will build on meaningful use to adopt electronic standards for the exchange of clinical data among facilities and community-based LTPAC settings, including, where available, standards for messaging and nomenclature. ONC will leverage the State HIE and Beacon Community grant programs in demonstrating methods for which the electronic exchange of information with LTPAC entities can improve care coordination. In addition, HHS will identify opportunities in the Affordable Care Act to support the use of health information exchange technologies by LTPAC and behavioral health providers to improve quality of care and care coordination.

SAMHSA, in collaboration with ONC, will explore approaches to support adoption of certified EHR technology within the behavioral health community.

ONC is working with SAMHSA and HRSA to address the policies and standards concerning the unique needs of behavioral health IT adoption and information exchange. This includes work on data and meta-data standards that can provide additional clinical context such as patient preferences and sources of data to help enable data segmentation and secure exchange of sensitive health information. The ability to integrate mental health data into the primary care and related safety net system is essential for coordinating care.

Recognizing that emergency care settings are essential places for patient care coordination, ONC and ASPR will explore ways to address the need for clinical data to be available in emergency care situations and identify policies and standards that are necessary to support these needs.

Goal II: Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT

The recently passed Affordable Care Act will transform American health care from a system that emphasizes transactions to a system that emphasizes improved care, improved population health, and reduced per capita costs of health care. The widespread adoption and meaningful use of certified EHR technology is a necessary interim step in this transformation. It will be essential to build upon this health IT infrastructure and use the information made available by EHRs in order to move toward HHS' three overarching aims. But while health IT is necessary to affect such changes, technology by itself is insufficient. For this reason, federal health IT investments are being made in lockstep with other reform efforts, many of which were initiated and funded by the Affordable Care Act.

Programs underway at ONC and AHRQ are looking at ways to combine more sophisticated uses of health IT and clinical care redesign to achieve better health outcomes and improve health system performance. The HITRC and REC programs will make these best practices – such as using clinical decision support tools, patient registries, and reminder systems – available to providers throughout the country. The CHIPRA Quality Demonstration grants are also expected to demonstrate promising new ways that health IT can be used to improve pediatric health care. CMS expects that for future stages of meaningful use, the financial incentives will encourage providers to use more sophisticated health IT to achieve higher level improvement measures. HHS will leverage both the Medicare and Medicaid EHR Incentive Programs and the implementation of administrative simplification requirements under Section 1104 of the Affordable Care Act to create cost savings through increased standardization and automation of health care administrative functions.

A key part of the Affordable Care Act is the development of quality and outcome measures. E-measures can facilitate the electronic capture, reuse and reporting of health data. E-measures will support federal and state quality improvement efforts and enable providers to assess their own performance with their patients.

Central to both the HITECH Act and the Affordable Care Act is fostering and learning from breakthrough examples of health care delivery system change, which can then serve as models for more widespread changes. The Beacon Community grants from the HITECH Act have created 17 demonstration communities in which clinicians, hospitals, payers, and patients will show how advanced uses of health IT can achieve improvement goals in care, efficiency, and population health. The new CMS Center for Medicare and Medicaid Innovation will test a range of innovative payment and service delivery models, many of which will require advanced uses of health IT to achieve their objectives. These examples may employ the latest health IT – remote monitoring, telehealth, mobile health (mHealth) applications, and the most advanced means of information exchange – and could become achievable, sustainable, and replicable examples of how the government can build upon the nationwide adoption and meaningful use of EHRs.

Finally, the Affordable Care Act directs HHS to develop a national strategy for prevention and health promotion. Health IT will play a fundamental role in supporting this national strategy, providing the necessary infrastructure for disease prevention, early detection, and condition management before an illness becomes severe. CDC, in collaboration with state, local, and other federal public health agencies, leads federal efforts to provide and improve the core capacities of the public health IT infrastructure. Health IT facilitates coordination across public health entities and other organizations, improves identification of at-risk populations and their adherence to public health guidelines, expedites responses to threats, notifiable conditions, and adverse population events, and promotes consumer

participation in public health by encouraging healthy behaviors and behaviors that screen for, detect, and effectively manage disease.

The government has four objectives to "Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT":

A. Support more sophisticated uses of EHRs and other health IT to improve health system performance

B. Better manage care, efficiency, and population health through EHR-generated reporting measures

C. Demonstrate health IT-enabled reform of payment structures, clinical practices, and population health management

D. Support new approaches to the use of health IT in research, public and population health, and national health security

Spotlight on Health Outcomes

Health IT and information sharing can improve medical decision-making

Meaningful use of EHRs can result in more effective management of the risk factors associated with heart disease. George's PCP works within a patient-centered medical home model that provides the organizational infrastructure and support so that she can best manage George's care. This model helps to improve coordination of George's care by enabling any specialists George sees and PCP to electronically access and share critical information to make better informed, appropriate and timely care decisions. Through electronic information exchange, all the providers on George's care team are able to seamlessly review George's most recent blood pressure reading, smoking status, labs, diagnostic tests, and clinic visit notes. George's cardiologist is able to make recommendations using information in real time, and his PCP can view the care plan in the EHR. All of these providers can share in the reward for providing better value health care and keeping George healthy.

While in the hospital, Jane's physician notices she is slurring her speech and exhibiting some slight right arm weakness. He believes she is having a stroke and instructs the care team to start the appropriate treatment protocol. To confirm the diagnosis, Jane's phycian consults her health record that is shared by all the providers on her care team. He notices that in a visit with her PCP last week, there is no indication of a problem with Jane's speech or strength in either arm, which suggests these symptoms are new. The physician discusses with Jane and her family that she is likely having a stroke. With the patient's and her family's consent, the medical team performs a CT scan of Jane's head and starts medication immediately to break up the clot and save Jane from a potentially debilitating stroke. Without the shared information on hand, Jane's symptoms may not have been noticed.

These "Spotlight on Health Outcomes" are intended to highlight exemplary ways that widespread adoption and use of health IT and electronic health information exchange could help transform and improve health care. Some of these examples are only aspirational today or only exist in select communities or health systems. However, these examples illustrate the type of transformed health care that could be possible with the achievement of the goals of this Plan. **See endnotes for citations.**

OBJECTIVE A
Support more sophisticated uses of EHRs and other health IT to improve health system performance

Strategy II.A.1: Identify and implement best practices that use EHRs and other health IT to improve care, efficiency, and population health.

Goal I of this plan describes the Medicare and Medicaid EHR Incentive Programs' payments available to providers who become meaningful users – the centerpiece of the government's health IT strategy. The success of the meaningful use program will create the fundamental health IT adoption within the health system necessary to support the health reform efforts outlined in the Affordable Care Act. The Medicare and Medicaid EHR Incentive Programs, as established by the HITECH Act, represent a significant step in enhancing the performance of the health system. The Medicare and Medicaid EHR Incentive Programs also create a basic health IT and information exchange foundation that can support further improvement interventions that are either not possible or too difficult and burdensome on providers without this foundation.

The HITRC program makes tools and best practices available to providers as they implement clinical care redesign and more sophisticated health IT into their offices. HITRC will identify ways to build on EHR use by changing clinical workflows and integrating EHR software, patient registries, and medication reminder systems. The use of these tools can support better decision-making at the point of care and increased adherence to treatment regimens, helping move health care from a reactive system to one that focuses on prevention and improved care management.

Clinical decision support (CDS) systems are tools that leverage EHRs to improve clinical processes. Broadly, these software systems build off of EHRs, giving providers helpful information and analytical support at the point of care. Various clinical decision support rules can help providers analyze patient information, supply them with performance reports against quality measures, and assist them with diagnoses.

AHRQ and CDC will continue their critical role in assessing and promoting best practices related to how health IT can be utilized to improve quality of care, patient engagement in self-care, management of chronic diseases, and management of public and population health.

Promising practices and lessons learned from the CMS CHIPRA Quality Demonstrations will be communicated on a regular basis to State Medicaid and CHIP programs to further promote successful HIT and EHR initiatives important to vulnerable populations.

With the establishment of the REC program, the government now has a way to disseminate tools and best practices to providers that need the most help in implementing them into their practices. The RECs will build on their existing relationships with these providers to help them achieve improved health outcomes through more sophisticated uses of EHRs and other health IT.

Strategy II.A.2: Create administrative efficiencies to reduce cost and burden for providers, payers, and government health programs.

For future stages of meaningful use, HHS expects to propose measures that simplify administrative processes and help lower costs in the clinical setting.

In January 2009, HHS adopted modifications to two HIPAA Administrative Simplification medical data code set standards for medical diagnosis and inpatient procedure coding. Under these regulations, covered entities will be required to transition from using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) in HIPAA-covered transactions to using the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM/PCS), Procedure Coding System in October 2013. ICD-10-CM/PCS code sets will enable a more granular understanding of health care treatments and outcomes, and more complete analyses of treatment

costs, ultimately allowing for better disease management and more efficient health care delivery.

In expanding coverage to as many as 32 million new Americans, the Affordable Care Act called for some specific technology-enabled improvements in the government's administration of health care. These include: standards and protocols for streamlining eligibility and enrollment into federal and state health and human services programs; a consumer portal for accessing health insurance information online; and the creation of new health insurance exchanges by 2014. To fulfill the requirement under Section 1561 of the Affordable Care Act to develop interoperable and secure standards and protocols to facilitate enrollment of individuals in federal and state health and human services programs, ONC organized a workgroup, under the auspices of the HIT Policy Committee and HIT Standards Committee, that produced recommendations to those committees, which were approved by the full committees to facilitate more seamless enrollment processes. The government will incorporate standards and criteria as a condition for receiving federal grant funding for these systems, and will employ other mechanisms to further the development of efficient eligibility and enrollment systems. ONC will support the implementation of these health information technology improvements where mandated by law, and in all cases will ensure that the Affordable Care Act technology implementation efforts are synchronized with federal priorities for meaningful use and health IT privacy and security. HHS will also reduce the burden for providers when reporting required data to federal agencies through use of data standards and efficient and effective information exchange planning and design.

OBJECTIVE B
Better manage care, efficiency, and population health through EHR-generated reporting measures

Strategy II.B.1: Identify specific measures that align with the National Quality Strategy.

In March 2011, HHS established the National Quality Strategy, as required by the Affordable Care Act. The Plan initially focuses on six priorities that have great potential for rapidly improving health outcomes and increasing the effectiveness of care for all populations. As the National Quality Strategy is implemented in 2011 and beyond, HHS will work with stakeholders to create specific quantitative goals and measures for each of these priorities. A part of these activities will be the development of e-measures that can collect and report data through EHRs. HHS agencies will work together to ensure the development of e-measures that are aligned across reporting programs to reduce the burden on providers and that can be supported by the implementation of the Medicare and Medicaid EHR Incentive Programs.

Strategy II.B.2: Establish standards, specifications, and certification criteria for collecting and reporting measures through certified EHR technology.

Based on the measures defined in II.B.1, ONC, in collaboration with others in HHS, VA, and DoD will establish standards, specifications, and certification criteria for EHRs that facilitate the collection and reporting of e-measures. Using the S&I framework, these e-measures will be harmonized with other standards used to support data collection and information exchange. The development of e-measures will lead to more cost efficient and timely assessments of health care performance.

Building e-measures into EHRs will allow providers to assess and monitor their health care performance. ONC will make available open source tools that help providers submit quality measures to government agencies, better understand their patient populations, and identify opportunities for improving the health of their patients.

OBJECTIVE C

Demonstrate health IT-enabled reform of payment structures, clinical practices, and population health management

Strategy II.C.1: Fund and administer demonstration communities to show how the advanced use of health IT can achieve measurable improvements in care, efficiency, and population health.

ONC is funding 17 Beacon Communities with the specific mission to identify and show improvement on care, efficiency, and population health outcomes through the use of health IT. VA and HRSA are partnering with ONC to support these Beacon Communities. By 2014, Beacon communities are expected to demonstrate that their advanced uses of health IT, and associated outcome improvements, are both possible and replicable. By 2015, they are anticipated to show how these efforts can be expanded to other communities and how they can be sustained over time. Key findings from these communities will be incorporated into guidance for RECs, State HIE programs, and meaningful use proposed objectives, and thus, will be expanded to a national scale.

Strategy II.C.2: Align health IT initiatives and clinical and payment reform pilots and demonstrations.

The Affordable Care Act authorized a wide range of innovative programs using payment reforms to promote quality, efficiency, and equity of care. These include bundled payment pilots, medical home pilots, and others. CMS will have the charge to quickly and effectively translate knowledge from these innovative programs into wider CMS policy. Health IT will be an important tool to support many of these demonstration projects. The federal government will work to assure that, when appropriate, health IT is properly leveraged for these innovative programs, and that proven outcomes associated with defined uses of health IT are encouraged in the wider health care community.

Outside of ONC and CMS, there are many other examples of health IT-enabled reform being implemented today. Private sector technology companies, provider networks, payers, and public providers such as VA, IHS, and DoD, are funding a wide range of initiatives that experiment with health IT in clinical settings, including the expanded potential for open source electronic health record systems that will complement private sector proprietary systems. These initiatives offer an important opportunity for capturing best practices and applying them to the wider health care system. The federal government will monitor and study such efforts around the country and seek to expand on already-successful programs.

OBJECTIVE D

Support new approaches to the use of health IT in research, public and population health, and national health security

Strategy II.D.1: Establish new approaches to and identify ways health IT can support national prevention, health promotion, public health, and national health security.

The Affordable Care Act included significant resources for improving public health and prevention. These new strategies will influence the way public health is administered across the country and health IT will be a fundamental part of that change. Public health IT infrastructure investments, such as those discussed in Strategy II.D.2 below, will be updated and aligned with these approaches to public and population health.

The Prevention and Public Health Fund has supported a new program entitled Strengthening Public Health Infrastructure for Improved Health Outcomes, to increase the performance management capacity of public health departments and ensure that public health goals are being met. Health IT and communications infrastructure is one of the four areas of improvement sought through the program. In FY 2010, CDC awarded a total of $42.5 million to

projects at state and local public health departments.[x]

Health IT is critical in supporting new approaches to national health security. The use of health IT during a public health emergency can facilitate continuity of care for the impacted population by enabling electronic health information to flow for emergency care. In the event of a natural disaster, having health records in an electronic form can help avoid the impact of destroyed paper records and ensure that the affected population's health information can be accessed in the event of displacement.

Strategy II.D.2: Invest in health IT infrastructure to support the National Prevention and Health Promotion Strategy.

CDC, in collaboration with public health agencies at the federal, state, and local levels, will invest in public health IT infrastructure to improve a number of the public health agencies' core capacities. These capacities include:

- Anticipating, preventing, and responding to health threats, reportable diseases, and adverse population events

- Identifying populations with specific health care needs (e.g. at risk populations, children, etc.) and promoting their adherence to public health guidelines

- Preparing for and responding to emergencies

- Communicating with consumers and encouraging their participation in public health

For instance, CDC programs support information exchange across jurisdictional boundaries by integrating with the Nationwide Health Information Network, and provide agencies with common tools for disease detection, monitoring, and real-time situational awareness. The National Electronic Disease Surveillance System (NEDSS) advances the transition to standards-based electronic data exchange for reportable disease surveillance, improving agencies' capabilities in detecting and responding to reportable diseases. The National Environmental Public Health Tracking Network melds data from environmental hazard monitoring

and human exposure and health effect surveillance into a network of standardized electronic data systems. Continued investments in these and other programs will support the National Prevention and Health Promotion Strategy.

Strategy II.D.3: Ensure a mechanism for information exchange in support of research and the translation of research findings back into clinical practice.

In order to support information exchange vital for research, information in an EHR, with the appropriate privacy protections, should be accessible by researchers, research systems, biorepositories, registries, and other types of research databases. In turn, adopted health IT interoperability standards should be used in research studies – and enhanced to cover unique research needs – in order to facilitate both the use of health care data in research and the translation of research results into clinical practice. This two-way interaction between research and clinical care, facilitated by health IT, has the potential to accelerate the generation of important new information on medical interventions, personalized treatments and public health initiatives utilizing population-based knowledge as well as the development of new tools for medicine, such as computerized decision support systems. For example, the Electronic Medical Records and Genomics (eMERGE) Network has developed and applied approaches to research that combine DNA biorepositories with EHR systems for large-scale, high-throughput genetic research such as genome-wide association studies on a variety of diseases. The consortia, like the NIH-supported Clinical and Translational Science Award (CTSA) programs, are maximizing the ability of researchers to leverage the wealth of existing data to strengthen knowledge building and evidence creation, and ultimately improve clinical and preventive care through a more rapid progression of knowledge from the laboratory to clinical care implementation. Another example is The Cancer Biomedical Informatics Grid (caBIG), an information network sponsored by the National Cancer Institute (NCI), which provides tools, data, and services to enable researchers, providers, and

patients throughout the oncology community to collaborate and share expertise and data.

Meaningful use of certified EHR technology in clinical research presents an opportunity to use data collected through routine operations in a clinical practice to generate and test hypotheses about the relationships among patients, diseases, therapies, prevention, treatment and recovery, and clinical outcomes. It can improve the understanding of the correlations between genotypes and phenotypes and genomic and epigenetic interactions and interrelationships, improve the identification and tracking of medical events such as epidemics and adverse events related to treatment, and facilitate surveys of the health of the public at speeds approaching real time. Data from EHRs are crucial for patient-centered research and can provide insights for researchers and benefits for patients and providers in terms of improved care and

personalized treatments. These efforts will be consistent with the privacy and security activities outlined in Goal III of this Plan. Using EHRs may eliminate redundant data entry, thus improving data quality and processing speed; may stimulate a learning health system in which the translation of research findings into clinical care supports continual improvement in knowledge, treatment and health; and may increase opportunities for patients to participate in research, particularly in underserved communities and public health settings.

The efficient collection and exchange of EHR data for research purposes, coupled with the use of applicable EHR interoperability standards in research studies, would also ensure that key findings that lead to improvements in population and individual health are rapidly translated back into clinical practice. This will help to create the learning health system envisioned in Goal V of this Plan.

Goal III: Inspire Confidence and Trust in Health IT

Protecting the privacy and security of health care information, and ensuring the safe use of health technology, have long been core responsibilities of the government. These responsibilities have needed to evolve constantly with the development of new technologies and the adoption of new health care practices. Health IT – with its potentially dramatic impact on the practice of medicine – requires the government to further evaluate and update policies and programs in privacy and security areas over the next five years. In evaluating and updating its policies and programs, the government will rely on the *Fair Information Practice Principles*[xi] and the *Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information.* [xii]

EHRs and other health IT will enhance the quality and value of health care, but only if there are appropriate protections in place to keep health information private and secure. Privacy and security are the bedrock of building trust, a must-have component that is essential to achieving meaningful use and realizing the value of health IT. Patients and providers must feel confident that laws, policies, and processes are in place to keep their health information private and secure, and that they will be enforced when violations occur.

To that end, the HHS Office for Civil Rights (OCR) is fulfilling new obligations under the HITECH Act to modify the Privacy and Security Rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to strengthen the privacy and security protections for health information and the enforcement of and penalties for violating the HIPAA rules.

These added privacy and security protections are an integral piece of the government's increased efforts to broaden the use of IT in health care. ONC is also exploring areas beyond HIPAA that are necessary to ensure trust in widespread health information exchange, including governance of the Nationwide Health Information Network. Through the health IT certification program and ONC's partnership with other federal entities, ONC is working to enhance privacy and security features in EHRs and to work with HITECH grantees to make sure appropriate privacy and security strategies are in place.

ONC is collaborating with OCR on a comprehensive communications plan to reach out to providers, consumers, and other stakeholders to educate and inform them of the importance of health IT security and ways they can help to keep protected health information secure.

In addition to added privacy and security protections, ONC and OCR recognize the importance of increasing efforts to inform individuals and providers of patients' rights with regard to their protected health information and to increase public transparency regarding the potential uses of protected health information. Individuals must understand their rights, be aware of the federal government's efforts to protect those rights, and be notified of any breaches of unsecured protected health information that occur.

In addition to the HIPAA Privacy and Security Rules, which provide a set of national standards for the protection of certain health information, other federal laws afford additional protections for information which may be particularly sensitive, such as that related to individuals who are treated for alcohol and/or drug abuse. SAMHSA, working with ONC and OCR will address issues of behavioral health privacy and confidentiality in the health IT environment.

EHRs and other health IT offer tremendous potential to improve patient safety and to help health care providers practice safer and more effective care. ONC took a key first step toward thoroughly assessing health IT patient safety concerns through the commission of a report by the Institute of Medicine (IOM). In addition, ONC is engaged in an ongoing effort to disseminate best practice resources to providers to help equip them with the latest information, so as to avoid common challenges to safe and effective implementation and use of EHRs and other health IT.

The government's objectives to "Inspire Confidence and Trust in Health IT" are:

A. Protect confidentiality, integrity, and availability of health information

   B. Inform individuals of their rights and increase transparency regarding the uses of protected health information

C. Improve safety and effectiveness of health IT

Spotlight on Health Outcomes

Use of health IT can enhance patient trust and care management

Three years ago, George's PCP's practice was flooded during a hurricane. Fortunately, George's provider had an EHR system that backed up all of George's medical information on a remote, secure server. When George was displaced after the storm, his new PCP was able to retrieve his entire medical record, rather than George having to reconstruct his medical history from memory. George's provider was able to see what medications, allergies, coexisting conditions, and risks she must manage to ensure that George's care is continued.

When Jane has concerns about her ability to manage her COPD and especially when she is concerned about developing an infection, she is able to exchange secure messages with her PCP to get feedback without requiring a trip to the provider's office. When Jane describes to her provider some early warning signs of an infection, her provider electronically prescribes antibiotics that she is able to take immediately to stem the possibility of an infection. Jane enjoys being able to log into her online portal and show her children that she is indeed managing her blood pressure well and can answer their questions regarding what medications she is taking and her latest lab test results. Jane's PCP is able to proactively address Jane's questions about the correct dosage of her medications in real time and without the added delay of having to wait until her next appointment.

These "Spotlight on Health Outcomes" are intended to highlight exemplary ways that widespread adoption and use of health IT and electronic health information exchange could help transform and improve health care. Some of these examples are only aspirational today or only exist in select communities or health systems. However, these examples illustrate the type of transformed health care that could be possible with the achievement of the goals of this Plan.

OBJECTIVE A
Protect confidentiality, integrity, and availability of health information

Strategy III.A.1: Promulgate appropriate and enforceable federal policies to protect the privacy and security of health information.

It is HHS' policy that the privacy and security of individually identifiable health information should be protected wherever it is electronically transmitted, maintained, or received. While the HIPAA Privacy and Security Rules are key safeguards, they are not the only means available for affording this protection. HHS will work with other federal agencies, states and other stakeholders to ensure that appropriate policies are in place.

The means for collecting, managing, storing, and transmitting electronic health information are rapidly advancing. ONC, along with its federal partners, will strive to ensure that federal privacy and security policies, including regulations and guidance, keep pace with this evolving field.

As a first step, OCR is crafting rules to implement the modifications to the HIPAA Privacy and Security Rules as required by the HITECH Act. Among other changes, these rules will:

- Impose direct liability on business associates for compliance with certain provisions of the HIPAA Privacy and Security Rules

- Establish new restrictions on the sale of protected health information

- Establish stronger restrictions on disclosing health information for marketing and fundraising purposes

- Provide increased transparency regarding how health information is shared

- Strengthen individuals' rights to access their health information electronically

OCR has also issued rules required by the HITECH Act that specify the conditions under which covered entities must notify individuals, HHS, and in some cases the media, of breaches of unsecured protected health information.

HHS has commenced the process of exploring broader privacy and security policies that may be necessary to ensure trust in electronic health information exchange. In exploring these topics, ONC will be guided by the *Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information,* a set of privacy and security principles grounded in the fair information practice principles (FIPPs) released in 2008. The process of updating HHS's approach to privacy and security policies begins with input from ONC's federal advisory committees – the HIT Policy Committee and HIT Standards Committee – which identify, assess and recommend solutions to evolving privacy and security issues. These recommendations are considered by ONC in light of other policies and activities and are brought by ONC to an HHS Inter-Division Task Force that is charged with establishing policy direction in this area. ONC then gathers broader Federal feedback through the Federal Health IT Task Force. The goal is to resolve federal policy direction on this first set of privacy and security issues by the end of 2011.

HHS will address, at a minimum, the following key policy areas:

- Individual choice to participate in health information exchange

- Access limitations and transparency for electronic health information exchange

- Security, including provider and patient authentication and de-identification of personal health information

- Integrity of health information

- Secondary uses of health information for the purposes of quality improvement, public health, and research

- In consultation with the Federal Trade Commission (FTC), potential regulation models with respect to personal health records (PHRs)

There are a number of potential levers for instituting any new privacy and security policies that develop

out of this process, including formal rulemaking where authorized, which would provide the opportunity for public comment. It is expected that privacy and security will be components of ONC's anticipated regulations to establish a governance mechanism for the Nationwide Health Information Network. Concerns with exchanging digital information over the Internet are not confined to the health care sphere. ONC is collaborating with other federal agencies to learn from and implement consistent approaches to privacy and security. For example, ONC is working with the Presidential workgroup formulating the National Strategy for Trusted Identities in Cyberspace. In addition, as a participant in the National Science and Technology Committee's Subcommittee on Privacy and Internet Policy, ONC is working with other agencies to address privacy issues arising from the evolving means of collecting and analyzing data, including health information, as it flows over the Internet.

Strategy III.A.2: Enforce existing federal privacy and security laws and maintain consistency with federal policy.

In order for providers and patients to have trust in health IT and information exchange, they must be confident that privacy and security laws are in place and will be enforced. OCR is charged with civil enforcement of the HIPAA Privacy, Security, and Breach Notification Rules, the primary federal regulations protecting health information. The HITECH Act strengthens OCR's civil enforcement of the HIPAA Rules by establishing four categories of violations that reflect increasing levels of culpability; four corresponding tiers of penalty amounts that significantly increase the minimum penalty amount for each violation; and a maximum penalty amount of $1.5 million for all violations of an identical provision during a calendar year. OCR also plans to conduct periodic audits that will assess covered entities' and business associates' compliance with the HIPAA Privacy and Security Rules. OCR will employ all of its enforcement tools – including imposing the increased penalty amounts for HIPAA violations, conducting compliance reviews, entering resolution agreements that are satisfactory to HHS for informally resolving indications of noncompliance, and conducting periodic audits – to improve compliance with the Privacy and Security Rules.

Strategy III.A.3: Encourage the incorporation of privacy and security functionality into health IT.

The use of appropriate technology can greatly enhance the privacy and security of health information. ONC, working with NIST and other federal partners, will encourage the incorporation of privacy and security functions into EHRs and other health IT. ONC and OCR seek to ensure that certified EHRs facilitate health care providers' compliance with the requirements of the HIPAA Security Rule. ONC's Final Rule on Standards and Certification Criteria for EHRs, issued in conjunction with the Medicare and Medicaid EHR Incentive Programs' stage one meaningful use requirements, requires that certified EHRs be capable of:

- Encrypting health information to keep it secure

- Establishing access controls that permit only authorized users to access the system

- Generating audit logs to record certain actions related to electronic health information

- Automatically logging off a user after a set time of inactivity

ONC will continue to identify additional security features that may be incorporated into EHR certification and standards in future stages of meaningful use.

Strategy III.A.4: Assess technical solutions that could support more granular patient choice and data segmentation.

Some individuals may want to give consent for some, but not all, of their personal health information to be exchanged (often called "data segmentation"). For example, an individual may not want information about his/her substance abuse treatment shared, but may still want to take advantage of the benefits of sharing the remainder of his/her health information electronically. Today, many EHR systems do not have the capability to

support more granular patient consent and data segmentation. In accordance with the HITECH Act, ONC is investigating, through research and potential demonstration projects, innovative means for protecting the privacy of health information, such as data segmentation and consent management tools. ONC will work closely with its SHARP grantee that is conducting research in this area.

In addition, ONC and SAMHSA are pilot testing the development of service specifications and reference models that can segment personal, electronic health care records into more or less sensitive parts and share sensitive parts only with appropriate authorization. This pilot will be broadly applicable, but particularly useful in the context of exchanging behavioral health information.

Strategy III.A.5: Identify health IT system security vulnerabilities and develop strategic solutions.

ONC will conduct analysis and research to identify the security vulnerabilities of existing and emerging health IT systems in order to identify where to best target its resources. As part of this effort, ONC will analyze health information breaches that are reported to HHS in order to identify the most likely sources of vulnerability. In addition, ONC will participate in the President's cybersecurity initiative and work with other federal partners, including the Federal CIO Council, to identify large-scale security threats and to develop strategic solutions. ONC will also conduct research to identify best practices for ensuring electronic health information remains available in the event of a system failure, cyber-attack, or other emergency event.

ONC is aware of the potential for the use of EHRs to facilitate fraud and will consider how to address the potential for fraud through its existing policies and programs. For example, ONC, following the leadership of the White House, is developing a national framework for high assurance physician identity management. The framework is intended to provide a simple but highly trustworthy means of assuring that physicians are who they claim to be in health information exchange. This framework, which will be piloted by key federal stakeholders such as

CMS and VA, should have a major impact on reducing medical identity theft and fraud. In addition, ONC will support the efforts of other federal agencies, including CMS and OIG, to explore a variety of options to improve efforts to combat fraud.

Strategy III.A.6: Identify health IT privacy and security requirements and best practices, and communicate them through health IT programs.

ONC, OCR, and SAMHSA will seek to ensure that privacy and security policies and recommended best practices remain aligned with advancements in technology. Privacy and security requirements and priorities will be identified based on analyses of security incidents and vulnerabilities, and best practices will be developed and disseminated. Where necessary, OCR will update guidance to reflect evolving privacy and security threats, for example the 2006 guidance on securing remote and mobile access, which has its basis in OMB memorandum M-06-16. ONC will work with OCR and SAMHSA to develop educational and guidance materials on privacy and security best practices for organizations implementing health IT. OCR will continue to issue guidance on complying with the HIPAA Privacy and Security Rules, and SAMHSA will continue to issue guidance on complying with 42 CFR Part 2. Additionally, State HIE Cooperative Agreements, Beacon Communities grants, and SHARP grants will demonstrate how privacy and security best practices can be identified, implemented, and brought to scale. Similarly, information on these privacy and security requirements and best practices will be channeled through the HITRC and the RECs, which offer opportunities to disseminate best practices to providers working to achieve meaningful use.

Some stakeholders have identified the variance in state health privacy laws as an impediment to exchanging health information among states. ONC will work with state governments and State HIE grantees to identify and develop best practices to exchange health information electronically among states with varying privacy laws. In addition, ONC is exploring technology solutions to aid implementation in a computable format of patient

consent and to enable information exchange among states.

State HIE grantees are required to incorporate privacy and security strategies into their implementation plans. ONC will work with the grantees to ensure that these privacy and security strategies are strong as part of its evaluation of the states' overall implementation plans. This work will be further informed by VA and DoD's experience with the VLER program, that facilitates information exchange of a Veteran's health record among different systems and states that may have differing privacy laws.

Privacy and security are key components in ONC's workforce education program as well as the materials being produced by the workforce curriculum development centers. ONC will review and evaluate these materials to help ensure that future health IT professionals are well educated on privacy and security requirements and best practices to ensure compliance with these policies.

OBJECTIVE B
Inform individuals of their rights and increase transparency regarding the uses of protected health information

Strategy III.B.1: Inform individuals about their privacy and security rights and how their information may be used and shared.

As part of its health IT education and outreach strategy, HHS will inform providers and individuals about the privacy and security rights and protections that are in place to safeguard their electronic health information. See Strategies I.A.6 and IV.A.2 for a more detailed discussion of this strategy. To support the goals of the HITECH Act (Sec. 13403(b), Education on Health Information Privacy), OCR and ONC are working in partnership to execute this education and outreach strategy over a two-year period in order to inform individuals about how their information is safeguarded, how their information may be used and shared, and how individuals can exercise their rights under the HIPAA Privacy Rule. This education and outreach

will also inform individuals about best practices that they can use to protect the privacy of health data they generate or maintain in consumer health IT tools. In order to accommodate the needs of non-English speaking individuals, these campaign materials will be available in multiple languages.

In an effort to help individuals easily access information about existing HHS privacy efforts and the policies supporting them, HHS launched an online resource center. The site provides transparency about HHS policies on the collection, use, and exchange of personally identifiable health information, and the privacy and security requirements for entities that collect and maintain health information.

Strategy III.B.2: Increase transparency regarding the development of policies and standards related to uses and sharing of protected health information.

ONC will engage with a wide range of consumer organizations and diverse communities in an effort to increase transparency of privacy and security issues and to develop policies and standards to address the consumer organizations and diverse communities' interests. The HIT Policy Committee and the HIT Standards Committee each have a Privacy and Security Workgroup that holds public meetings and makes recommendations to its parent federal advisory committee (FACA) related to privacy and security requirements, which in turn considers the workgroup's advice and may submit related recommendations to the National Coordinator. To date, these federal advisory committees have made recommendations on various privacy and security issues, including meaningful use criteria, certification criteria, individual consent, provider authentication, patient identification and use of intermediaries or third party service providers in arrangements to exchange individually identifiable health information. The Committees will explore new issues as they arise. ONC will actively seek public input into the development of these policies and standards through its federal advisory committees.

Strategy III.B.3: Maintain strong breach notification requirements.

To maintain consumer trust in EHRs and other health IT, individuals must be adequately informed of the use and sharing of their health information and appropriately notified when their personal health information has been compromised. OCR has issued an interim final regulation on breach notification that improves transparency and acts as an incentive to the health care industry to improve privacy and security by requiring HIPAA-covered entities to promptly notify affected individuals, the HHS Secretary, and, in some cases, the media, of a breach of unsecured protected health information, as well as requiring business associates to notify covered entities of a breach of unsecured protected health information. OCR is in the process of issuing a final breach notification regulation that responds to comments on the interim final breach notification rule. Similar breach notification provisions implemented and enforced by the FTC apply to non-HIPAA covered entities, such as vendors of certain PHRs and their third party service providers.

OBJECTIVE C
Improve safety and effectiveness of health IT

Strategy III.C.1: Provide implementation and best practice tools for the effective use of health IT.

AHRQ's Health IT Portfolio supports health services research grants and contracts that create new knowledge, synthesize and disseminate best evidence and provide tools for implementation addressing health IT's impact on the quality of health care. Current initiatives address clinical decision support, patient safety, patient centered care, quality measurement, and usability and workflow issues. In addition, ONC is actively working to make resources available to providers that allow them to maximize the value of using health IT by avoiding common challenges and legal issues associated with adoption, implementation, and use of EHRs and other health IT. Professional societies, licensing boards, and continuing education

programs are developing best practice resources related to issues such as workflow redesign, the need for ongoing maintenance and upgrades, and legal concerns related to vendor contract clauses. There are important legal issues that providers should be aware of when entering into agreements with EHR and other health IT vendors. ONC will work to equip providers with information and help address potential barriers they may face in achieving meaningful use, including improved usability of EHR technology (*see Strategy I.A.9*). ONC and RECs will ensure that appropriate best practice resources about these issues are distributed to the providers that need them.

Strategy III.C.2: Evaluate safety concerns and update approach to health IT safety.

ONC has commissioned the Institute of Medicine (IOM) to conduct a formal study of health IT patient safety concerns and to recommend additional actions and strategies to address those concerns, as well as to define the role of public and private sectors in ensuring safety of health IT-assisted health care services.

Strategy III.C.3: Monitor patient safety issues related to health IT and address concerns.

While developing an updated overall approach to health IT safety, HHS agencies are monitoring patient safety issues and addressing immediate concerns. ONC is exploring mechanisms to improve data integrity, including an assessment of existing and emerging technologies that may allow for automated resolution of inaccurate or questionable data in EHRs and PHRs.

AHRQ, in conjunction with FDA and ONC, developed a new protocol for reporting patient safety events involving HIT devices. This protocol was developed as part of the AHRQ Common Formats for reporting patient safety events and is available on the AHRQ Web site. AHRQ and FDA collaborated in order to harmonize HIT event reporting not only with Common Formats for other event types but also with FDA's MedSun system for reporting adverse events associated with devices. It is the goal of AHRQ, FDA, and ONC that providers

experiencing adverse events involving HIT will be able to report such events once and have the information flow to those interested in and authorized to receive it, e.g., Patient Safety Organizations, state reporting systems, accrediting bodies, and the FDA. It is expected that by providing standardized Formats for reporting HIT events efficiently, information can be aggregated, learning accelerated, and care made safer.

Goal IV: Empower Individuals with Health IT to Improve their Health and the Health Care System

Individual participation is a critical, yet currently underutilized, component in improving health and the overall health care system. Health care, which often means initiating medical solutions after something has gone wrong, can only go so far in improving health. Individuals' behaviors, and the ways in which communities foster healthy behaviors, are much more powerful forces for improving population health. But medical solutions, too, can become more centered on the individual: by arming people with knowledge and by giving them and their loved ones greater control over their own care. [xiii]

Health IT, which encompasses a broad category of tools and services, is critical in both empowering individuals to manage their health and shifting care to be more patient-centered so patients can be more active in health decisions and treatments. Existing and emerging technologies allow data to flow directly to and from the individual, wherever the individual may be. As a result, patient interactions with the health care system are no longer confined by the walls of the clinical setting and may occur frequently in between visits. PHRs allow patients to capture their own health observations and in some instances, to access their health information from providers. Mobile phones with glucometers allow individuals to track their blood sugar levels through their mobile devices. Mobile phones and related applications are also being used to send reminders to take medications or to send free health tips to help during a pregnancy. In mental health, mobile apps are being utilized to track moods and provide therapeutic interventions with personalized messages, exercises, and coaching. Using these tools and others, individuals can become more attuned to healthy behaviors, monitor their health, make informed personal health decisions, and receive preventative care. Patients managing illnesses or other ailments can use health IT to connect with other patients that share a similar condition, keep better track of their health care, receive health care solutions remotely, and participate in their care coordination.

However, only 7 percent of Americans have used a web site to access their health information online.[xiv] Even fewer have used mobile health (mHealth) applications and remote monitoring technologies. These low rates are the result of multiple dynamics: most consumers are not aware of nor able to afford the technologies, do not have access to their health information, or do not expect to take as active a role in their health and health care as they might in other aspects of their lives. As a result, they have not created a robust marketplace for technology innovation. To truly empower consumers and move the health care system to become more patient-centered, the government will need to help change these dynamics.

For individuals to become empowered they need to be included in the policymaking process. This means both understanding the government's approach to health IT and being able to shape the direction of policies and programs. An HHS-led health IT education and outreach strategy will seek to engage the public in dialogue about health IT and provide an opportunity to shape its future and the public's own expectations.

The single biggest lever to individual empowerment is access to data. Individual access to data can augment and improve patient-provider communications. It is not meant to replace this relationship, but rather to enhance it. Such data liquidity will make health IT meaningful for individuals, promote technological innovation, move care to center more on the individual, and ultimately have a direct effect on population health. Right now, there are too many barriers to individual and caregiver access to personal health care information. Engaging individuals with health data is a top priority of the Medicare and Medicaid EHR Incentive Programs. Other policies and regulations, such as the HIPAA Privacy Rule, will work in concert with meaningful use efforts to facilitate improved individual access to data. And the government intends to continue to develop tools

and serve as a model for exchanging data with individuals, as reflected in the Blue Button initiative at VA, DoD and CMS (see strategy IV.B.2 below for more information).

Consumer health IT is an emerging industry – it is new, fast-growing, and on the cutting edge of technology innovation. While the government will not lead the innovation that is likely to take place over the next five years – that is the role of the private sector – it will remain an active partner to address a number of key steps to collaborate with the industry and foster health IT research and innovation. If the government makes more of the data it collects available—as well as encouraging others to do the same--technology companies can develop applications and business models that make the information relevant and marketable to individuals. NIH and other government institutions directly fund research and development. HHS launches contests and challenge grants to focus innovation on specific areas that will benefit health care and the public good. These strategies to promote health IT innovation are discussed in more detail in Goal V Objective B, "Broaden the capacity of health IT through innovation and research."

As consumer technologies evolve and become more prevalent, and as individuals grow more accustomed to interacting with their health information using health IT, there will be a need to better integrate clinical practices with individual use of health IT outside of the care environment. Through ONC's EHR certification program, the government will facilitate the creation of clinical EHR systems that can accept information from consumer applications. The government will also help clinicians empower individuals with technology, and will encourage clinical practices to take advantage of consumer-generated health information, both of which are steps in achieving the ultimate aim of moving to more patient-centric care.

The government's objectives to "Empower Individuals with Health IT to Improve their Health and the Health Care System" are:

A. Engage individuals with health IT

B. Accelerate individual and caregiver access to their electronic health information in a format they can use and reuse

C. Integrate patient-generated health information and consumer health IT with clinical applications to support patient-centered care

Spotlight on Health Outcomes

Empowering patients with health IT can improve care management and quality of life

The ability to easily access health information electronically has spurred innovation in the development of mobile technology applications and other tools that can help patients better manage chronic diseases and stay healthy. After George is diagnosed with chronic heart failure, he and his PCP decide to use a new mobile health device to help him track his health status. Using sensors and an easy-to-use interface on his Smartphone, the device records his exercise patterns, heart rate, weight and diet. This information is uploaded to an online site where George sets goals, tracks progress, and engages in contests with other individuals managing CHF. Periodically, over the course of a year, George notices abnormalities in his trends and logs onto his personal health portal: a site where his personal health information is stored and both he and his provider have access to this electronic health information. There he uploads data from his mobile app, and sends a secure email to his provider to ask questions about what he is viewing in the portal. Without having to wait until the next appointment, the provider is able to tell George that everything looks fine and to encourage him to keep up the good work. When George does have his regular in-person visit a year later, his blood pressure is under control at 128/88 and his LDL is 70. These results, which George anticipated after noticing positive trends in his data and feeling better, indicate a significant improvement in George's cardiovascular health and a dramatic decrease in risk of a heart attack.

After her hospitalization, Jane's family decides they would like to take care of her at home and are equipped by the hospital with a remote monitoring system. Remote monitoring systems may reduce medical complications and hospitalizations by giving providers more frequent data readings on their patients. When used by homebound, chronically ill patients, these systems could be linked to EHRs to alert providers of a problem and allow the provider to react more quickly to adjust a medication or troubleshoot the problem. Jane's particular device allows her to do weekly remote visits with a nurse, instead of returning to a medical facility for these visits. The nurse is able to take readings on Jane's blood pressure, glucose levels, and weight, while interacting with her over video conference to check in on symptoms and see how Jane is doing with her medications. Using this device, the nurse is able to answer Jane's questions without needing an in-person office visit, and to identify major problems before they require an emergency room visit. Jane's quality of life is greatly improved, and she has been able to reduce the number of times she and her family have needed to go to the hospital and spend time in waiting rooms. These remote monitoring systems have also enabled Jane from needing to live in an assisted living environment.

These "Spotlight on Health Outcomes" are intended to highlight exemplary ways that widespread adoption and use of health IT and electronic health information exchange could help transform and improve health care. Some of these examples are only aspirational today or only exist in select communities or health systems. However, these examples illustrate the type of transformed health care that could be possible with the achievement of the goals of this Plan.

OBJECTIVE A
Engage individuals with health IT

Strategy IV.A.1: Listen to individuals and implement health IT policies and programs to meet their priorities.

The benefits of health IT can only be realized if individuals are fully involved in the development of health IT policy and confident that electronic health information is kept private and secure. When including individuals in the health IT policymaking process, the government cannot expect them to come to Washington, D.C. or to seek out rulemaking processes. To truly be representative, ONC will seek to participate in on-going public conversations about health IT. These conversations are already taking place, whether it is in online forums serving specific demographics, community-based faith groups, or chronic disease advocacy groups. ONC will participate in these public dialogues with the aim of learning how health IT policy and programs can support individual empowerment.

These efforts will be complemented by the primary formal mechanism established by the HITECH Act for public input into health IT policy: the federal advisory committees. As mentioned previously, there are two committees – the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC) – and several "sub-committees," or workgroups. The HITPC and HITSC make recommendations to the National Coordinator on crucial policy and program decisions on an ongoing basis. While individuals and consumer advocates have been represented on some of the Committees already, the federal government will strengthen that representation going forward.

ONC will also reach out to consumer organizations directly, both to engage them in its own work and to encourage them to reach out to their constituents in the context of their own efforts as well.

Strategy IV.A.2: Communicate with individuals openly and spread messages through existing communication networks and dialogues.

The HHS-led education and outreach strategy discussed in strategies I.A.6 and III.B.1 will engage consumers as an important audience. Education and outreach efforts will be aimed at helping people understand the transition to EHRs, the value of health IT more broadly and how health IT can be leveraged to make informed choices and support behavioral change related to their physical and behavioral health and care. In order to effectively reach millions of Americans, HHS intends to collaborate whenever possible with communication networks that already exist (such as health care advocacy groups, faith-based groups, groups aimed at supporting specific demographics, etc.) and to take advantage of social media (such as blogs and online social forums).

ONC has already reached out to numerous consumer organizations, including those representing individuals with disabilities, non-English speaking populations, and people with lower literacy levels, to involve them in discussions to shape ONC's programs and activities.

OBJECTIVE B
Accelerate individual and caregiver access to their electronic health information in a format they can use and reuse

Strategy IV.B.1: Through Medicare and Medicaid EHR Incentive Programs, encourage providers to give patients access to their health information in an electronic format.

A primary barrier to individual access to information is the lack of a business case for providers to share that information. Providers record and store patient health data in a health record; for them to also share that information with patients has historically caused additional administrative burden and cost. While individuals have a right to access their health information under the HIPAA Privacy Rule, there has been little financial incentive for providers to proactively share a copy of the medical record with the patient or to minimize the burden for the patient

to obtain a copy of the medical record. EHRs, however, reduce this additional burden and meaningful use incentive payments help make a business case for doing so. The first stage of meaningful use requires providers to send patients a clinical summary of each office visit and an electronic copy of their health information within three days of their request, and includes a menu set item to identify and provide patient-specific education resources to patients. We expect that future stages of meaningful use will build on these requirements.

ONC is exploring ways to encourage EHR vendors to add features that would allow patients to access and download their health information through consumer e-health tools, such as PHRs and secure mHealth application on smart phones and other mobile devices. It is important that personal health data be not only downloadable, but also available in a format that can be re-used by other applications and support interactions between EHRs and external sources of patient-specific education resources, such as those available through NIH/NLM's MedlinePlus Connect interface.

Strategy IV.B.2: Through federal agencies that deliver or pay for health care, act as a model for sharing information with individuals and make available tools to do so.

Beyond simple access, better tools and processes are necessary to make information more useful to individuals and their caregivers. The government will be a leader in providing information to individuals. For example, the Blue Button is a web-based feature through which patients may easily download a copy of their health information and share it with health care providers, caregivers, and others they trust. This feature is available on the DoD, VA, and CMS websites for their respective beneficiaries to use. This model is a key step forward in privately and securely sharing information with individuals, which will be enhanced over time. Using the Blue Button in combination with PHRs and other consumer health IT, individuals will be able to collect, aggregate, and analyze their health care information. Over the next five years, the government will consider more

advanced features of health information sharing with individuals, including data subscriptions, standardized code sets, standards for consumer health IT applications, and applications that enable information to be exchanged through mobile devices.

The Nationwide Health Information Network has already demonstrated sharing of patient-health information between the VA, DoD, SSA, and many private sector partners. Extending the Nationwide Health Information Network specifications with additional building blocks such as the Direct specifications will include protocols for provider-patient secure messaging, which is a major step towards patient-centered care.

The Federal Health IT Taskforce has recognized individual access to data as a primary objective. As done with the Blue Button initiative, it will continue to seek ways to align government investments with methods for giving individuals useful and reusable copies of their own data.

Strategy IV.B.3: Establish public policies that foster individual and caregiver access to their health information while protecting privacy and security.

While the Medicare and Medicaid EHR Incentive Programs provide incentives for individual and caregiver access to health information, there remain policy opportunities and barriers that the government will address outside of this program. For instance, CMS and OCR are looking at ways to enable individuals to request access to their test results directly from laboratories. CMS has also issued guidance to laboratories to clarify this issue. OCR has proposed to revise the HIPAA regulations such that a covered entity health plan would be required to provide an enrollee access to the enrollee's electronic claims data in the electronic form and format requested by the enrollee, if it is readily producible in such form and format. These policy issues may evolve over the next five years, but HHS will support approaches that:

- Feature a transparent, understandable, and easy to use online process that enables consumers to download and reuse their data

- Accommodate the range of user capabilities, languages and access considerations, including effective strategies for ensuring accessibility and usability of electronic health information for people with disabilities and meaningful access to such information for individuals with limited English proficiency

- Provide strong privacy and security protections

Some of HHS' priority policy work related to individual access to information has been discussed in Goal III, including: modifications to HIPAA as stipulated in the HITECH Act, individual consent to participate in health information exchange, and authorization and authentication.

OBJECTIVE C

Integrate patient-generated health information and consumer health IT with clinical applications to support patient-centered care

Strategy IV.C.1: Support the development of standards and tools that make EHR technology capable of interacting with consumer health IT and build these requirements for the use of standards and tools into EHR certification.

There are a number of compelling examples of technologies that enable individuals to manage their own health and care, and capture more complete information about themselves. EHRs should be able to interact with these devices, so that a provider can access information that a patient using health IT chooses to share with him or her. ONC, in partnership with FDA and other federal agencies, will promote standards to enable integration, including standards for devices and EHR interoperability, standards for data integration, such as glucometer measurements and unique device identifiers (UDI), for identifying the source of the device generated data. Through the adoption of certification criteria, ONC could encourage the use of these standards and tools that may enable EHRs to receive information from any consumer health IT device that also uses similar standards and tools.

Strategy IV.C.2: Solicit and integrate patient-generated health information into EHRs and quality measurements.

There are two main types of patient-generated health information - both of which could help achieve the goal of improved care, improved population health, and reduced per capita costs of health care:

1. "Patient-generated insights" are individual's observations and perceptions about their own health or care. These observations of daily living could come in the form of surveys, health journal entries, online blog entries, or any number of other media

2. "Device-generated data" is data captured by medical devices or other consumer health IT.

While we acknowledge there are policy questions that need to be examined related to the integration of patient-generated health information into EHRs, this information can be valuable to providers in adjusting treatment regimens, valuable to individuals in understanding and improving their health choices, and valuable to the health system in measuring and rewarding for health care quality. As part of its health care quality activities, HHS is studying opportunities to encourage providers to solicit and report patient-generated information on physical and behavioral health. This includes ensuring that this information could be captured and integrated into EHRs as part of meaningful use, and exploring standards and specifications that will enable that integration.

Strategy IV.C.3: Encourage the use of consumer health IT to move toward patient-centered care.

Today, eighty percent of people on the Internet use it to search for health information.[xv] Online resources, including advice from peers, are a significant source of health information. Many people use the Internet to seek advice and to share their experience, but far fewer have gone online to review test results, used a PHR, or emailed their doctor.[xvi] Consumers have expressed interest in the use of health IT tools to make sure their health record is correct, review test results, email providers,

schedule appointments online, and refill prescriptions online, all of which lend themselves to more patient-centered care.[xvii]

To further the use of consumer health IT, ONC and CDC are working with two Beacon communities to design tools that aim to help patients better manage their diabetes. This program is modeled after Text4Baby, a free text messaging service for pregnant women and new moms that delivers timely and practical tips customized for each stage of a woman's pregnancy or her baby's age. Text4Baby is the result of a public-private partnership with HHS, the White House Office of Science and Technology Policy and many private sector partners.

For care to truly become more patient-centered, providers will need to adopt new processes and uses of health IT that empower individuals in understanding and directing their care. HHS' primary approach to encouraging changes in provider behavior is through the implementation of quality measures and the attachment of incentives or penalties to improving on these measures. To this end, the National Quality Strategy, the National Prevention and Health Promotion Strategy and the Medicare and Medicaid EHR Incentive Programs will work in concert to promote the integration of consumer technologies and patient provided health information into clinical workflows to improve physical and behavioral health and care.

There are four domains of quality improvement that can help lead to patient-centered care:

1. **Self-management/activation** refers to measures of quality improvement that assess the degree to which patients understand the role they are meant to play in their care process, and the degree to which patients have the knowledge, skills, confidence, and self management resources/support to move forward in this role.

2. **Honoring patient preferences and shared decision making** refers to measures of quality improvement that assess the degree to which patients have the knowledge to make informed decisions about their care. It also encompasses measures that assess the quality of decision making, patient connectedness to resources, patient preferences, and care provider adherence to patient preferences.

3. **Patient health outcomes** refers to measures of quality improvement that assess the degree to which the care provided affects disease/disability, health risk, and functional health status at the individual patient and population level.

4. **Community resources coordination / connection** refers to measures of quality improvement that assess if, and to what extent, patients are connected to community resources.

Certain consumer health IT applications, when used by consumers and providers in concert, enable improvement in these domains. Future quality measures and meaningful use requirements will help to realize these benefits.

Goal V: Achieve Rapid Learning and Technological Advancement

Meaningful use of certified EHR technology will help the health care system "catch up" with proven technology and process changes that have been available for years. Technology is not in stasis – it is a dynamic industry prone to innovation which, though at times disruptive, can yield enormous benefits. There are two areas where the government is working in concert with the framework of meaningful use and the Affordable Care Act to prepare for a future that is hard to predict: 1) enabling health IT innovation and research, and 2) leading the creation of a learning health system.

Health IT Innovation and Research

The future of health IT rests in innovation. The government will embrace ongoing technology advancements whether they are incremental or fundamental. This means both adapting government strategy to advances in technology, and continuing to encourage rapid industry innovation.

Though there have been great leaps in health IT in the past few years, the most remarkable gains are likely still ahead of us. Possibilities include new ways of engaging individuals with their health information, new ways of aggregating and analyzing data, new ways of connecting the clinical setting more directly with individuals' everyday lives, and new ways of protecting privacy and ensuring the security of health information. The government's first step to enabling innovation is liberating data that is useful to consumers, providers, and innovators. But the government will also invest directly in research and development, use government mechanisms as levers for fostering adoption of innovative technology, and encourage collaboration and targeted innovation in the health IT industry.

The Learning Health System

A nation of providers who are meaningful users of health IT will create very large amounts of clinical information that is captured and stored in electronic, computable form, and represented using defined standards. Developing effective privacy policies and technologies that can de-identify personally identifiable health information will be challenging, yet is essential to ensuring public trust and safeguarding sensitive information. Through carefully designed and trusted mechanisms, this data will be able to flow securely from the system that collected it to other systems, such as research consortia, registries, and biorepositories, with an authorized use for it. The secondary use and population level analysis of this information holds great promise for many forms of biomedical research, public and population health, such as tracking and management of epidemics, and improving quality and efficiency of prevention and care.

The government's vision for realizing the value of this information is a learning health system – an environment where a vast array of health care data can be appropriately aggregated and analyzed, turning data into knowledge that can be put to immediate use. A learning health system can shorten the gap between the creation of new knowledge and its widespread adoption in health care from the often-quoted 17 years to 17 months, or even 17 weeks. Through a learning health system, the right information will be available to support a given decision, whether it is about the efficacy of a treatment or medication for an individual patient, predicting a national pandemic, or deciding whether to proceed with the research and development for a potential new treatment.[xviii]

The learning health system will benefit from the potential of Medicare and Medicaid EHR Incentive Programs payments and payment reforms initiated by the Affordable Care Act to motivate demand for health care information, and to create the policies and infrastructure for information exchange. The government's strategy to promote health information exchange is described in Goal I, and focuses on fostering exchange at the local level

where there are existing business models for information exchange. We expect future stages of meaningful use to require more rigorous information exchange requirements and will work in concert with the Affordable Care Act to create demand for health care information throughout the health care system. Drivers for information exchange will be coupled with federal leadership on national standards, privacy and security requirements, and infrastructure that supports information exchange.

The learning health system will use the policies, requirements, and infrastructure created to support meaningful use of certified EHRs, and will build on them to support more sophisticated modes of information exchange necessary for a system that can "learn." ONC commissioned the Institute of Medicine (IOM) to convene national private and public sector leaders in health care for a workshop series on *The Electronic Infrastructure to Support a Learning Healthcare System*. The report resulting from

these workshops series describes how lessons from current smaller-scale examples of learning health care systems, can be put into a policy framework that could be implemented on a national scale.[xix]

After soliciting input from the private sector, ONC will work with federal partners to establish an initial group to ascertain how to structure a learning health system. Initial efforts will focus on creating a federated model for the learning health system that bridges disparate systems. Additional efforts will focus on expanding the learning health system to include additional public and private sector entities.

The government's objectives to "Achieve Rapid Learning and Technological Advancement" are:

A. Lead the creation of a learning health system to support quality, research, and public and population health

B. Broaden the capacity of health IT through innovation and research

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Spotlight on Health Outcomes

A learning health system can lead to earlier detection and better risk management

The use of health IT can enable a learning health system to help prevent and monitor adverse events caused by new drugs. As George begins therapy using a new drug, information about his health can be captured in the EHR and findings may be automatically transmitted from the EHRs in which they are collected and reported in aggregate via a standard format to oversight agencies, such as the FDA, or to the company which manufactures the drug. By making this information available quickly in the learning health system, population-level data could be aggregated for earlier signaling of possible adverse reactions to new drugs. If a potential adverse reaction is identified, EHRs can serve another role in helping providers to quickly identify each of their patients taking a certain medication and notify the patients via their preferred communication channel about the potential risks.

The nationwide adoption and meaningful use of EHRs could facilitate the collection of clinical and research data from disparate sources including hospital systems, provider offices, laboratories, biorepositories, registries, and other research databases. Some stakeholders within the health care industry – such as researchers – are currently on the cutting edge of analyzing EHR-generated data to identify patient populations that are at-risk for preventable hospitalizations. EHR-generated data combined with analytical systems can be a boon to predictive modeling and knowledge generation. As an elderly woman with multiple medical conditions, Jane is part of an at-risk population. As these populations are identified earlier and risk factors are better understood, the learning health system could also enable resources, such as disease management and case management, to be deployed earlier to help avoid preventable hospitalizations. Currently, good clinical information regarding patient-centered outcomes on the best treatment options for patients with multiple diagnoses is lacking. In the long-term, EHR-generated data could be used to translate research findings to better inform preventive approaches, establish correlations, identify risks, and develop a deeper understanding of disease in patients with multiple conditions.

These "Spotlight on Health Outcomes" are intended to highlight exemplary ways that widespread adoption and use of health IT and electronic health information exchange could help transform and improve health care. Some of these examples are only aspirational today or only exist in select communities or health systems. However, these examples illustrate the type of transformed health care that could be possible with the achievement of the goals of this Plan.

OBJECTIVE A

Lead the creation of a learning health system to support quality, research, and public and population health

Strategy V.A.1: Establish an initial group of learning health system participants.

The learning health system's success will depend in part on the participation of a select number of institutions that collect and use large amounts of health care data. ONC recognizes this initial group of participants is only a sub-set of a broader set of activities occurring in the public and private sectors, and plans to engage both sectors early in the process and expand participation in the learning health system over time (see Strategy V.A.4).

Several federal organizations are already fostering learning health systems scaled to their own agencies, and some of these agencies will be key initial members of this group. The efforts of these agencies provide a base of experience on which to build the system at a larger scale. FDA's Sentinel Initiative is a national electronic system that is currently being designed to enhance FDA's ability to track the safety of drugs, vaccines, biologics, and medical devices after they reach the market. CDC's programs are supporting a national surveillance network through which health care organizations, public health entities, health information exchanges, and others are able to contribute to the picture of the health of the nation. Its goal is to be able to provide nationwide and regional situational awareness for all-hazard health-related threats and to support national, state, and local responses to those threats. CDC also has the National Environmental Public Health Tracking Network, which integrates health, exposure, and hazard data from a variety of national, state, and local sources. It offers new understanding of how hazardous substances can contribute to illness and potentially be prevented.

Strategy V.A.2: Develop standards, policies, and technologies to connect participants within the learning health system.

In order to make the learning health system a reality on a national scale, standards, policies, and mutually reinforcing technologies must be put in place to ensure that data collected at the point of care can be de-identified, aggregated, queried and analyzed for population health studies and quality improvement. Data used in these studies must be represented compatibly across participating organizations. Many of these can be built upon already-existing standards, policies, and technologies stemming from meaningful use and the State HIE, Beacon Community and SHARP grantees, but new standards, policies and technologies will also be needed.

To begin identifying specific standards, policies, and technologies needed for the learning health system, the Institute of Medicine (IOM) convened, with ONC support, an *Electronic Infrastructure to Support a Learning Healthcare System* workshop series in 2010. The report stemming from the workshop series, *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care – Workshop Series Summary,[xx]* takes lessons from current examples of learning health care systems, including those in the private sector, and broadens them to propose technologies and policies that could be implemented on a national scale. It provides the federal government a path forward to implement such a framework, and makes recommendations to address the policy and technical barriers that will need to be addressed.[xxi] ONC is working to ensure that its ongoing efforts related to standards, certification, and governance of nationwide health information exchange will align with the vision for a learning health system.

Strategy V.A.3: Engage patients, providers, researchers, and institutions to exchange information through the learning health system.

The learning health system will only be as valuable as the information that is exchanged. As more organizations and members participate in the learning health system, more knowledge will reach more entities to make a positive impact on clinical and research practices. ONC will engage the sources of critical information – patients and providers – so

that they understand the learning health system, its relation to and interaction with research, and the benefits of such research to inform the learning health system. Increasing the engagement and understanding of patients and providers may increase their willingness to participate in information sharing that they trust and that is private and secure, including for secondary uses of EHR data in research. Consumers stand to directly benefit from more information flowing into the learning health system which would allow for a better understanding of which subgroups may respond better to certain medications or treatments. Consumers are also likely to benefit from the availability of population level data in interacting with their clinicians about what treatment is right for them. Work to engage patients and providers will be done directly and through representative consumer and provider groups, as well as in public health settings in underserved communities.

Strategy V.A.4: Grow the learning health system by adding more members and expanding policies and standards as needed.

The government will seek to expand participation in the learning health system early in the process, beyond the initial group of federal partners, to add private sector partners. Future participants could include public and private provider groups, Health Information Exchanges, payers, small community medical and behavioral health practices, registries and additional federal agencies. Incentives to join this group will include the positive results of the initial exchange activities and the possibility of reciprocal benefit. The private sector is already coming together to share data and knowledge via various consortiums, and ONC will continue to coordinate and learn from these efforts. As standards and policies are expanded to support system growth, the learning health system will engage the private sector and will also support government efforts at the state, local, and tribal levels. Over the next five years, the government will expand on the findings of the IOM study (see strategy V.A.2) and continue evolving the federal plan for the learning health system.

OBJECTIVE B
Broaden the capacity of health IT through innovation and research

Strategy V.B.1: Liberate health data to enable health IT innovation.

Facilitating access to health data, in accordance with privacy and security protections, is a key mechanism of the government to encourage innovation in the industry and demonstrate to the public the value of health IT. Rich and high quality data are the starting point for building applications that provide value to individuals and care providers. For instance, PHRs become much more interesting if they can use the patient's entire medical history to provide advice on how to reach personal health goals. Huge quantities of data exist already, but in forms that are not easily usable for those that could benefit from the data. The government is working on multiple fronts to correct this.

The first priority is giving individuals timely access to their electronic personal health information. The government is working to facilitate the ability for users to successfully access, retrieve, process, and act on the data easily and efficiently. This approach is discussed at length in Goal IV Objective B. In addition, the government is also seeking innovative means for protecting users' personal health information, including effective techniques to de-identify and segment data, and to facilitate informed choice. As individuals become empowered with their health data, demand for consumer health IT applications will likely accelerate.

Outside of individual health information, the government is a leading generator of health care data. HHS maintains valuable information about the health care system's performance (e.g., the safety and efficacy of treatments, disease surveillance). Although much of this data is already public, it has historically been stored in disparate datasets that are largely inaccessible or unusable for developers. HHS is now taking an active role in getting this data in the hands of developers to activate innovation. This includes the launch of **HHS.gov/Open**, a website tailored to providing the public more transparency

into HHS' administration, and the Community Health Data Initiative (CHDI), a public-private partnership committed to innovation through the use of public data. CHDI is making many large data sets, and tools that make those data sets useful, readily downloadable from the CHDI website. It has also organized contests and challenges to ignite innovation using this data, such as the Health 2.0 Developer Challenge. In that ongoing contest, anyone interested in submitting a challenge can do so. Technology companies, health care companies, and government agencies work together to both identify specific market needs, and develop software solutions using data to meet those needs. Dozens of compelling applications have already been built as a result of this challenge.

Strategy V.B.2: Make targeted investments in health IT research.

The federal government is committed to investing directly in health IT research and development in areas that hold great promise for improving the health of individuals and populations. NIH and ARHQ, in particular, are funding dozens of research projects related to the development of health IT. Through the HITECH Act, ONC established the Strategic Health IT Advanced Research Projects (SHARP) Program, a four-year program funding research in health IT security, patient-centered cognitive support, health care applications and network platform architectures, and secondary use of EHR data. The progress made by grantees will assist in developing best practices which can be applied nationwide, possibly through meaningful use requirements. AHRQ sponsors projects focused on best practices and integration of health IT into the practice of medicine. Focus topics include usability of EHRs, clinical decision support, consumer health IT, health information exchanges, and telehealth.

The Networking and Information Technology Research and Development (NITRD) Program coordinates federal research and development investments in computing, networking, and software. As required under the HITECH Act, NITRD is developing a program and strategic plan to coordinate research and development relating to health IT. This work will make the pursuit of

important opportunities for technology breakthroughs through coordinated inter-agency initiatives possible, and will ensure that programs of different agencies are non-redundant and mutually reinforcing. In December 2010, PCAST issued a report on all NITRD activities called *Designing a Digital Future: Federally Funded Research and Development in Networking and Information Technology*, which emphasizes the importance of research to improve health IT.[xxii]

Strategy V.B.3: Employ government programs and services as test beds for innovative health IT.

Government agencies are leaders in adopting innovative health IT into provider and payer settings. Applying advanced health IT to the government's own health care practices and payment administration creates a large market for technologies, helps to prove their value, and creates best practices for wider adoption.

VA's Care Coordination Services uses health informatics, e-care, and disease management technologies to avoid unnecessary admission to long-term institutional care facilities. Technologies include videophones, messaging devices, biometric devices, digital cameras, and remote monitoring devices. VHA also has an award-winning PHR, "My Health*e*Vet," which gives its patients access to their health information along with other VA information and services. DoD's MiCare portal enables its patients to manage their medical information through a PHR of their choice. IHS is in the process of developing a PHR for its patients which will support meaningful use requirements.

CMS is piloting free PHR options for Medicare recipients. "Medicare PHR Choice" gives people living in Arizona and Utah a choice among four vendors' PHRs, and automatically updates their online record with Part A and Part B claims. "My Personal Health Record South Carolina" allows participants to see their medical history based on the past two years of claims. Additional information can be added manually, and the PHR provides helpful resources to understand diagnoses, conditions, and procedures.

Strategy V.B.4: Monitor and promote industry innovation.

The government facilitates and monitors the health IT industry and stays abreast of innovation's impact on federal policies and programs in order to further promote innovation within the industry. Such activity is conducted primarily through panels, conferences, white papers, and similar outreach efforts. The government also plans to promote innovation through open innovation prizes and challenge grants focused on specific health IT problems. Potential focus areas include helping to ensure privacy and security in the digital health infrastructure, increasing the usability of health information systems to enhance provider interactions, the creation of new analytical techniques to inform improved care, and the development of more efficient methods of data compression and communication through modalities such as mobile health.

Strategy V.B.5: Provide clear direction to the health IT industry regarding government roles and policies for protecting individuals while not stifling innovation.

ONC commissioned the Institute of Medicine (IOM) to thoroughly evaluate health IT patient safety concerns and to recommend additional actions and strategies to address those concerns, as well as to define the role of public and private sectors in ensuring the safety of health IT-assisted health care services. Over the next two years, ONC, in collaboration with federal partners, will develop a consistent approach to health IT that protects individuals without stifling innovation. The government is committed to being as open and transparent as possible in formulating its approach.

Appendix A: Performance Measures

The performance measures below reflect key aspects of progress towards achieving the goals in this Federal Health IT Strategic Plan for 2011-2015, and the overarching goal that all Americans will benefit from EHRs. These performance measures are not intended to be a complete set, but a subset of key indicators in assessing progress. Supporting information for these performance measures is contained in ONC's Annual Performance Plan and Report, which is integrated into the annual Congressional Budget Justification, which is available on the HHS website. The most recent assessment about the status of meeting each goal is also included to provide a baseline from which ONC aims to improve performance.

Goal	Performance Measures	Most Recent Assessment of Performance	Data Sources
I. Achieve Adoption and Information Exchange through Meaningful Use of Health IT	▪ Increase the percentage of eligible professionals receiving Medicare and Medicaid EHR Incentive Programs payments	▪ N/A Baseline TBD (FY 2011)	▪ Centers for Medicare & Medicaid Services (CMS) Meaningful Use Registration and Attestation System
	Better performance in hospitals: ▪ Increase the percentage of eligible hospitals receiving Medicare and Medicaid EHR Incentive Programs payments ▪ Increase the percentage of hospitals that have adopted electronic health records	▪ N/A Baseline TBD (FY 2011) ▪ 12% (CY 2009)	▪ CMS Meaningful Use Registration and Attestation System ▪ American Hospital Association (AHA) Annual Survey of Hospitals, IT Supplement
	Better performance for physicians: ▪ Increase the percentage of eligible primary care professionals receiving meaningful use incentive payments ▪ Increase the percentage of Federally Qualified Health Centers (FQHCs) that are affiliated with providers that receive Medicare and Medicaid EHR Incentive Programs payments ▪ Increase the percentage of office-based physicians who have adopted electronic health records ▪ Increase the percentage of office-based primary care physicians who have adopted	▪ N/A Baseline TBD (FY 2011) ▪ N/A Baseline TBD (FY 2011) ▪ 21% (CY 2009) ▪ 20% (CY 2009)	▪ CMS Meaningful Use Registration and Attestation System ▪ TBD ▪ CDC National Ambulatory Medical Care Survey, IT Supplement ▪ Centers for Disease Control and Prevention (CDC), National Ambulatory Medical

Goal	Performance Measures	Most Recent Assessment of Performance	Data Sources
	electronic health records		Care Survey, IT Supplement
	▪ Increase the percentage of community pharmacies in the U.S. that are capable of exchanging health information electronically	▪ 85% (CY 2009)	▪ Surescripts National Progress Report on E-Prescribing
II. Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT	▪ Proportion of eligible providers in Beacon Communities that receive Medicare and Medicaid EHR Incentive Programs payments	▪ N/A Baseline TBD (FY 2011)	▪ ONC Office of State and Community Programs, Beacon Division
	▪ Number of providers participating in Beacon Community interventions	▪ N/A Baseline TBD (FY 2011)	▪ ONC Office of State and Community Programs, Beacon Division
III. Inspire Confidence and Trust in Health IT	▪ Decrease the percentage of Americans who are very concerned about the security of electronic health records	▪ N/A Baseline TBD (FY 2011)	▪ ONC Privacy and Security Attitudes Survey
IV. Empower Individuals with Health IT to Improve their Health and the Health Care System	▪ Increase the percentage of Americans who have been given electronic access to any part of their health care record	▪ N/A Baseline TBD (FY 2011)	▪ ONC Privacy and Security Attitudes Survey
V. Achieve Rapid Learning and Technological Advancement	▪ Measure TBD	▪ N/A Baseline TBD	▪ Data Source TBD

Appendix B: Programs, Initiatives, and Federal Engagement

- **Department of Agriculture (USDA)** improves agricultural productivity and competitiveness and contributes to the national economy and the public health. The Recovery Act appropriated funds to the Department of Agriculture's Rural Utilities Service (RUS) and the Department of Commerce's National Telecommunications Information Administration (NTIA) to expand broadband access and adoption in communities across the U.S., to increase jobs, spur investments in technology and infrastructure, and provide long-term economic benefits.

- **Department of Commerce (DoC)** has cross-cutting responsibilities in the areas of trade, technology, entrepreneurship, economic development, environmental stewardship, statistical research, and analysis. Its involvement with health IT has been evident through one of its agencies, the National Institute for Standards and Technology.

  – **National Institute of Standards and Technology (NIST)** is a non-regulatory federal agency whose mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve quality of life.

    - NIST collaborates with HHS/ONC in realizing the health IT goals of the Administration and Congress. This relationship allows ONC to draw upon NIST expertise in applying IT to health care through standards, conformance measurement, prototype implementation, security, and usability, and in consulting on the Nationwide Health Information Network, standards, and certification processes.

    - NIST has funded a grant on the "Relationship Between Health IT Usability and Patient Safety: A Human Factors Engineering Framework for Action." This grant will develop a framework explaining how the multiple facets of usability may be linked to different aspects of patient safety.

- **Department of Defense (DoD)** provides health care to all U.S. military personnel worldwide through the Military Health System (MHS) and is supported by a robust EHR system.

  – **Armed Forces Health Longitudinal Technology Application, (AHLTA)** the military's EHR, is an enterprise-wide medical and dental information management system that provides secure online access to Military Health System (MHS) beneficiaries' records. It is used by medical clinicians in all fixed and deployed Military Treatment Facilities (MTFs) worldwide. This centralized EHR allows health care personnel worldwide to access complete, accurate health data to make informed patient care decisions.

  – **Virtual Lifetime Electronic Record, (VLER)** will permit information vital to health care, benefits and services to be available to the DoD and the VA from the moment a service member enters the military until the death of the service member or veteran. Both the DoD and VA have begun to work together to define and build a seamless system of integration that will provide a framework to ensure that health care providers have all the information they need to deliver high-quality health care, while reducing medical errors. VLER is intended to be a lifetime, personal record that ensures a seamless continuum of care and benefits. VLER leverages the work of CONNECT and the Nationwide Health Information Network in service to military and veteran personnel.

  – **Electronic Health Record (EHR) Way Ahead** is a proposed Major Automated Information System (MAIS) program designed to replace/sunset the current portfolio of systems providing initial EHR capability, primarily AHLTA and Composite Health Care System (CHCS). EHR Way Ahead will

establish a comprehensive, longitudinal, electronic health record that is available anytime and anywhere for the lifetime of every patient. This longitudinal electronic health record will support a virtual lifetime electronic record (VLER) for a service member by being a source system for health care information to be shared via VLER.

– **"Blue Button"** is a web-based portal enabling individuals to download their personal health information and share this information with health care providers, caregivers, and others they trust. It provides consumers with a standardized and reusable copy of their health information through a simple download function on DoD, VA and CMS' websites.

▪ **Department of Health and Human Services (HHS)** is the principal agency responsible for protecting the health of all Americans and has many agencies and initiatives that work towards advancing health IT within the U.S. and implementing various aspects of the Affordable Care Act and the HITECH Act.

– **Text4Baby** is a free mobile information service designed to promote maternal and child health by connecting women to prenatal and infant care services, as well as providing tips on what women need to know during pregnancy and the baby's first year. Text4baby is made possible through a broad, public-private partnership that includes government agencies, corporations, academic institutions, professional associations and non-profit organizations.

– Section 2041 of the Affordable Care Act authorizes the Secretary of HHS to make grants to long-term care facilities for the purpose of assisting such entities in offsetting the costs related to the purchasing, leasing, developing, and implementing of certified EHR technology.

– **Agency for Healthcare Research and Quality (AHRQ)** is the lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. AHRQ supports health services research that seeks to continuously improve the quality of health care and promote evidence-based decision-making.

  ▪ AHRQ's Health IT Portfolio has supported health services research grants and contracts that create new knowledge, synthesize and disseminate best evidence and provide tools for implementation addressing health IT's impact on the quality of health care since 2004. Current initiatives address clinical decision support, patient safety, patient centered care, quality measurement, and usability and workflow issues. Examples like treating chronic illness in an effective and efficient manner using telemedicine through Project ECHO in New Mexico, texting diabetic patients in Colorado to incorporate their blood sugar readings into an EHR, or using health IT to reduce the incidence and impact of pressure ulcers in long term care facilities in Utah, demonstrate the power of health IT to revolutionize the health care system. In this portfolio, AHRQ has developed a publically available web site, United States Health Information Knowledgebase (USHIK.ahrq.gov) where information (metadata: such as name, definition, how they are represented) about the data elements from the HHS Secretary's National Interoperability Standards (HIPAA transactions, Consolidated Health Informatics, Health Information Technology Standards Panel, and others) is related to the data elements' use cases and the standards from which they come. This site promotes understandable health information exchange and the uniformity of data used for health research and decision-making.

  ▪ AHRQ's Patient-Centered Health Research/Effective Health Care Portfolio supports projects that develop the information infrastructure needed to conduct patient--centered health research and enable a learning health care system. Current initiatives are supporting infrastructure development projects, EHC distributed data research networks and enhanced clinical registries, and methods work to support them. The Portfolio includes efforts like the

Safe Surgery Project at the University of Washington, which has implemented a standardized surgical checklist statewide to improve safety.

– **Assistant Secretary for Preparedness and Response (ASPR)** serves as the Secretary's principal advisor on matters related to bioterrorism and other public heath emergencies.

  ▪ ASPR is looking to health IT, EHRs, and Joint Patient Tracking Systems (JPTS) to assist in addressing various functions, including Identifying at Risk Individuals, Strategic National Stockpiling, City Readiness Initiative, Medical Reserve Corps coordination, Emergency System Management for Advance Registration of Volunteer Health Professionals, Hospital Preparedness, and National Disaster Medical Management.

– **Assistant Secretary for Planning and Evaluation (ASPE**) is the principal advisor to the HHS Secretary on policy development, and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis and is currently building a multi-payer, multi-claim database to support patient-centered research using Medicare, Medicaid, and private payer claims data.

  ▪ ASPE is leading the Department's research initiatives and focus on health IT adoption by post-acute and long-term care providers, including identifying health IT standards to advance interoperable health information by post-acute and long-term care providers, and producing the HITECH required Report to Congress in which the Secretary is to determine the extent to which and manner in which incentives and other funding for using certified EHRs should be made available to providers who are not eligible for incentives or other funding for such purposes.

– **Centers for Disease Control and Prevention (CDC)** collaborates to create the expertise, information, and tools that people and communities need to protect their health – through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.

  ▪ **The Public Health Information Network (PHIN)** is a national initiative to increase the capacity of public health to exchange data and information electronically across organizational and jurisdictional boundaries by promoting the use of standards and defining functional and technical requirements. PHIN strives to improve public health by enhancing research and practice through best practices related to efficient, effective, and interoperable public health information systems.

  ▪ **The National Healthcare Safety Network (NHSN)** is a voluntary, secure, Internet-based surveillance system that integrates patient and health care personnel safety surveillance systems and has the capacity for health care facilities to share data in a timely manner between health care facilities and with other entities.

  ▪ **The National Electronic Disease Surveillance System (NEDSS)**, a major component of PHIN, advances the transition to standards-based electronic data exchange for reportable disease surveillance to improve local/state/territorial capacity to detect and respond to reportable diseases and the nation's ability to support the revised International Health Regulations.

  ▪ **BioSense** is a national program to improve capabilities for rapid disease detection, monitoring, and real-time situational awareness through access to existing data from health care organizations. BioSense enables local and state public health departments to share and access

data, providing a more complete picture of potential and actual health events both locally and across jurisdictional boundaries.

- **The National Environmental Public Health Tracking Network** integrates health, exposure, and hazard data from a variety of national, state, and city sources and offers a new understanding of how hazardous substances can contribute to illness.

- **National Center for Health Statistics,** as the Nation's principal health statistics agency, provides statistical information that will guide actions and policies to improve the health of the American people. NCHS collects data from birth and death records, medical records, interview surveys, and through direct physical exams and laboratory testing. NCHS is a key element of the national public health infrastructure, providing important surveillance information that helps identify and address critical health problems.

- **"Strengthening Public Health Infrastructure for Improved Health Outcomes"** is funded within the Prevention and Public Health Fund under the Affordable Care Act and is designed to advance any or all of the key areas for infrastructure investment and to help ensure successful implementation of the Affordable Care Act, specifically by: improving the public health workforce, developing information systems to support adoption and implementation of rules and regulations, reengineering of infrastructure to improve networking and coordination, implementing best health care practices and impact evaluation, improving information and data system capacity, and improving organizational capacity. The new program is seeking to increase the performance management capacity of public health departments and ensure that public health goals are being met.

- CDC's Public Health Informatics and Technology Program Office (PHITPO) at the Office of Surveillance, Epidemiology and Laboratory Services (OSELS) is leading the development of public health standards that align with certified EHR technology. As with clinical data, public health departments require public health standards and may benefit from certified public health information systems to effectively exchange information.

- **Centers for Medicare & Medicaid Services (CMS)** is the federal agency that oversees the Medicare and Medicaid EHR Incentive Programs, thus playing a key role in the overall direction of the health care system. The HITECH Act established the incentive programs to provide payments for the meaningful use of certified EHR technology. The Medicare and Medicaid EHR Incentive Programs provide payments to eligible professionals and hospitals who meet meaningful use requirements. These incentive programs are designed to instill the use of EHRs in a meaningful way to support the nation in improving care, efficiency, and population health.

  - **The Center for Medicare and Medicaid Innovation (Center for Innovation or CMMI)** was established to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care.

  - **My Personal Health Record South Carolina (MYPRSC)** is a Personal Health Record (PHR) pilot conducted by CMS that provides an online PHR to Medicare beneficiaries who reside in South Carolina and have original (fee-for-service) Medicare.

  - **Medicare PHR Choice**, a PHR pilot conducted by CMS, for people with original (fee-for-service) Medicare residing in Utah and Arizona.

  - Under the **Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA)**, CMS has awarded ten Quality Demonstration grants in a total of 18 States to

implement and evaluate provider performance measures, utilize health information technologies such as pediatric electronic health records, and test the effectiveness of provider delivery models such as medical homes.

- The Affordable Care Act also provides $300 million dollars for the development and implementation of a voluntary **Medicaid Adult Health Quality Measures Program** - including quality measures that can be collected via electronic health records.

- **"Blue Button"** is a web-based portal enabling individuals to manage their personal health information and provide access to health care providers, caregivers, and others they trust. The Blue Button feature allows individuals to access and download information into a text file (or an enhanced PDF) that can be read, printed, or saved on any computer. The download can be broken out by data class or data range. Blue Button allows control of information without special software – and enables individuals the ability to share data with their health care providers, caregivers, or people they trust. It provides consumers with a standardized and reusable copy of their health information through a simple download function on DoD, VA and CMS' websites.

- **Food and Drug Administration (FDA)** is the primary federal agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and providing oversight of the nation's food supply, cosmetics, products that emit radiation, and tobacco products. FDA also promotes the public health by promptly and efficiently reviewing clinical research and taking timely and appropriate action on the marketing of regulated products. The agency's actions support innovations that make medical products more effective and safer. FDA also helps the public obtain the accurate, science-based information they need to use medical products and appropriately consume foods to improve their health. FDA's Center for Devices and Radiological Health (CDRH) is responsible for assuring the safety and effectiveness of medical devices. CDRH will continue to monitor health IT patient safety concerns using its existing programs and initiatives.

  - **Medwatch-Plus** provides electronic capability for receiving adverse event data, processing, storing and analyzing adverse event reports and other safety information for human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. Alerts issued based on this data contain useful information.

  - **FDA Adverse Event Reporting System (FAERS)** is a program within MedWatch Plus. FAERS will provide a back-end database for processing, storing and analyzing post-market adverse event reports and other safety information for FDA-regulated drug, biologic, and medical device products.

  - **The Sentinel Initiative** is building a national electronic system, the Sentinel System, to enhance FDA's ability to track the safety of drugs, vaccines, biologics, and medical devices once they reach the market. The Sentinel Initiative aims to develop and implement an active surveillance system that will augment existing systems that the FDA has in place to track reports of adverse events linked to the use of its regulated products.

  - **Structured Product Labeling (SPL) is an el**ectronic document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information. SPL is also used by FDA and NLM DailyMed initiative, which provides information on human drugs and biologi**cs in electronic format in an eff**ort to improve patient safety.

- **Health Resources and Services Administration (HRSA)** is the primary federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable. In an effort to use health IT to extend access to health care, HRSA is working to identify, disseminate and provide technical assistance to health centers and other HRSA grantees in adopting model practices and technologies. HRSA is also working collaboratively with foundations, national organizations, the private sector, and other government agencies to help HRSA grantees adopt health IT.

  - **The HRSA Health Disparities Collaborative (HDC)** was created to assist in the transformation of primary health care practices to improve the health care provided to everyone and to eliminate health disparities. This initiative was originally funded by HRSA but now continues as a public-private endeavor.

  - **HRSA's Telehealth Network Grant Program** supports established telehealth networks that are looking to expand the number of sites receiving clinical services.

  - **HRSA's Telehealth Resource Program** funds Centers of Excellence that provide technical assistance on telehealth to any HRSA grantee in the country.

  - **Telehealth Services for Children and Youth with Epilepsy grants** fund initiatives to demonstrate ways to improve the system of services for children and youth with epilepsy through the use of telehealth/telemedicine.

  - **Health Center Controlled Networks (HCCNs)** improve operational effectiveness and clinical quality in health centers through the provision of management, financial, technology and clinical support services. An overwhelming number of community health centers who have signed on with an HCCN have successfully adopted an EHR system.

  - **Health IT Toolboxes** provide a compilation of resources to help community health centers, safety net providers and ambulatory care providers implement health IT and better understand meaningful use.

  - **The National Health Service Corps (NHSC),** through scholarship and loan repayment programs, helps Health Professional Shortage Areas (HPSAs) in the U.S. get the medical, dental, and mental health providers they need to meet their tremendous need for health care.

  - **The Rural Health Network Development Planning Grant Program (Network Planning)** expands access to, coordinates and improves the quality of essential health care services and enhances the delivery of health care, in rural areas. The program provides one-year grants to rural entities to plan and develop a formal health care network.

  - **HRSA Pediatric Primary Care Electronic Health Record (EHR) Network for Comparative Effectiveness Research (CER).** The CER study is testing, via a cluster randomized trial, a point-of-care clinical decision support system linked to electronic health records in improving the quality of care for a chronic pediatric condition.

  - **The Community Health Applied Research Network (CHARN)** is a consortia of researchers based at community health centers funded under the 2009 Recovery Act. The CHARN will demonstrate that a well conceived and fully operational data infrastructure can be put in place to support patient-centered outcomes research (PCOR) on diverse populations and patient subgroups that are often underrepresented in health outcomes research. The CHARN will actively disseminate research results to patients and clinicians in safety net treatment settings.

- Integrating Child Health Information Systems through health information exchange funds allows states to develop an interoperable system of collecting and exchanging information including immunizations, vital statistics, and newborn screening. States and public health departments are implementing systems that enhance communication and facilitate the exchange of information between multiple partners including clinicians, laboratorians, public health agencies, researchers and various community support services.

– **Indian Health Service (IHS)** is responsible for providing federal health services to American Indians and Alaska Natives. The IHS is the principal federal health care provider and health advocate for Indian people and its goal is to raise their health status to the highest possible level. The IHS provides a comprehensive health service delivery system for approximately 1.9 million American Indians and Alaska Natives who belong to 564 federally recognized tribes in 35 states. The IHS has long leveraged health IT to serve its populations, some of whom are located in the most remote areas of the country. Indian Health Service, along with its Tribal and Urban Program partners, have developed and deployed a comprehensive suite of software applications to support the provision of quality services and the secure management of health information.

   - **IHS Resource and Patient Management System (RPMS)** is the suite of health IT applications that support health care delivery throughout the IHS. The RPMS includes an EHR, population management tools, clinical decision support, quality reporting, integrated behavioral health, electronic dental record, practice management, patient registration and management, and other integrated applications. In April 2011, IHS became the first federal agency to have part of its health information system certified for stage one meaningful use. The IHS RPMS Suite is certified as a Complete EHR for both inpatient and ambulatory settings. Part of the EHR system development included creation of a personal health record (PHR) portal to support meaningful use requirements related to engaging patients and their families in their health care.

   - **IHS Population Health Management (iCare)** is the IHS' population management tool that enables providers to easily identify groups of patients (populations) that share similar characteristics. It presents diverse patient data in a user-friendly view by retrieving patient information from the various underlying components of the RPMS database and bringing it together under a single interface. User-defined patient lists (panels) are easily created, sorted and filtered in a variety of ways to form the core functionality of iCare. The Care Management Event Tracking (CMET) electronically tracks and manages certain pre-defined events related to breast, cervical, colon, and skeletal health from screening through completion. "Anonymous Community Alerts" related to CDC Nationally Notifiable Diseases and Suicidal Behavior are mined on a nightly basis and displayed in a variety of locations to promote early awareness and allow for prompt intervention.

   - **IHS Patient Wellness Handout (PWH)** is a paper-based report for patients that combines information from their medical records along with an explanation of their results. It can be used to provide patients with a listing of the recommended health maintenance services that are due, serve as a tool to promote health communication, or as a portable record of selected health information. The PWH can be generated on demand by anyone who is providing care services to the patient.

   - **IHS National Patient Information Reporting System (NPIRS)** is the national data warehouse for the IHS. The NPIRS maintains historical data from RPMS and other sources to

provide information on health trends, cost and quality reporting, and individual data marts for specific chronic health care challenges, such as diabetes.

- **IHS Infrastructure, Office Automation, and Telecommunications (IOAT)** is the foundational network of hardware, software and services that support RPMS, NPIRS and the operations of the IHS. The IOAT enables information exchange for RPMS and security for all IHS operations.

– **The Office of Minority Health (OMH)** has developed and supports the National Health Information Technology (NHIT) Collaborative that works to bridge gaps between coordinating and implementing health IT within underserved communities, helping to educate health care providers and advocate within these communities concerning the use and application of health IT, and advising other federal, state and local agencies of how to best coordinate the use of health IT within underserved communities of color.

– **National Institutes of Health (NIH)** is the primary federal agency for the support and conduct of biomedical and behavioral research. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and apply it to enhance health, lengthen life, and reduce the burdens of illness and disability. In terms of health IT, NIH supports and conducts research and standards development to advance the meaningful use of certified EHR technology in research and clinical practice. Given the unprecedented opportunities to answer new and important research questions using the information contained in EHRs, NIH is working assiduously to facilitate appropriate access and exchange of data for research purposes. Health IT is of interest and relevance to all of the NIH Institutes and Centers. A few examples of relevant NIH activities include the following:

- **The National Library of Medicine (NLM)** has a lead role in federal health IT policy as the central coordinating body for clinical terminology standards within HHS. NLM supports, develops, and disseminates key health data standards that are designated to enable certain users to achieve meaningful use of the certified EHRs. NLM supports and conducts research and development related to health IT, including clinical terminologies, clinical decision support, personally controlled EHRs, health information exchange, syndrome surveillance, anatomical image databases, natural language processing, information retrieval, advanced telecommunications, and information infrastructure for emergency response. NLM also manages the ClinicalTrials.gov databank which contains public information and data on clinical trials. NLM also supports the training of health IT professionals through academic biomedical informatics research training centers.

- **Cancer Biomedical Informatics Grid (caBIG®)** is an information network supported by the National Cancer Institute (NCI) enabling members of the cancer community – researchers, providers, and patients – to collect, manage, and analyze large volumes of biomedical and clinical data. The components of caBIG® are widely applicable beyond cancer as well.

- **The Electronic Medical Records and Genomics (eMERGE) Network**, an initiative of the National Human Genome Research Institute (NHGRI), is developing, disseminating, and applying approaches to research that combine DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genetic research.

- NHGRI and NCI have collaborated with the Office of the Surgeon General and the Office of the Secretary to develop standards and tools for the collection, storage and dissemination of family history information. The U.S. Surgeon General's **My Family Health Portrait (MFHP)** has been a centerpiece of these activities to date. It is a free web-based tool for family history

collection that is standards-based and potentially interoperable with EHR systems. Recently an inter-agency NIH working group has been established to address future governance of MFHP. Future activities include the development of clinical decision support tools for common heritable conditions that are compatible with MFHP.

- **The National Institute of Biomedical Imaging and Bioengineering's Radiological Society of North America RadLex Ontology Project** provides uniform terms and concepts for indexing and retrieving imaging research databases, educational materials, and clinical imaging reports in an EHR. The project develops and deploys radiology reporting templates for EHR software.

- The NIH Clinical Center, in association with a number of NIH Institutes, developed the **Biomedical Translational Research Information System (BTRIS)**, a repository of clinical research data that facilitates the conduct of intramural clinical trials. BTRIS is also addressing important questions related to the standardization and aggregation of EHR data that will be relevant to other national efforts involving EHR data reuse.

– **Office for Civil Rights (OCR)** administers and enforces four key privacy and security laws: 1) the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; 2) the HIPAA Security Rule, which sets national standards for the security of electronic health information; and 3) the HIPAA Breach Notification Rule, which requires HIPAA covered entities to notify individuals, HHS, and in some cases the media of impermissible uses and disclosures of health information that compromise the privacy and security of such information; and 4) the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety. Together, ONC and OCR are the lead HHS offices for health-IT-related privacy and security policy.

- OCR also enforces federal civil rights laws protecting individuals from discrimination on the basis of race, color, national origin, gender, age, and disability and works with ONC to ensure that health information technology benefits all individuals, including those who are protected by these laws.

– **Office of the National Coordinator for Health IT (ONC)** is at the forefront of the administration's health IT efforts and is a resource to the entire health system to support the adoption of health IT and the promotion of nationwide health information exchange. ONC is the principal federal entity charged with coordinating nationwide efforts to implement and advance the use of health IT and promote the electronic exchange of health information.

- **The Health Information Technology Extension Program (Regional Extension Centers or RECs)** offers technical assistance, guidance and information on best practices to support and accelerate health care providers' efforts to become meaningful users of certified EHR technology.

- **The Health Information Technology Research Center (HITRC)** helps support the RECs by gathering information on effective practices and helping the RECs collaborate with one another and with relevant stakeholders to identify and share best practices in EHR adoption, meaningful use, and provider support.

- **The State Health Information Exchange Cooperative Agreement Program** supports states or state designated entities in building health information exchange capacity for exchanging health information electronically across the health care system both within and across states.

- **The Beacon Community Cooperative Agreement Program** supports communities at the cutting edge of EHR adoption and health information exchange to build and strengthen their health IT infrastructure and exchange capabilities to push them to achieve new levels of sustainable health care quality and efficiency. These communities will focus on demonstrating measurable improvements in care, efficiency, and population health.

- **The Health IT Workforce Development Program** focuses on several key resources needed to rapidly expand the availability of skilled health IT professionals who will support broad adoption and use of health IT in the provider community.

- **The Strategic Health IT Advanced Research Projects (SHARP) Program** funds research focused on achieving breakthrough advances to address well-documented problems that have impeded adoption of health IT. The knowledge generated from this program will help accelerate progress towards meaningful use of health IT and a high performing, adaptive, nationwide health care system.

- **The Nationwide Health Information Network** is a set of standards, services and policies that enable secure health information exchange over the Internet. The Nationwide Health Information Network will provide a foundation for the exchange of health information across diverse entities, within communities, and across the country.

- **The Federal Health Architecture (FHA)** is an E-Government Line of Business initiative managed by the Office of the National Coordinator for Health Information Technology. FHA was formed to coordinate health IT activities among federal agencies that provide health and health care services to citizens.

- **The CONNECT project** is an E-government initiative managed by ONC. CONNECT was formed as a consortium of interested federal agencies to develop software based on the Nationwide Health Information Network specifications to support standards-based exchange. The CONNECT software is available through an open source license and is used by both federal and private sector organizations.

- **Substance Abuse and Mental Health Services Administration (SAMHSA)** is the lead agency within the Department of Health and Human Services charged with Behavioral Health Services integration into community and existing provider-based prevention and treatment systems at community, State and national levels. The role of health IT in SAMHSA is incorporated into a broad range of activities that include but are not limited to:

  - Working with the VA and DOD on Suicide Prevention National Lifeline activities to expand and strengthen use of the VA model for EHR with a "flag" protocol to identify and coordinate interventions and services for those at high risk of suicide, or with a past history of attempts.

  - Working with the VA's Virtual Lifetime Electronic Record (VLER) initiative to demonstrate privacy protected exchange of sensitive clinical records between community-based behavioral health programs and VA health centers.

  - Working with several State behavioral health and Medicaid agencies to develop open source EHRs and HIE services that integrate behavioral health within community-based health homes and State Health and Human Service programs.

  - Testing the usability and feasibility of smartphone-based applications and patient links to clinical services, including, but not limited to a recovery tool called **Addiction Comprehensive Health Enhancement Support System (A-Chess)** – an online peer

support group and clinical counselors, a GPS feature that sends an alert when the user gets near an area of previous drug or alcohol activity, real-time video counseling, and a "panic button" that allows the user to place an immediate call for help with cravings or triggers.

- **Open Behavioral Health Information Technology Architecture (OBHITA)** supports the creation of a behavioral health EHR reference model information technology architecture. OBHITA will also build on privacy protection standards developed over the past five years.

- **The SAMHSA Health Information Network (SHIN)** includes the National Clearinghouse for Alcohol and Drug Information (NCADI) and the National Mental Health Information Center (NMHIC). SHIN connects the behavioral health workforce and the general public to the latest information on the prevention and treatment of mental and substance use disorders. The NMHIC was developed to provide information about organizations dedicated to treating and preventing medical illness, as well as information about federal grants, conferences, and events.

- Exploring the use of pharmacy and medical provider information from individual State Prescription Drug Monitoring Programs and the National All Schedules Prescription Electronic Reporting Act, or NASPER, to inform state and community treatment and prevention programs, including community coalitions that will be using the Strategic Planning Framework to identify and provide local, real time information regarding questionable prescription drug abuse.

- Providing Grants to Expand Substance Abuse Treatment in Targeted Areas of Need - Technology Assisted Care (TCE - TAC). The purpose of this program is to enhance and/or expand the capacity of substance abuse treatment providers to serve clients who have been underserved because of lack of access to treatment in their immediate community due to transportation concerns, an inadequate number of substance abuse treatment providers in their community, and/or financial constraints, through the use of therapeutic techniques that involve innovative, creative and cost-effective advanced technology. This approach includes the use of various technological modalities such as Internet, tele-behavioral health, chatlines, videocams, etc.

- Regulating 1230 opioid treatment programs that dispense the treatment medications methadone and buprenorphine to 288,824 patients nationwide. Through an interactive online "Extranet," providers extract patient health information from medical records, and submit an electronic form that is evaluated concurrently by Federal and State regulatory authorities. The system addresses exemptions from certain Federal and State regulatory requirements.

- Working with the field to develop a digital access to medication (DAT-M) system. This Web-based system would concentrate selected patient health information, including dose levels, into an interoperable data base that could be securely accessed by providers throughout the country. DAT-M is being developed to address opioid dependent patients to continue care after being displaced by various disasters.

- Providing U.S. public health statistics on the use of alcohol, illegal drugs, prescription drugs and mental health issues through the Center for Behavioral Health Statistics and Quality. This Center also provides information on substance use disorder treatment episodes. It also publishes brief reports based on the National Survey on Drug Use and Health, the Drug Abuse Warning Network, and the Treatment Episode Data set.

- Request for Application (RFA) for Supplemental Funds for Health IT Infrastructure Development. Two new RFAs were announced that are specifically designed for the following entities: 1) current Primary and Behavioral Health Care Integration (PBHCI) grantees ($11.2 million); and 2) State-Designated-Entities (SDEs), including for technical assistance to States and grantees ($3.8 million). The purpose of the PBHCI program is to improve the physical health status of people with serious mental illnesses, including individuals with co-occurring substance use disorders, by supporting communities to coordinate and integrate primary care services into publicly funded community mental health and other community-based behavioral health settings. The overarching goal for the supplemental funding for HIT is to integrate care across and among providers via the appropriate use of certified EHR technology.

- **Department of Veterans Affairs (VA)** provides Veterans with health benefits and uses EHR systems to better their service and accelerate consumer use.

  - **Veterans Health Information Systems and Technology Architecture (VistA)** is an enterprise-wide information system built around an EHR, used throughout the VA medical system which is known as the Veterans Health Administration (VHA). VistA is one of the most widely used EHRs in the world.

  - **Virtual Lifetime Electronic Record, (VLER)** will permit information vital to health care, benefits and services to be available to the DoD and the VA from the moment a service member enters the military until the service member or veteran's death. Both the DoD and VA have begun to work together to define and build a seamless system of integration that will provide a framework to ensure that health care providers have the information they need to deliver high-quality health care, while reducing medical errors. VLER is intended to be a lifetime, personal record that ensures a seamless continuum of care and benefits. VLER leverages the work of CONNECT and the Nationwide Health Information Network in service to military and veteran personnel.

  - **"Blue Button"** is a web-based portal enabling individuals to manage their personal health information and provide access to health care providers, caregivers, and others they trust. It provides consumers with a standardized and reusable copy of their health information through a simple download function on DoD, VA and CMS' websites.

  - **My Health*e*Vet** is VA's e–health website, which offers Veterans, active duty service members, their dependents, and caregivers access anywhere, anytime via the Internet to VA health care information and services. My Health*e*Vet is a free, online PHR that empowers Veterans to become informed partners in their health care by allowing access to trusted, secure, and current health and benefits information, as well as the ability to record, track and store important health and military history information.

  - **Care Coordination/Home Telehealth (CCHT)** is the national program the VHA uses to coordinate the care of veteran patients with chronic conditions. CCHT involves the systematic use of health informatics, e-care, and disease management technologies to avoid unnecessary admission to long-term institutional care facilities. Technologies include videophones, messaging devices, biometric devices, digital cameras, and remote monitoring devices. E-care is an appropriate and cost-effective way to manage chronic care patients in urban and rural settings and enables patients to live independently at home.

  - **Healthcare Associated Infection & Influenza Surveillance System, (HAIISS)** is a national VA IT initiative that will allow VA healthcare providers to detect the development of healthcare acquired infections in near real time; perform syndromic surveillance and track microbiological organisms of epidemiologic significance, including automated reporting of infectious diseases to local public health

agencies and CDC; and provide tools for tracking multidrug resistant organisms and monitoring antimicrobial utilization in VA medical centers to improve the quality of care for Veterans. VA and DoD are also working together to build a bi-directional biosurveillance system that will provide improved situational awareness for public health related events.

- **Federal advisory committees** are established or authorized by statute to provide advice or recommendations to federal officials on issues or policies that are within the purview of the federal government. These committees include groups from outside the federal government that afford an expertise or perspective not available within the Department of other federal agencies. They provide a mechanism for public input into health IT policy.

  – **National Committee on Vital and Health Statistics (NCVHS)** advises the HHS Secretary in the area of health data, statistics, and national health information policy and the Department's strategy to best address those issues.

  – **HIT Policy Committee (HITPC)** was created by the HITECH Act to make recommendations to the National Coordinator for Health IT on a policy framework for the development and adoption of a nationwide health information infrastructure, including standards for the electronic exchange and use of patient medical information.

  – **HIT Standards Committee (HITSC)** was created by the HITECH Act to make recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information.

- **Federal Communications Commission (FCC)** is the federal agency responsible for regulating interstate and international communications, and is actively involved in efforts to build the communications infrastructure necessary to facilitate information exchange. FCC's investments are helping to connect rural health communities and improve access to health IT for more Americans.

  – **The Rural Health Care Pilot Program** facilitated the creation of a nationwide broadband network dedicated to health care and connecting public and private non-profit health care providers in rural and urban locations.

  – The **Expanding Investment in Broadband Health Care Technology** program will invest $400 million annually to enable doctors, nurses, hospitals and clinics to deliver, through communications technology, world-class health care to patients no matter where they live. It is one of four programs in the Universal Service Fund administered by the FCC.

- **Federal Health IT Taskforce** serves as the overall government coordination body for policy development, coordination and implementation of federal health IT activities. This Taskforce also aims to improve transparency of federal government activities related to health IT and communication among federal agencies as they execute federal health IT policy. The Taskforce is chaired by the National Coordinator, with OMB's Health Program Associate Director and the federal government's Chief Information Officer and Chief Technology Officer serving as vice chairs. Agency participants include senior policy officials from HHS (and its relevant offices and operating divisions), DoD, VA, SSA, USDA, OPM, and Commerce.

- **Federal Trade Commission (FTC)** advances consumers' interests by sharing its expertise with federal and state legislatures and U.S. and international government agencies. The Commission has been actively involved in enforcing competition in health care markets. Alongside ONC and OCR, the FTC continues to analyze and update breach notification policies and procedures to ensure they protect individuals' rights and meet their needs.

- **Office of Personnel Management (OPM)** provides comprehensive human resource services to all federal agencies and employees. It continues to develop plans to encourage health insurance plans purchased by the government to support meaningful use among their network of providers.

- **Social Security Administration (SSA)** administers the Social Security Act, which provides benefits for retirement, disabilities, and survivors. SSA is an important partner and early adopter of the Nationwide Health Information Network. In partnership with MedVirginia, SSA uses the Nationwide Health Information Network to obtain electronic medical records in disability cases, and is working with ONC and other Nationwide Health Information Network cooperative members to expand this effort.

- **White House Office of Science and Technology Policy (OSTP)** leads interagency efforts to develop and implement sound science and technology policies and to work with the private sector, state and local governments, the science and higher education communities, and other nations toward this end.

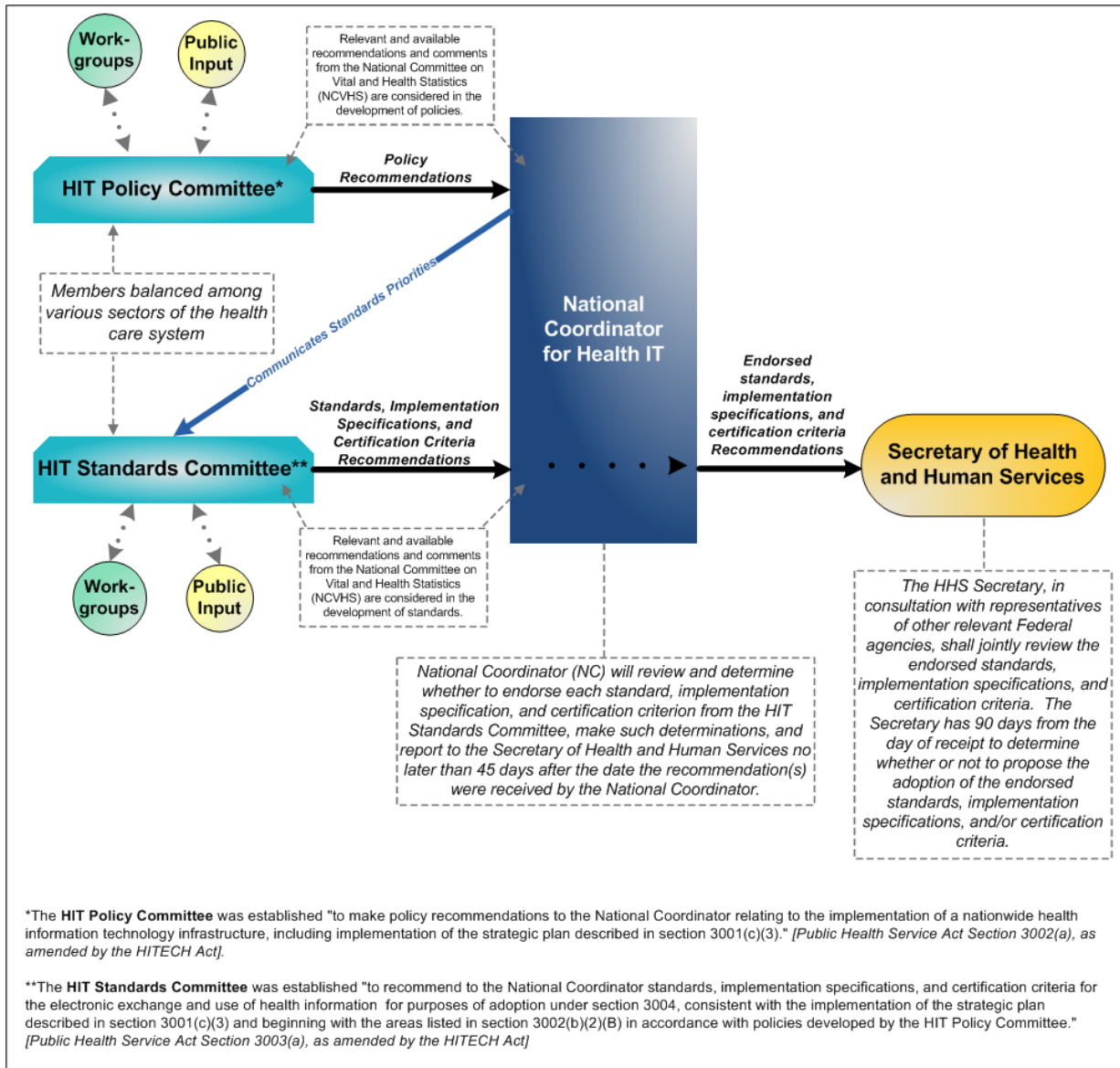# Appendix C: HIT Standards and HIT Policy Committees Information Flow

Figure 2; Flow of recommendations through the HIT Policy and Standards Committees, ONC, and the HHS Secretary

Appendix D: Process Approach

In creating the Federal Health IT Strategic Plan, several methods and key sources were utilized and incorporated in order to achieve the final document. The process for obtaining input included working collaboratively with both the public and private sectors, as well as gathering input from current policy and regulations.

At its core, the plan leverages the work of the Strategic Plan workgroup of the HIT Policy Committee. Beginning in January 2010, the workgroup met regularly to devise a strategic plan framework that was submitted to the Health IT Policy Committee which in turn submitted its recommended approach for consideration to the National Coordinator. This framework served as a key input for consideration as ONC wrote the Federal Health IT Strategic Plan. The framework was developed by members of the Workgroup which included health IT leaders from across both the public and private sectors, and also incorporated feedback from the public gathered during public meetings and a listening session.

Due to the diverse scope and multi-agency nature of the plan, it was essential to engage the federal health community in various ways during the plan's development and refinement. ONC conducted interviews and conversations with representatives from key federal agencies and offices in order to create a cohesive and integrated health IT plan across the federal government. After the meetings and discussions were held, ONC looked to these federal agencies and leaders for valuable feedback on drafts of the plan, and intends to continue this collaboration as the plan advances in the future.

ONC actively sought public input into the plan via its Health IT Blog and hosted a consumer working group discussion with health IT leaders in the public and private sectors to gather input in developing its consumer strategy (Goal IV).

The Federal Health IT Strategic Plan was developed with the crucial understanding that several policies and regulations have critical implications pertaining to the current and future state of health IT *(See Appendix E)*. The Plan has also undergone a public comment period and has been updated to reflect input gathered from the public during this process.

Appendix E: Statutes and Regulations

Statutes

American Recovery and Reinvestment Act of 2009 (The Recovery Act)

On February 17, 2009, the President signed the Recovery Act. This statute includes the Health Information Technology for Economic and Clinical Health Act (the HITECH Act) (see below) which establishes the Medicare and Medicaid EHR Incentive Programs that encourage meaningful use of certified EHRs and other health information technology (IT) to improve quality of care.

Health Information Technology for Economic and Clinical Health Act of 2009 (The HITECH Act)

The Health Information Technology for Economic and Clinical Health (HITECH) Act, passed as part of the Recovery Act, allocated billions of dollars for the health care system to adopt and meaningfully use health IT to improve health. A number of provisions in the HITECH Act strengthen the privacy and security protections for health information established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

HIPAA called for the establishment of standards and requirements for transmitting certain health information to improve the efficiency and effectiveness of the health care system while protecting patient privacy. The Administrative Simplification Regulations have been developed to implement the Administrative Simplification provisions of HIPAA.

The Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act)

On March 23, 2010, the President signed the Patient Protection and Affordable Care Act of 2010, later amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), which, among other things, is estimated to expand health care coverage to 32 million currently uninsured Americans by 2019. The Affordable Care Act builds on the HITECH Act and recognizes health IT as a critical enabler to broad transformations in health care.

Regulations

Medicare and Medicaid Programs: Electronic Health Record Incentive Programs Final Rule

This rule implements the Recovery Act provisions that provide incentive payments to eligible professionals and eligible hospitals that adopt and use certified EHR technology in a meaningful way. The programs seek to help improve care, efficiency, and population health. This rule also specifies the initial criteria that eligible providers must meet to qualify for the Medicare and Medicaid EHR incentive payments, and it includes other incentive programs participation requirements.

Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Interim Final and Final Rules

Under these rules, the Secretary has adopted the initial set of standards, implementation specifications and certification criteria that are required for the certification of EHR technology. These rules have been aligned to support the achievement of meaningful use stage one by eligible professionals, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs.

Establishment of the Temporary Certification Program for Health Information Technology Final Rule

This final rule establishes a temporary certification program for the purposes of testing and certifying health IT, thereby ensuring the availability of Certified EHR Technology for eligible health care providers seeking incentive payments available under the Medicare and Medicaid EHR Incentive Programs. This final rule is issued under the authority granted to the National Coordinator by section 3001(c)(5) of the Public Health Service Act (PHSA), as added by the HITECH Act. Under the temporary certification program, the National Coordinator will authorize qualified organizations that meet specified requirements to conduct the testing and certification of Complete EHRs and/or EHR Modules.

Establishment of the Permanent Certification Program for Health Information Technology Final Rule

This final rule establishes a permanent certification program for the purpose of certifying health IT. This final rule is issued pursuant to the authority granted to the National Coordinator for Health Information Technology (the National Coordinator) by section 3001(c)(5) of the PHSA, as added by the HITECH Act. The permanent certification program will eventually replace the temporary certification program that was previously established by a final rule. The National Coordinator will use the permanent certification program to authorize qualified organizations to certify certain types of EHR technology, such as Complete EHRs and/or EHR Modules. The permanent certification program could also be expanded to include the certification of other types of health IT.

Breach Notification for Unsecured Protected Health Information Interim Final Rule

This rule implemented section 13402 of the HITECH Act by requiring HIPAA covered entities to provide notification following a breach of unsecured protected health information to individuals, HHS, and in some cases the media. This rule also requires business associates to notify covered entities following a breach of unsecured protected health information.

HIPAA Privacy and Security Rules

The HIPAA Privacy Rule provides federal protections for individually identifiable health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of protected health information needed for patient care and other important purposes. The HIPAA Security Rule specifies a series of administrative, physical, and technical safeguards for covered entities to implement to assure the confidentiality, integrity, and availability of electronic protected health information.

Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the HITECH Act Proposed Rule

This rule proposes a number of provisions that would implement certain parts of the HITECH Act that are designed to strengthen the privacy and security protections for health information established under HIPAA. In addition to seeking to implement these HITECH Act provisions, this rule proposes a number of modifications to improve the HIPAA Rules, which are not mandated in the HITECH Act. The Department issued this proposed rule in 2010 and expects to finalize it in 2011.

HIPAA Privacy Rule Accounting of Disclosures Under the HITECH Act Proposed Rule

This rule proposes modifications to the HIPAA standard for accounting of disclosures of protected health information. The modifications in part would implement the statutory requirement under the HITECH Act to require covered entities and business associates to account for disclosures of protected health information to carry out treatment, payment, and health care operations if such disclosures are through an electronic health record. The

rule also proposes to expand the accounting provision to provide individuals with the right to receive an access report indicating who has accessed electronic protected health information in a designated record set.

Appendix F: Goals, Objectives, and Strategies

Goal I: Achieve Adoption and Information Exchange through Meaningful Use of Health IT	
Objectives	**Strategies**
I.A. Accelerate adoption of electronic health records	I.A.1. Provide financial incentive payments for the adoption and meaningful use of certified EHR technology.
	I.A.2. Provide implementation support to health care providers to help them adopt, implement, and use certified EHR technology.
	I.A.3. Support the development of a trained workforce to implement and use health IT technologies.
	I.A.4. Encourage the inclusion of meaningful use in professional certification and medical education.
	I.A.5. Establish criteria and a process to certify EHR technology that can support meaningful use criteria.
	I.A.6. Communicate the value of EHRs and the benefits of achieving meaningful use.
	I.A.7. Align federal programs and services with the adoption and meaningful use of certified EHR technology.
	I.A.8. Work with private sector payers and provider groups to encourage providers to achieve meaningful use.
	I.A.9. Encourage and facilitate improved usability of EHR technology.
I.B. Facilitate information exchange to support meaningful use of electronic health records	I.B.1. Foster business models that create health information exchange.
	I.B.2. Monitor health information exchange options and fill the gaps for providers that do not have viable options.
	I.B.3. Ensure that health information exchange takes place across individual exchange models, and advance health systems and data interoperability.
I.C. Support health IT adoption and information exchange for public health and populations with unique needs.	I.C.1. Ensure public health agencies are able to receive and share information with providers using certified EHR technology.
	I.C.2. Track health disparities and promote health IT that reduces them.
	I.C.3. Support health IT adoption and information exchange in long-term/post-acute, behavioral health, and emergency care settings.

Goal II: Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT	
Objectives	**Strategies**
II.A. Support more sophisticated uses of EHRs and other health IT to improve health system performance	II.A.1. Identify and implement best practices that use EHRs and other health IT to improve care, efficiency, and population health.
	II.A.2. Create administrative efficiencies to reduce cost and burden for providers, payers, and government health programs.
II.B. Better manage care, efficiency, and population health through EHR-generated reporting measures	II.B.1. Identify specific measures that align with the National Quality Strategy.
	II.B.2. Establish standards, specifications, and certification criteria for collecting and reporting measures through certified EHR technology.
II.C. Demonstrate health IT-enabled reform of payment structures, clinical practices, and population health management	II.C.1. Fund and administer demonstration communities to show how the advanced use of health IT can achieve measurable improvements in care, efficiency, and population health.
	II.C.2. Align health IT initiatives and clinical and payment reform pilots and demonstrations.
II.D. Support new approaches to the use of health IT in research, public and population health, and national health security	II.D.1: Establish new approaches to and identify ways health IT can support national prevention, health promotion, public health, and national health security.
	II.D.2: Invest in health IT infrastructure to support the National Prevention and Health Promotion Strategy.
	II.D.3: Ensure a mechanism for information exchange in support of research and the translation of research findings back into clinical practice.

Goal III: Inspire Confidence and Trust in Health IT	
Objectives	**Strategies**
III.A. Protect confidentiality, integrity, and availability of health information	III.A.1. Promulgate appropriate and enforceable federal policies to protect the privacy and security of health information.
	III.A.2. Enforce existing federal privacy and security laws and maintain consistency with federal policy.
	III.A.3. Encourage the incorporation of privacy and security functionality into health IT.
	III.A.4. Assess technical solutions that could support more granular patient choice and data segmentation.
	III.A.5. Identify health IT system security vulnerabilities and develop strategic solutions.
	III.A.6. Identify health IT privacy and security requirements and best practices, and communicate them through health IT programs.
III.B. Inform individuals of their rights and increase transparency regarding the uses of protected health information	III.B.1. Inform individuals about their privacy and security rights and how their information may be used and shared.
	III.B.2. Increase transparency regarding the development of policies and standards related to uses and sharing of protected health information.
	III.B.3. Maintain strong breach notification requirements.
III.C. Improve safety and effectiveness of health IT	III.C.1. Provide implementation and best practice tools for the effective use of health IT.
	III.C.2. Evaluate safety concerns and update approach to health IT safety.
	III.C.3. Monitor patient safety issues related to health IT and address concerns.

Goal IV: Empower Individuals with Health IT to Improve their Health and the Health Care System	
Objectives	**Strategies**
IV.A. Engage individuals with health IT	IV.A.1. Listen to individuals and implement health IT policies and programs to meet their priorities.
	IV.A.2. Communicate with individuals openly and spread messages through existing communication networks and dialogues.
IV.B. Accelerate individual and caregiver access to their electronic health information in a format they can use and reuse	IV.B.1. Through Medicare and Medicaid EHR Incentive Programs, encourage providers to give patients access to their health information in an electronic format.
	IV.B.2. Through federal agencies that deliver or pay for health care, act as a model for sharing information with individuals and make available tools to do so.
	IV.B.3. Establish public policies that foster individual and caregiver access to their health information while protecting privacy and security.
IV.C. Integrate patient-generated health information and consumer health IT with clinical applications to support patient-centered care	IV.C.1. Support the development of standards and tools that make EHR technology capable of interacting with consumer health IT and build these requirements for the use of standards and tools into EHR certification.
	IV.C.2. Solicit and integrate patient-generated health information into EHRs and quality measurements.
	IV.C.3. Encourage the use of consumer health IT to move toward patient-centered care.

Goal V: Achieve Rapid Learning and Technological Advancement	
Objectives	**Strategies**
V.A. Lead the creation of a learning health system to support quality, research, and public and population health	V.A.1. Establish an initial group of learning health system participants.
	V.A.2. Develop standards, policies, and technologies to connect participants within the learning health system.
	V.A.3. Engage patients, providers, researchers, and institutions to exchange information through the learning health system.
	V.A.4. Grow the learning health system by adding more members and expanding policies and standards as needed.
V.B. Broaden the capacity of health IT through innovation and research	V.B.1. Liberate health data to enable health IT innovation.
	V.B.2. Make targeted investments in health IT research.
	V.B.3. Employ government programs and services as test beds for innovative health IT.
	V.B.4. Monitor and promote industry innovation.
	V.B.5. Provide clear direction to the health IT industry regarding government roles and policies for protecting individuals while not stifling innovation.

Appendix G: Acronyms

Term/Acronym	Description
AHLTA	Armed Forces Health Longitudinal Technology Application
AHRQ	Agency for Healthcare Research and Quality
ASPE	Office of the Assistant Secretary for Planning and Evaluation (HHS)
ASPR	Office of the Assistant Secretary for Preparedness and Response (HHS)
caBIG®	The Cancer Biomedical Informatics Grid
caGrid	Infrastructure that supports caBIG
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CHDI	Community Health Data Initiative
CMS	Centers for Medicare & Medicaid Services
DHS	U.S. Department of Homeland Security
DoD	U.S. Department of Defense
DoEd	U.S. Department of Education
DoL	U.S. Department of Labor
DURSA	Data Use and Reciprocal Support Agreement
EHR	Electronic Health Record
FACA	Federal Advisory Committee Act
FCC	Federal Communications Commission
FDA	U.S. Food and Drug Administration
FHA	Federal Health Architecture
FTC	Federal Trade Commission
HDC	Health Disparities Collaborative (HRSA)
Health IT	Health Information Technology
HHS	U.S. Department of Health and Human Services
HHS/OS	U.S. Department of Health and Human Services, Office of the Secretary
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH ACT	Health Information Technology for Economic and Clinical Health Act
HITPC	HIT Policy Committee
HITRC	Health Information Technology Research Center

Term/Acronym	Description
HITSC	HIT Standards Committee
HITSP	Healthcare Information Technology Standards Panel
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IOM	Institute of Medicine
LTPAC	Long-term and post-acute care
mHealth	Mobile health
NAMS	National Ambulatory Medical Survey
NEDSS	National Electronic Disease Surveillance System
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NITRD	Networking and Information Technology Research and Development Program
NLM	National Library of Medicine
NPRM	Notice of Proposed Rulemaking
NQF	National Quality Forum
NRC	The National Resource Center for Health Information Technology
OCR	Office for Civil Rights
OGC	Office of the General Counsel
OPM	Office of Personnel Management
ONC-ATCB	Office of the National Coordinator for Health IT – Authorized Testing and Certification Body
ONC	Office of the National Coordinator for Health Information Technology
OPP	ONC's Office of Policy and Planning
OSI	ONC's Office of Standards and Interoperability
OSTP	The White House Office of Science and Technology Policy
PCAST	President's Council of Advisors on Science and Technology
PHR	Personal Health Record
REC	Regional Extension Center
RPMS	Resource and Patient Management System (Indian Health Service's Electronic Health Record)
SAMHSA	Substance Abuse and Mental Health Services Administration
SDO	Standards Development Organizations
SSA	U.S. Social Security Administration

Term/Acronym	Description
State HIE	State Health Information Exchange Cooperative Agreement Program
SHARP	Strategic Health IT Advanced Research Projects
S&I	Standards and Interoperability
USDA	U.S. Department of Agriculture
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration
VistA	Veterans Health Information Systems and Technology Architecture (VA's Electronic Health Record)

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