POLICY STUDY ON THE FEDERAL GOVERNMENT’S STRATEGY FOR IMPLEMENTING WIDESCALE HEALTH INFORMATION TECHNOLOGY

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Jayce Arakaki

Thesis Committee:

Jenifer Winter, Chairperson
Christina Higa
Hanae Kramer
Executive Summary

This policy study analyzes the federal government’s role in the widescale implementation of health IT across the U.S. Through an Executive Order, the Office of the National Coordinator for Health Information Technology (ONC) was created and tasked with overseeing and governing all health IT related activities. The ONC led several initiatives including the creation of regional extension centers (RECs) to provide technical assistance and help providers with implementing health IT. A workforce development program was also created in partnership with academic institutions across the U.S. in order to provide the education to develop skilled workers for the health IT industry. The Electronic Health Record (EHR) Incentive Program was also created under the ONC to entice providers into implementing an EHR system and using it in a manner that improves patient care. The last initiative led by the ONC was the state health information exchange (HIE) program which allocated grant money to each state and U.S. territory to build up the infrastructure in order to establish a nationwide health information network.

A thorough analysis was conducted of the entire health IT landscape to identify potential areas of improvement and to provide insight into future potential scenarios. The federal government began playing a key role in health IT upon the creation of the ONC in 2004. The ONC is responsible for developing the standards and protocols for certified EHR systems. The timeline in which the standards and protocols have been coming out have been putting vendors and healthcare organizations in a disadvantageous position because systems already being used needed to be upgraded to comply with new standards. In order to alleviate this ongoing issue, creating a tiered timeline for certification and compliance would be ideal. Once the new standards and guidelines are
finalized, vendors should be given a timeframe in which to comply. After that, the products can be made available in the marketplace and healthcare organizations would be given a different timeline to follow in order to implement and ensure the requirements for the EHR Incentive Program are met.

Another issue currently plaguing the industry is that vendors are creating niche products for specific health IT functions. Part of the goal behind the Executive Order that started the health IT movement was to allow protected health information to be exchanged across different platforms, states, and organizations. Vendors offering niche products are not helping to facilitate HIE. The underlying issue is that big corporations that have systems capable of all the technical functionality to achieve the goals from the Executive Order have no desire to scale their products down for smaller organizations. This in turn forces smaller organizations to piecemeal their implementations. The recommendation is for the ONC to start a federally-funded financial matching program with the smaller organizations in order to double their financial resources. Through a federally-funded financial matching program, it would allow small health organizations to double their financial resources, which would in turn attract the large health IT vendors to build scalable products designed for them. This public-private partnership model has been a consistent way to fund projects nationwide at all levels of government and private organizations.

In order to participate in the EHR Incentive Program and get reimbursed $44,000 or $63,750, the provider needs to see a certain amount of Medicare or Medicaid patients. Providers that do not treat Medicare or Medicaid patients do not qualify for the incentive program. The ONC would need to collaborate with private insurers nationwide to
develop a funding model so those providers only seeing patients with private insurance can receive some type of incentive to implement an EHR system.

Two of the main ONC programs were rolled out in the same year. The EHR Incentive Program launched in the fall of 2010 and is scheduled to run until 2021. The goal of the program is to get widespread implementation of certified EHR systems across the U.S. The state HIE program was also launched in 2010 with the goal being to achieve a nationwide health information network. Implementing a certified EHR system is the precursor to obtaining HIE functionality in that the EHR digitizes the patient record and gets all protected health information into an electronic format. The patient record needs to be in an electronic format prior to being exchanged. Staggering the launch of the state HIE program at least five (5) years after the start of the EHR Incentive Program could have led to more success with HIEs.

A remaining question regarding the future of health IT is whether the ONC will continue to exist once all the monies have been expended. In the scenarios section, two scenarios are presented: one in which the ONC becomes a permanent federal agency and one in which the ONC dissolves. There is not much indication or of the future of the ONC, but through analysis and forecasting of the industry, it appears as if they will eventually dissolve. Should that occur, the ONC-appointed non-profit organizations tasked with overseeing the standards and future developments will play a much larger role moving forward.
Key Terms and Abbreviations

*American Recovery and Reinvestment Act (ARRA)* – commonly referred to as “the stimulus” which was an economic stimulus package signed into law on February 17, 2009 by President Barack Obama to save existing jobs and create new ones immediately in education, health, and renewable energy.

*Authorized Testing Certification Body (ATCB)* – ONC-designated certification body that can test and certify any health IT product.

*Center for Medicare and Medicaid (CMS)* – a federal agency under the DHHS that administers the Medicare and Medicaid programs.

*Certified Health IT Product List (CHPL)* – a list of all certified Health IT products maintained by the ONC.

*Clinical Data Repository (CDR)* – a real-time database that stores all clinical information from a given EHR or HIE system.

*Data analytics* – the capability to run analytic capabilities on patient health information stored in the CDR for the purposes of syndromic surveillance, public health monitoring, and research.

*Department of Health and Human Services (DHHS)* – the U.S. government’s principal agency for protecting the health of all Americans and providing essential human services.

*Direct Secure Messaging (DSM)* – Secure messaging standard for the healthcare industry that allows the exchange of patient health information through SMTP and X.509 certificates.
eHealth Exchange – the nationwide health information network that allows for the querying of any patient located in any facility that participates in the exchange.

Electronic Health Record (EHR) – computerized system for maintaining patient health information that may include but not be limited to: vitals, illnesses, diagnosis, medical history, laboratory history, medications, etc.

Hawaii Health Information Exchange (HHIE) – non-profit organization that received $5,602,318 from the ONC to facilitate the building and exchanging of health information so Hawaii can exchange protected health information with the rest of the U.S.

Health Information Exchange (HIE) – the process of moving electronic patient health information over disparate systems for the purpose of facilitating the access and retrieval of clinical data.

Health Information Technology for Economic and Clinical Act (HITECH Act) – enacted as part of the American Recovery and Reinvestment Act of 2009 to promote the adoption and meaningful use of health IT.

Health Information Technology (health IT) – the technical framework that includes the design, development, creation, use, and maintenance of information technology systems in the healthcare environment.

Interface Integration Engine – Software application that uses standard protocols to allow different systems to accurately exchange information.

Office of the National Coordinator for Health Information Technology (ONC) – the federal division under the U.S. Department of Health & Human Services that promotes the utilization of health information technology.
Master Patient Index (MPI) – a software application capable of matching patient information in a single system using algorithmic functionality to determine if a record is a duplicate.

Meaningful Use – to use a certified EHR system to: 1) improve the quality, safety, and efficiency of care; 2) engage patients and families; 3) improve care coordination and public health; and 4) maintain privacy and security of protected health information.

Patient Portal – web interface for patients to access their protected health information via a web address.

Protected Health Information (PHI) – any type of health-related information that can be linked to a specific individual.

Provider – any medical professional rendering billable medical services to a patient (i.e. doctors, dentists, optometrists, practitioners, etc.).
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Chapter 1
INTRODUCTION

Over the past twenty years, the U.S. has undergone major transformation because of information technology (ONC, 2013a). The infusion of information technology (IT) into almost every industry across the nation has impacted the way things get done. What were once manual processes have now been automated and streamlined through the use of computers and information technologies. Over the last several decades, the world’s largest industries have adopted some form of IT to improve business processes, streamline workflow, and simplify complex scenarios resulting in more advanced capabilities. However, the healthcare industry has been one of the slowest to adopt and implement information technologies.

Health information technology (health IT) has been slow to diffuse across the healthcare industry. Paper-based records have been the staple in hospitals and provider offices for decades; even after widespread IT diffusion in other industries. Because of the fragmentation associated with having paper-based records and the lack of diffusion of health IT, care coordination and overall efficiency have remained low. In a study conducted by the Bloomberg organization (2013), the U.S. ranked 46th in international healthcare efficiency. The study utilized the following criteria to determine an efficiency score: life expectancy, relative per capita cost of healthcare, and absolute per capita cost of healthcare. The U.S. had the second highest healthcare cost per capita at $8,608, behind Switzerland, which had a healthcare cost per capita of $9,121.

Although report numbers vary, there are several documented studies connected to measuring the effects of medical errors throughout the healthcare industry. One of the most commonly cited studies was conducted by the Institute of Medicine (1999) titled To
Err is Human and it was found that between 44,000 to 200,000 people die each year as a result of preventable medical errors. The errors have been estimated to cost between $17 billion and $29 billion annually through hospitals nationwide. Another study (Starfield, 2000) estimated that there are 106,000 adverse reactions to improperly prescribed prescription drugs, 80,000 infections, 20,000 other errors, 12,000 unnecessary surgeries, and 7,000 medication errors that occur annually in hospitals across the nation. The National Council for Patient Information and Education (2012) reported an additional 125,000 deaths occur annually due to adverse reactions to drugs physicians should never have prescribed.

The medical errors were due in large part to decentralized, incompatible, and disconnected health systems. Technology has been prevalent in the healthcare landscape, but the fragmentation of the industry has led to inefficiencies and silos of data not conducive for interoperability. In order to stimulate the deployment and diffusion of health IT on a national level, federal initiatives were created, including financial incentive programs for early adopters, financial penalties for late adopters, and additional funding streams via national grant opportunities at statewide levels. The federal initiatives have helped gain widespread adoption of certified EHR systems, but they have still been met with resistance from some in the medical communities due to the lack of clear interoperability standards and governing framework. In extreme cases, some providers have stated they will work until financial penalties go into effect and retire instead of adopting and implementing health IT into their practices.

There have been many research studies conducted on EHR adoption and diffusion, but computerized clinical documentation and EHRs are but a piece of a much
larger picture. For the purposes of this policy study, health IT is defined as encompassing all the technologies that contribute to the achievement of President Bush’s Executive Order (2004) to establish a nationwide health information network. The Executive Order changed the health IT landscape through the introduction of new policies, governance, and funding streams made available through legislative action. Some of the core health IT elements that contribute to achieving the goals outlined in the Executive Order include certified EHR systems, HIE components, and any other IT products (hardware or software) that facilitate the secure exchange of protected health information. Providers that simply adopt an EHR system do not immediately achieve nationwide interoperability because most systems, as is, still lack the ability to exchange protected health information across geographic borders. It is for this reason that the policies governing health IT will be analyzed.

1-1 Statement of the Research Problem

The healthcare industry has been slow to adopt health information technologies that could result in improved patient care, improved care coordination, reduction in medical errors, and easier access to patient information (ONC, 2013a). The U.S. Department of Health and Human Services (DHHS) (2013a) defines health IT as the combination of software and hardware to facilitate the exchange of health information in an electronic environment. The first element of health IT is the EHR system that is utilized for storing a patient’s health information in a computerized format available to the provider at the time and place of care in order to reduce errors, costs, and promote a more efficient workflow (ONC, 2013e). The second element of health IT is health information exchange (HIE) components which allow for the improved coordination of
care and exchange of information among disparate systems based on standards for interoperability. The combination of EHR systems and HIE components form the core of health IT that make it possible to achieve the goals outlined in President Bush’s Executive Order. The objective of this policy study is to analyze the existing landscape and identify barriers or shortcomings that impede effective usage and deployment of health IT at the private, state, or federal levels.

This policy study will 1) discuss the background of health IT; 2) outline the various health information technologies; 3) introduce the key stakeholders; 4) offer recommendations to improve the health IT landscape; and 5) describe alternative scenarios for the future of health IT.
Chapter 2
HEALTH IT LANDSCAPE

The U.S. has been consistently lagging behind other nations in the international community for the diffusion of health IT. Thirteen years ago, Arthur Garson (2000), president of the American College of Cardiology, proclaimed the U.S. healthcare system “broken” (p. 2). He held that “new technology [would] increase efficiency” but that “the cost of new tests and treatments [would] outweigh the savings” (p. 3). Garson, like many other providers across the nation, worried about the rising costs associated with healthcare and the lack of structure in the industry when it came to the coordination of care. The U.S. has always been a world leader in medical innovations but has also been criticized for skyrocketing costs, diminishing quality of care, limited accessibility, and limited care coordination (Sebelius, 2013). While some of the world’s best medical institutions reside in the U.S., they do not represent the healthcare system as a whole.

2-1 Executive Order

The widescale change that sparked the overhaul of the national healthcare system came on April 27, 2004, when President George W. Bush signed an Executive Order to, “provide leadership for the development and nationwide implementation of an interoperable health IT infrastructure to improve the quality and efficiency of health care” (Executive Order No. 13,335, 2004, p. 1). The Executive Order was a result of heightened awareness brought about by a series of Institute of Medicine reports about the chronic lack of health IT in the U.S.

Part of the Executive Order called for the creation of the Office of the National Coordinator for Health Information Technology (ONC), which was tasked with accelerating the effective use of health IT to improve the quality, efficiency, and safety of
healthcare for all Americans. The newly created ONC is an agency that falls under the DHHS and the top post of the ONC (National Coordinator for health IT) reports directly to the Secretary of the DHHS. Currently, that post is held by Dr. Karen Salvo, and she oversees all health IT initiatives. Funding for the ONC comes from the *American Recovery and Reinvestment Act (ARRA)*, which was signed into law by President Barack Obama in 2009 (ONC, 2013a). Salvo leads the ONC and, under the Executive Order (2004), ensures the nationwide interoperable health IT infrastructure achieves the following six core goals:

a) Ensure that appropriate information to guide medical decisions is available at the time and place of care;

b) Improve health care quality, reduce medical errors, and advance the delivery of appropriate, evidence-based medical care;

c) Reduce health care costs resulting from inefficiency, medical errors, inappropriate care, and incomplete information;

d) Promote a more effective marketplace, greater competition, and increased choice through the wider availability of accurate information on health care costs, quality, and outcomes;

e) Improve the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers through an effective infrastructure for the secure and authorized exchange of health care information; and

f) Ensure that patients’ individually identifiable health information is secure and protected. (p. 1)
The goals outlined in the Executive Order have established the path and direction the nation will take towards health IT in order to better facilitate the exchange of protected health information electronically over geographic borders.

2-2 Background of Health IT

While the widescale implementation of health IT on a federal level is relatively new, EHR technology is not. According to the American Medical Association (2011), the first EHR system was known as a clinical information system and was developed in the mid-1960s by a company called Lockheed. The rights to the system then changed hands several times from Technicon, to TDS Healthcare, Eclipsys, and now Allscripts (Amatayakul, 2007). It influenced later systems because of its processing speed and flexibility which allowed many users to access it simultaneously (Institute of Medicine, 1997).

In the early 1970s, the Department of Veterans Affairs (VA) became the first federal department to start using an EHR system (American Medical Association, 2011). The VA system, aptly named the Veterans Health Information Systems and Technology Architecture (VistA), was the start of the federal government’s involvement with electronic health records and marked the beginning of heavy government investments in the technology. Several years after its inception, the federal government made VistA available as an open source product, and programmers took the source code to develop proprietary EHR systems. This led to an explosion in the amount of EHR systems available in the marketplace because each system offered different graphical user interfaces (GUIs) with varying technical functionality differences.
There were no standards that existed to ensure the quality of EHR systems, the security, the functionality, and the ability to interoperate at that time. The protected health information sitting in the repositories for each system was still fragmented because there were no interoperability standards. In 2010, that changed because a certification program for health IT products was implemented by the ONC (DHHS, 2010). Any provider that wanted to participate in the federal EHR Incentive Program needed to adopt a certified EHR system. The certification program provided assurance to providers that any certified EHR system offered the necessary technological capability, functionality, and security to maintain quality and consistency across the healthcare landscape (ONC, 2013c). The certified Health IT Product List (CHPL) was created in 2011 and modified for use beyond 2014. Products certified on the 2011 list could be used for the federal incentive program up until 2014, before new requirements went into effect. One of the key requirements of a certified EHR system from 2011 was the ability to electronically record, store, retrieve, and modify medications, laboratory results, and radiology/imaging scans (ONC, 2013d). Being able to electronically record demographics, provide clinical decision support, and support the ability to calculate and submit clinical quality measures are other examples of the requirements a certified EHR system in 2011 needed to have. In 2011, there were 4,552 certified EHR systems (both inpatient and ambulatory). For the 2014 certification criteria, there are only 830 certified EHR systems at the time of this writing (ONC, 2014). As the certification requirements get more stringent, it is expected that the number of systems available in the market will decrease significantly because of increased sophistication of technological requirements, mergers, and acquisitions, as evidenced by the amount of certified systems available for 2014 compared to 2011.
For a vendor to get their EHR system certified, they are required to go through a process with an ONC-authorized testing certification body (ATCB). Currently, the ONC has five full ATCBs: Certification Commission for Health Information Technology, ICSA Labs, InfoGard Laboratories Inc., SLI Global Solutions, and the Drummond Group (ONC, 2013c). Each of these certification bodies can grant certification to any health IT vendor through a rigorous testing process. They are geographically located all over the continental U.S. in the following locations: Chicago, IL; Mechanicsburg, PA; San Luis Obispo, CA; Denver, CO; and Austin, TX. The prices vendors must pay to gain initial certification can range from $20,000-$40,000 plus annual maintenance costs as well (ONC, 2013c). The ONC does not regulate pricing for ATCBs, choosing instead to let the market dictate pricing models. Each ATCB differentiates themselves from the others through varying cost models, procedural differences during the certification process, and past experience/expertise (Patel, 2011). Vendors have the flexibility of going through the certification testing with any of the authorized ATCBs.

Prior to the release of the 2011 certification standards for EHR systems, having thousands of companies in the marketplace was not conducive to the exchange of protected health information because the data was sitting in disparate systems, built off different coding languages, and lacked interoperability functionality. The framework for allowing interoperability between systems is what allows protected health information to be exchanged with other organizations and is one of the main features of HIE functionality. To help facilitate health information exchange, standards were developed to enable the exchange of protected health information.
2-3 American Recovery and Reinvestment Act (ARRA)

On February 17, 2009, five years after President Bush signed the Executive Order to create the ONC that sparked all health IT related activities at the federal level, President Barack Obama signed the ARRA. The ARRA, also referred to as the Stimulus or the Recovery Act is an economic stimulus package with three immediate goals: 1) create new jobs and save existing ones; 2) spur economic activity and invest in long-term growth; and 3) foster accountability and transparency in government spending (ARRA, 2009). The cost of the economic stimulus package was estimated at $840 billion, of which $22 billion was earmarked for health IT purposes. In order to achieve the goal of transparency, recipients of ARRA funds are required to report every January, April, July, and October how the monies are used. The data provided is then posted on the website www.recovery.gov so the public has the ability to track how ARRA monies are being spent.

2-4 Health Information Technology for Economic and Clinical Health Act (HITECH Act)

Under the ARRA, in Title XIII, the HITECH Act was created and appropriated $19 billion to incentivize the adoption and implementation of EHR systems (ARRA, 2009). It also provided $2 billion to the DHHS and its sub-agency the ONC. Of the $2 billion allocated to the DHHS and the ONC, $320 million was earmarked for HIE-related activities with no specific guidelines on how the rest was to be spent, although areas that were singled out for investment included developing interoperability standards, infrastructure upgrades for telemedicine, and expanding health IT to public health departments (ONC, 2013f). The breakdown of the allocation of monies related to the
HITECH Act funds is available in Appendix A. The ONC oversees several health IT initiatives that include but are not limited to the establishment of Regional Extension Centers (RECs), the EHR Incentive Program, state HIE programs, and workforce development programs.

2-4-1 Regional Extension Centers

The ONC appropriated $720 million to the REC program in order to address the issue that most providers lacked a technical understanding of how EHR systems worked (Lynch et al., 2013). The ONC was aware that most providers lacked a high-level understanding of health IT, so a program was developed in which RECs were created across the country to provide technical assistance for providers that lacked the knowledge and experience to implement health IT. The RECs served as advisors to the providers and assisted them with meeting objectives that would help them qualify for financial incentive payments from the Centers for Medicare & Medicaid Services (CMS) (ONC, 2013a). The REC program was designed to leverage the expertise of local professionals in health IT to provide practical, customized support to meet the needs of local providers. RECs have served as change agents to providers implementing health IT. The main types of activities undertaken by RECs were customized to address the barriers and local market conditions of providers in their respective areas. Because different regions face a variety of problems specific to their geographic location, the core mission of the program was to ensure local professionals in the specific areas were familiar with the local barriers that needed to be addressed and overcome.

Through ARRA, the ONC established 62 RECs to assist priority primary care providers in the adoption and use of electronic health records (ONC, 2013a). Priority
primary care providers were defined by the ONC as any licensed medical professional with prescription writing privileges that provide primary care services and belong to a practice of 10 or less providers (Blumenthal, 2010). The 62 recipients were very diverse in that some were newly formed not-for-profit organizations with expertise in EHR adoption, consulting organizations, research organizations, universities, quality improvement organizations, and health center controlled networks. Each REC was awarded based on the priority primary care provider population they sought to support, which ranged between 525 to 6,000 providers (Lynch et al., 2013). In the report conducted by Lynch et al, as of June 2013, RECs enrolled 133,922 priority primary care providers across 30,000 practices and about 80% of those enrolled had an EHR system installed and were routinely using health IT. This equates to roughly 44% of the total 303,000 primary care providers in the U.S. (ONC Data Brief, 2013).

The goals of the REC program align directly with that of the EHR Incentive Program which will be detailed in the following section. Priority primary care providers enrolled in the REC program were given assistance on how to adopt, implement, or upgrade an EHR system in order to receive the financial incentive monies being awarded through the EHR Incentive Program. A milestone grading system was utilized to monitor the success of each REC with the three programmatic milestones being to get providers enrolled into the REC program, get them to implement a certified EHR system, and help them achieve the first stage of the EHR Incentive Program. Once a milestone was achieved, the REC would receive a one-third payment from the ONC through <i>ARRA</i> monies.
2-4-2 EHR Incentive Program

The $17 billion from the *HITECH Act* was earmarked for incentive payments to eligible providers and hospitals across the nation. The EHR Incentive Program was created to provide a financial incentive for eligible providers and hospitals to adopt, implement, or upgrade their EHR systems (CMS, 2013a). Through terms in the *ARRA*, CMS was authorized to award financial incentive payments to eligible providers and hospitals that demonstrated they were using certified EHR technology in a meaningful way (ONC, 2013d). Using the certified EHR technology in a meaningful way means the providers are meeting certain measurement thresholds that range from recording patient information as structured data to exchanging summary care records (ONC, 2013e).

Providers were encouraged to adopt, implement, upgrade, or demonstrate in a meaningful way how they use their certified EHR technology (CMS, 2013a). In the EHR Incentive Program, eligible providers could receive up to $44,000 through Medicare or up to $63,750 through Medicaid if they joined by 2012. The EHR Incentive Program provided supplemental financial payments for eligible providers to use health IT in ways that positively impacted patient outcomes. Payment schedules that span over five or six years were created in order to facilitate the ongoing use of health IT. If a provider saw any amount of Medicare patients, they could participate in the Medicare EHR Incentive Program and upon meeting the Meaningful Use criteria per year, would receive payments of $18,000; $12,000; $8,000; $4,000; and $2,000 in consecutive years (CMS, 2013c). If they enrolled in the program in 2013, the provider would qualify for up to $39,000 from Medicare in payments of $15,000; $12,000; $8,000; and $4,000. If they waited until 2014, the maximum reimbursement would be $24,000 in payments of $12,000; $8,000;
and $4,000. If 30% of a provider’s patients paid with Medicaid, they could participate in the Medicaid EHR Incentive Program which runs until 2016 and they would receive $63,750 in payments of $21,250 in the first year and $8,500 for the next consecutive 5 years (CMS, 2013b).

Beginning in 2015, Medicare will begin to penalize providers for not using a certified EHR system. If a provider has not adopted a certified EHR system and demonstrated they are using it in a meaningful way, an annual 1% Medicare payment reduction will take place in 2015. In 2016, the deduction will increase to 2% and in 2017, it will be 3%. If less than 75% of all Medicare eligible providers are meaningful users of EHR by 2018, the adjustment will change by 1% each year to a maximum of 5% (CMS, 2013c). If a provider does not see any Medicare or Medicaid patients, they do not qualify for participation in the incentive program, nor would the penalties be enforceable.

Hospitals are also eligible to receive incentive payments through Medicare, Medicaid, or both. A hospital qualifies for Medicare reimbursement if they see any amount of Medicare patients. For a hospital to collect the incentive money from Medicaid, at least 10% of their patient volume needs to be insured under Medicaid. Children’s hospitals have no Medicaid requirement.

In order to receive any of the financial incentive payments, providers need to attest to the three stages of Meaningful Use. CMS has established the objectives for Meaningful Use that eligible providers and hospitals must meet in order to receive incentive payments. All providers begin participation in the EHR Incentive Program by fulfilling a 90-day reporting period their first year and a full year in the second year of Meaningful Use (CMS, 2013b). However, an exception was made for 2014 when
attesting to stage 2 in that any provider attesting in that year is only required to fulfill a 90-day reporting period. Once providers meet stage 1 requirements, they are required to meet stage 2 requirements for the next two years. The requirements for stage 1 were finalized in 2010, stage 2 was finalized in 2012, and stage 3 has yet to be finalized at the time of this writing. A full listing of the requirements for stage 1 and 2 for eligible providers can be found in Appendix B.

2-4-3 State HIE Programs

In March 2010, the ONC announced the list of all State Health Information Exchange Cooperative Agreement Program awardees. A total of 56 states and territories were allocated money in an effort to “rapidly build capacity for exchanging health information across the health care systems both within and across states” (ONC, 2013g, p. 1). The awardees were responsible for increasing the connectivity amongst providers in their areas and enabling a more patient-centered flow of information in order to improve the quality and efficiency of care (ONC, 2013g). The program was given a four year performance period from March 2010 and recently concluded on February 7, 2014.

One of the key goals of this program was to advance regional and state-level HIE functionality and eventually move toward a nationwide interoperability model. The state HIE programs fulfill the fifth goal of the Executive Order which is to “improve the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers through an effective infrastructure for the secure and authorized exchange of health care information” (Executive Order No. 13,335, 2004, p. 1).
Locally, in Hawaii, a local non-profit organization called the Hawaii Health Information Exchange (HHIE) was designated by the state and tasked to build the statewide health information exchange. HHIE was awarded $5,602,318 through the State Health Information Exchange Cooperative Agreement Program (ONC, 2013g). As of April 2012, there were 300 enrolled providers and Hawaii Pacific Health and Castle Medical Center organizations were recently added as participants (HHIE, 2013). At the time of this writing, the HHIE is capable of exchanging direct secure messages among participants from various organizations but has not yet accomplished full HIE capability between providers across different systems, organizations, or locations.

2-4-4 Workforce Development Programs

Anticipating a need for qualified individuals in the health IT industry, the ONC developed workforce development programs to provide training and assistance with the widescale health IT implementation nationally. The primary goal of the workforce development program is to train a new workforce of health IT professionals that would be ready to help providers implement certified EHR systems and improve health care quality, safety, and cost-effectiveness (ONC, 2013h). The gap that existed between the need for qualified professionals and the direction of health IT was alleviated by the workforce development programs. The ONC awarded $116 million in funding for the following health IT workforce development activities:

- $68 million for community college consortia to educate health IT professionals
- $32 million for program assistance for university-based training
- $10 million for curriculum development centers
- $6 million for a competency examination program. (ONC, 2013i)
The $68 million awarded grants to 82 community colleges in all 50 states. The community colleges trained more than 10,500 new health IT professionals in 2012 in areas like practice workflow, implementation support specialists, implementation managers, technical support, and technical trainers (ONC, 2013i). The $32 million for program assistance for university-based training was split into nine grants awarded to colleges and universities to establish or expand health IT training programs at the university level. Six professional areas of expertise were taught that included clinicians, health information management specialists, privacy and security specialists, research scientists, programmers, and health IT sub-specialists. The Curriculum Development Centers Program awarded $10 million to the Oregon Health & Science University, University of Alabama at Birmingham, The Johns Hopkins University, Columbia University, and Duke University for the purpose of developing educational materials for the Community College Consortia Program (ONC, 2013g). Materials developed were made available to other schools across the country. With the exception of the Oregon Health & Science University, who received $2,720,000, the other institutions received $1,820,000 (ONC, 2013g). Lastly, a two-year $6 million grant was awarded in order to fund the development of competency exams for health IT professionals.

Through the ONC, many different programs and resources have been available like the regional extension centers, EHR Incentive Program, state HIE programs, and workforce development programs. Each one has a specific role towards contributing to the health IT landscape as a whole. The ONC goes beyond strictly providing incentive payments to eligible providers for implementing a certified EHR system. They have assisted in developing skilled workers that will need to be hired for the industry as well as
laying the groundwork for a nationwide health information network. The next section will go more in depth on the specific health IT elements that directly impact patient care and patient care coordination.
Chapter 3
HEALTH INFORMATION TECHNOLOGIES

Health IT has been used as an umbrella term thus far and is inclusive of various pieces of technology to achieve the goals stated in President Bush’s Executive Order. From a technical perspective, the specific technologies needed to achieve the goals are a certified EHR system and HIE functionality. Depending on the circumstances for each provider, EHR or HIE functionality can be provided by a single vendor or provided a la carte by various vendors. Both EHRs and HIEs are complex systems that contain multiple dimensions and functionalities. At a general level, EHR systems are used to input and store protected health information while the HIE system is used to facilitate the exchange of the protected health information over disparate systems across geographic boundaries. Basically, an EHR is required in order to achieve HIE.

3-1 Health Insurance Portability and Accountability Act

With health IT, and similarly with any technology that involves personal information, privacy and security are paramount. The law that governs protected health information is called the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which was enacted on August 21, 1996 upon the signature of President Bill Clinton (DHHS, 2013b). With the rapid diffusion of health IT that involves an increased amount of stakeholders and new channels of information being disseminated, new rules needed to be created and amended to ensure protected health information stays secure and private. The privacy and security rules of HIPAA are what govern how protected health information has been exchanged even before the widescale implementation of EHRs and HIEs. Prior to the digitization of patient charts and information, rules already
existed that required certain technical, administrative, and physical safeguards be met to ensure protected health information stays private.

Any person, organization, or entity is required to abide by all HIPAA regulations. Many of the HIPAA regulations prior to the EHR Incentive Program did not specifically deal with electronic protected health information (ePHI) so when the HITECH Act was created in 2009 and updated in 2013, it included new provisions dealing specifically with ePHI and the safeguards that must be in place (DHHS, 2013b). The rules of HIPAA are what all stakeholders dealing directly with protected health information must abide by and, for vendors, the technological requirements to safeguard the information must be in place or severe fines and sanctions will be levied. In the eyes of HIPAA, there are two parties that are actively working with protected health information, and that includes covered entities and business associates. Any covered entity is one of three things: a healthcare provider, insurance company, or health clearinghouse (DHHS, 2013b). Any business associate of a covered entity is defined as an entity that has direct access to protected health information. HIPAA was intended to make the healthcare system in the U.S. more efficient by standardizing healthcare transactions. The Center for Medicaid/Medicare Services enforces HIPAA and has the authority to conduct audits and investigate any data breaches. Heavy fines are levied to entities if they are found guilty of willful negligence or gross misconduct and can reach up to $1.5 million depending on the severity.

Health IT needs to be compliant with HIPAA privacy and security rules both on a technological level as well as policy level. The systems available on the market need to have safeguards in place to ensure the data stays secure. Some of the basic technical
safeguards include timing out a session after a period of inactivity, strong password requirements, and audit logs to document all access to protected health information at any specified time. Facilities also need to have security and privacy policies to ensure rules are in place to protect the information and prevent any type of breach or unauthorized access. Some of the basic policy safeguards would be identity authentication with a designated compliance officer, restricted access to data to specific employees, and ensuring the location and setup of all technological equipment is in a secured physical environment. Vendors of health IT products need to ensure the technological functionalities meet all HIPAA requirements.

3-2 Electronic Health Records

The first health IT element is the EHR which is the most complex because of the various components required to be functional and interoperable in order for it to work effectively. There are two types of EHR systems: inpatient and ambulatory. While both have similar functionalities, they differ in that an inpatient system is more robust and is designed specifically for use in an inpatient hospital environment where there are overnight patient stays with in-house services like pharmacy, laboratory, radiology, etc., and the other is for an ambulatory environment like an outpatient clinic or provider’s office where there are no overnight stays. Most EHR systems have the following components built into the system: patient medical record; clinical documentation; laboratory interface; pharmacy/medication interface; clinical decision support system; and a practice management module for administrative functions like patient registration, scheduling, billing, and accounts receivable (ONC, 2013d). EHRs are very complex.
because of the vast amounts of modules they are capable of having, but the components listed here are the baseline requirements for any certified EHR system.

The EHR is what gets the information into a digital environment, but it is the HIE components that allow for the protected health information to be exchanged across different organizations, providers, and across any geographic borders. The HIE element has several core technological components and must operate within a designated framework of standards for interoperability. The core components of most HIE systems include a direct secure messaging (DSM) feature, clinical data repository (CDR), master patient index (MPI), interface integration engine (IIE), and patient portal. Each of these components, when combined, enable the ability to accurately exchange protected health information and allow patients to play a more active role in their own health.

3-3 Direct Secure Messaging

DSM is an encrypted messaging functionality that uses secure x.509 digital certificates and public key infrastructure (PKI) to allow for a secure channel to be established between two entities over the Internet using Secure Messaging Transport Protocol (SMTP) (ONC, 2013f). The secure channel between nodes is the established connection needed to exchange DSM messages between two entities. DSM follows a push model, as one user is pushing protected health information across the Internet to a recipient. It functions similarly to email, but because email is unsecure and not HIPAA compliant, it is the only messaging solution available to electronically transmit protected health information that is both HIPAA and direct-compliant. DSM is essentially the first stage of HIE functionality since it provides an electronic medium for protected health information to be exchanged among two parties in two different locations. DSM
functions on a one-to-one basis, meaning any single provider or organization can exchange a digital certificate with only one other entity at a time. If organization A has an individual trust relationship with five other organizations and you exchange a digital certificate with organization A, it does not inherently mean you now have an established trust relationship with the other five organizations. The technology was intentionally built this way to ensure the DSM system remains closed and secure because a validation process is also required in order to receive access to the system. In order to better facilitate the certificate exchange in a more efficient manner, a non-profit organization called DirectTrust was created to promote and enforce the rules and best practices necessary to maintain security and trust within the DSM community (DirectTrust, 2012).

3-4 Clinical Data Repository

The CDR is the centralized database where all clinical information is stored. CDRs are not language specific and can be configured in any of the most common database languages like Microsoft SQL, Oracle, Java, Ensemble, etc. CDRs can be configured at any type of level whether that is organizational, state, regional, national, etc. All protected health information is uploaded into the CDR through the IIE and can be accessed through a web interface by medical professionals, public health agencies, and even patients. If a CDR is configured on a state level, it would have an interface for each type of EHR being used because every organization uses their own. Through the interface, the data in each EHR would be able to be uploaded and synced in real time with the CDR. Complex CDRs have the capability to store both identifiable data for clinical purposes and de-identified data for research purposes.
3-5 Interface Integration Engine

The software that allows protected health information to flow from one system into another is the IIE. The IIE sits between two disparate systems and compiles the data being exchanged into readable formats. In different EHR systems, the data collection method may vary in that a field like gender may be represented by one of the following formats: male/female, m/f, 0/1, etc. Another system may not interpret male/female or m/f so it is the job of the IIE to ensure the information being received correlates correctly with the information being sent. It does so by using commonly used standards and formats like XML, HL7, CCD, CCR, etc. and sends/receives information through different channels and compiles the information into a format the receiving system can read. The IIE could be used to pass information from an EHR to a CDR, an EHR to another EHR, or an EHR to any other type of system (laboratory, radiology, pharmacy, etc.). The IIE is a critical part of achieving interoperability.

3-6 Master Patient Index

When discussing HIE capabilities and exchanging protected health information across disparate systems, the idea of having multiple records for a single patient would become a real cause for concern, especially because it would not be in the best interests of the patient if they have multiple records with differing information. It would defeat the purpose of trying to improve care coordination if a single record was not being utilized for every patient. In order to prevent duplicate patient records from being created, the MPI was created, which is an algorithmic functionality that sits on top of the CDR and matches patient information so as to avoid duplicate records. It is a weighted algorithm that matches demographic patient information (i.e., last name, first name, social security
number, date of birth, etc.) and compiles a score to reflect the likelihood that the two different records are linked to the same patient. Without an MPI, the buildup of duplicate patient records would lead to inefficiencies and differing patient records, resulting in lower quality of care. As the exchange of protected health information gains momentum nationwide, the statistical likelihood of duplicate records increases exponentially so it is vital to have the technological capability to match records and merge them when necessary.

3-7 eHealth Exchange

The eHealth Exchange is the nationwide health information network that allows providers to query patient information across the U.S. It is a group of federal agencies and non-federal organizations that partnered up for the purpose of improving patient care, streamlining disability benefit claims, and improving public health reporting through a secure, trusted, and interoperable HIE (Healtheway, 2014). Health organizations will eventually need to implement health IT that is capable of joining the eHealth Exchange which will lead to the achievement of the fifth goal in the Executive Order which is to “improve the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers through an effective infrastructure for the secure and authorized exchange of health care information” (Executive Order No. 13,335, 2004, p. 1). In order to participate with the eHealth Exchange, applicants need to fill out a Data Use and Reciprocal Support Agreement (DURSA) as well as go through a rigorous testing phase to ensure the technical capabilities of the system meet the requirements outlined by Healtheway.
3-8 Patient Portals

One of the requirements of Meaningful Use stage 2 is to allow patients the ability to access their own medical information. The patient portal is what allows the patient to view their protected health information through a web-based graphical user interface. Many EHR or HIE systems have a web portal that patients can go to via a web address and view their entire medical history including the notes from past visits, medications, laboratory results, radiology images, etc. The patient portal can be built on an organization’s EHR or a disparate HIE system and is ideal because the information the provider is seeing at the point of care is the exact same information a patient can access at their own convenience. Typically, a patient would be given credentials following a visit to their provider they can use to access their information online. The patient portal allows the patient to play a more active role in their own healthcare and empowers them to ensure all information is correct so they can better monitor their own health.

3-9 Data Analytics

The data analytics functionality allows the information in the CDR to be analyzed on a very widescale level. The protected health information can potentially be integrated with national public health databases for the purpose of monitoring disease outbreaks or widescale public health issues. The National Electronic Disease Surveillance System (NEDSS) is one such database that is connected with the Public Health Information Network (PHIN) for the purpose of detecting outbreaks rapidly and monitoring the health of an entire nation (Goldstein, Groen, Ponkshe, & Wine, 2007). Analytics could be run on de-identified data that has the potential to lead to medical discoveries because the
concept of having massive repositories of protected health information has not been achieved prior to all of these federal initiatives.

These are the key health IT elements that when used comprehensively will result in a nationwide health information network. Health IT systems are highly complex on a technical level but are typically built to be as user friendly as possible in order to provide efficient and accurate care to a patient in need at the time of service. Getting widescale implementation of these health IT elements would achieve all goals listed in President Bush’s Executive Order.
Health IT consists of various stakeholders at all levels: federal, state, non-profit, and for-profit sectors. Stakeholders at these levels guide the direction of health IT as an industry and work in conjunction with those directly impacted by the technologies like hospital systems, clinics, providers, medical professionals, medical supply companies, patients, insurers, laboratories, pharmacies, etc. The stakeholders at the federal level include the DHHS, CMS, and ONC agencies. The state level stakeholders include state designated entities which are either for profit organizations, non-profit organizations, or state agencies. Most of the non-profit organizations are state-designated entities, federally-appointed organizations to oversee specific areas of health IT, or standards-based development organizations. Lastly, the for-profit stakeholders include all health IT vendors and any state-designated entity appointed to oversee specific areas of health IT. Each stakeholder has their own perspective and vested interest in the overall direction of health IT.

4-1 Federal Sector

The most influential stakeholder in the health IT landscape is the federal government. The ONC is the main agency to oversee all health-IT-related activities including the creation of the RECs, development of the Meaningful Use standards for the EHR Incentive Program, state HIE grant funding, and workforce development programs. The ONC, having been created by Executive Order, has been the key federal influence in health IT. Working in conjunction with the ONC is their sister agency, the CMS, which oversees all payments for providers participating in the EHR Incentive Program and oversees all HIPAA rules and regulations. Both agencies fall under the DHHS as the
heads of ONC, Karen DeSalvo, and CMS, Marilyn Tavenner, report directly to the Secretary of the DHHS, Kathleen Sebelius. The stance of the federal government in regard to health IT has always been to guide the development and foster a competitive marketplace so the industry can stand on its own without federal subsidization.

4-2 State Sector

Through the REC and state HIE programs, states and territories were appropriated grant monies to create RECs and develop HIE infrastructure. States were given the freedom to appoint a state agency to oversee these initiatives or delegate it to another entity whether non-profit or for-profit. In Hawaii, the HHIE was created as a non-profit organization to serve as both the REC and HIE for Hawaii and subcontracted the University of Hawaii’s Telecommunication and Social Informatics Research Program to provide support to providers in the Pacific Island territories. The core award value for Hawaii’s REC was $72,000 as compared to larger provider population states like Nebraska and Georgia who received $1,068,000 and $1,008,000 respectively (DHHS, 2011). In addition to core funding, payments were made to the RECs for every priority primary care provider that enrolled. The HHIE was awarded $5,602,318 for HIE-related initiatives as compared to other states like California and Texas who received $38,752,536 and $28,810,208 respectively because they have larger provider populations (ONC, 2013h). HIE awardees designated to oversee all HIE activity in other states across the U.S. have included Medicaid agencies, governor offices, public health departments, financing authorities, departments of health, and many others.

The state-level stakeholders like the RECs and the HIEs are entirely subsidized through grant monies from the ONC, and in order to sustain their existence, will need to
be funded by each individual state government or develop a sustainability model to ensure enough revenue is generated to cover operating expenses. Without new funding streams, the RECs and the HIEs will cease to operate. The state-level stakeholders will need to justify their role in health IT moving forward once there is widespread implementation of health IT nationwide. Their current objectives are focused on the initial phase of getting widespread health IT implementation with no clear roadmap for services beyond that.

4-3 Non-profit Sector

The non-profit stakeholders in the health IT landscape are multifaceted. As mentioned in the previous section, non-profit organizations appointed as state-designated entities (SDE) will need to develop sustainability plans to cover operating expenses once grant funding runs out. If a sustainability model is not developed, transitioning into a state agency or securing monies from third party sources would need to be identified. There also exist many other non-profit organizations doing a variety of things including standards development, certifications, and oversight in specific health IT areas. There are three main organizations appointed by the ONC to oversee the progress on health information exchange and interoperability. They include the Electronic Healthcare Network Accreditation Commission, DirectTrust, and Healtheway Inc. Each organization oversees a different area of HIE, but all are led through partnerships and collaborations of industry leaders. A close relationship exists between the ONC and these appointed organizations so in the event the ONC ever dissolves, a clear plan of action would need to be developed to ensure the industry moves forward seamlessly. These organizations also will be tasked with justifying the fees associated with their services in order to sustain
their existence. Convincing the other stakeholders like healthcare systems, hospital organizations, vendors, etc. to continue paying fees will be challenging.

**4-3-1 DirectTrust**

DirectTrust is an independent non-profit association created by participants in the direct secure messaging community that is voluntary and self-governing. They were the recipient of an ONC Cooperative Agreement award in the amount of $280,205 as part of the Exemplar HIE Governance Program (DirectTrust, 2013). DirectTrust was charged by the ONC to develop a trusted accreditation program and to build out a national trust anchor bundle distribution service for direct secure message exchange. DirectTrust was tasked with establishing policies, interoperability requirements, and business practice requirements for the purpose of enhancing public confidence in privacy, security, and trust in identity (DirectTrust, 2012).

**4-3-2 Electronic Healthcare Network Accreditation Commission (EHNAC)**

The EHNAC is a voluntary, self-governing standards development non-profit organization founded in 1993 (EHNAC, 2013). The organization develops standards criteria and accredits organizations that electronically exchange healthcare data. The different types of data exchange they certify includes e-prescriptions, electronic health networks, financial service firms, health information exchanges, health information service providers, medical billers, third-party administrators, management services organizations, outsourced service providers, and payers (EHNAC, 2013). The EHNAC formed a partnership with DirectTrust to accredit trusted agents using direct secure messaging in order to avoid the need for costly and inefficient implementations.
4-3-3 Healtheway Inc

Healtheway Inc., which is a non-profit organization, public-private collaboration was created to oversee the eHealth Exchange, which is the nationwide health information network. The eHealth Exchange allows participants to query for any patient’s protected health information across the nation. Participation in the eHealth Exchange allows providers at one facility to query for any patient’s information from anywhere in the country. The mission of Healtheway Inc. is to expand trusted, secure, and interoperable exchange of protected health information across the nation by fostering cross-industry collaboration through shared governance (Healtheway, 2013).

4-3-4 Standards Developing Organizations

There are several standards-developing organizations but one of the organizations most responsible for fostering an interoperable healthcare environment is Health Level 7 (HL7), an international, non-profit standards developing organization. The mission of HL7 is to provide standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity, and enhance knowledge transfer amongst various stakeholders (HL7, 2013). HL7 is the name of the organization as well as the name standard. There are standards in the health IT landscape, like HL7 and Consolidated Clinical Document Architecture (CCDA) that ensure components of EHR and HIE systems can communicate (American Medical Association, 2011). The members of HL7 provide a framework and create standards for the exchange, integration, sharing, and retrieval of any type of electronic protected health information.

Since monies from the HITECH Act will eventually run out, the approach the ONC has taken up to this point has been to appoint non-profit organizations as the
governing bodies for specific areas of the health IT industry. These governing and standards-developing organizations are not federal entities; rather, they are composed of industry leaders that help make decisions to promote interoperability and health information exchange. In order to get certified or participate with these non-profit organizations, fees have been implemented to sustain their existence. These non-profit organizations may potentially be around longer than even the ONC. It is in their interest that payment models be implemented and followed in order for their services to be rendered.

4-4 For-profit Sector

The for-profit sector of the industry consists of all vendors providing health IT services. These stakeholders are a crucial part of maintaining the competitive marketplace because a decreasing number of vendors typically results in an increase in prices and a more monopolistic landscape. Vendors provide various health IT products and services in the marketplace, as described in Chapter 3. According to Richards (2013), the top five EHR vendors based on market share are Epic Systems Corporation (21.89%), Allscripts (11.9%), eClinicalWorks LLC (8.46%), NextGen Healthcare (6.7%), and GE Healthcare (5.94%) (p. 1). As the industry matures, it has seen an increasing number of mergers, acquisitions, and exits from many of the existing vendors. Technical functionalities have been getting increasingly sophisticated as mandated by the ONC, causing the vendor marketplace to shrink. As that occurs, it remains to be seen whether it is positive or negative for the industry but with fewer options for health organizations to choose from, it is possible the shrinking number of vendors will negatively impact the landscape. The
for-profit stakeholders directly impact the speed at which health IT advances through research and development.

4-5 Directly-Impacted Stakeholders

4-5-1 Providers and Medical Professionals

The core mission of implementing health IT and developing HIE infrastructure is to improve the healthcare system and make it better for the patient. Hospital systems and health organizations spend millions of dollars implementing enterprise level health IT systems. Providers and medical professionals make up the largest group of end users of most health IT products. These stakeholders interact with health IT on a daily basis in order to provide clinical care to patients. Providers have the loudest voice regarding the implementation of health IT because it directly impacts workflows and the way in which care is provided. Initially, the widespread implementation of EHR systems was met with resistance from providers across the nation and is still an uphill battle to get complete buy-in. Through analysis of the health IT landscape, it appears resistance to implementing health IT has decreased significantly and an increasing number of providers are using their respective systems in a manner that will improve patient care.

4-5-2 Patients

Nationally, the entire health IT plan has always been to improve patient care through the implementation of technology. Patients are the ones that ultimately benefit the most. Whether it is increased care coordination or a life-changing diagnosis being made because the data in the system provided a more comprehensive view of the entire patient’s history, patients are the ones that ultimately benefit from health IT. Health IT was not developed for providers, payers, or researchers. It was developed to make a
positive impact on patient care. Having said that, there has not been much of an effort to inform and educate the patients of these benefits. Many patients are unaware of the national movement involving health IT and must rely on their providers to disseminate the information, many of which do not. The perspective of the patients may vary in that some may perceive all of this positively because it improves care, but there will also be those concerned about privacy and security issues regarding their protected health information.
Chapter 5
RECOMMENDATIONS

This policy study has discussed in depth the health IT landscape from a macro-perspective which has included the federal government’s role in wide-scale implementation, the various technologies, and key stakeholders, but it has yet not identified nor provided any recommendations for improvement. Health IT as an industry is very much in its infancy stage and has not garnered the traction to “stand up on its own” yet because of the federal government’s financial involvement. It is possible that health IT could develop into its own multi-trillion dollar industry, but the alternative is also possible in that the industry could collapse much like the “dotcom bubble.” This section provides recommendations to help the industry thrive in the future and highlights areas that could have been addressed differently to result in a better outcome.

5-1 Increased Coordination and Regulation with the Health IT Vendors

The health IT landscape has been very fluid from 2004, when the federal government started to play a large role in the nationwide implementation. Oftentimes the fluidity has meant that standards and protocols are being developed after the technologies are already on the market, which creates a situation in which healthcare entities need to go back and ensure the products they have are compliant with industry standards. The industry standards being created by the ONC and their appointed organizations create gaps in the services being provided because organizations that have adopted and implemented non-certified technologies are forced to find alternative solutions or wait until their vendor updates the technologies. The time it takes to develop health IT can vary greatly and cause project implementation timelines to be delayed which causes a
trickledown effect that ultimately affects the quality of care for the patient. For a hospital system, healthcare organization, or private practice, they are put in a disadvantageous situation because they have already committed resources to one product and are at the mercy of the vendor’s timeline for getting it certified or upgraded.

A recommendation to alleviate this issue would be for the standards and protocols developed by the ONC and their appointed organizations to be provided to the vendors on a different timeframe from when hospital systems, healthcare organizations, and private practices are required to implement certified health IT. If the vendors and stakeholders that develop health IT products were given deadlines of new requirements prior to deadlines in which the hospitals and healthcare organizations must be compliant, then a more competitive marketplace would evolve because products available would be in compliance with any new requirements put forth by the ONC and their appointed organizations. This would cut down on some technologies being sold as “vaporware” which is another issue in the health IT landscape. Vaporware is any product not immediately available and is still in a development phase at the time it is sold. Health IT vendors across the nation have been trying to keep pace with the timelines and guidelines imposed by the ONC and their appointed organizations before the technology is fully developed, which causes delays in implementations.

Increased coordination between the ONC, appointed organizations, and for-profit stakeholders needs to take place to discuss the issue of selling health IT products prior to being fully developed. One way for the health organizations to protect themselves from vaporware would be through specific contractual language during the procurement process. The contracts need to specifically state dates and expected deliverables the
selected vendors are required to meet. The ONC could provide oversight and guidance on suggested contractual language for health organizations purchasing health IT products or services.

5-2 **Address the Gap in Technological Functionality across the Healthcare Landscape**

The goal of achieving an interoperable nationwide health information network has been hindered by vendors providing niche products and services. It was the goal of President Bush’s Executive Order to remove the silos of information that exist throughout the healthcare landscape and foster an open, communicable network that has the ability to exchange protected health information across geographic boundaries. For-profit stakeholders, like vendors that provide health IT products to meet only specific areas, are not helping to foster an open network because information still remains in silos and is unable to be exchanged.

Much like many other industries, the evolution of health IT has not followed a logical progression because, since the creation of the ONC, products already on the market and in hospitals or offices have had to become certified through one of the ATCBs. Further development has needed to occur in order for systems to be deemed certified. When the requirements for stage 1 of Meaningful Use came out, vendors were faced with the decision of getting certified or continuing business as an uncertified entity. What began to happen in the early stages of Meaningful Use was the creation of companies and health IT products geared toward fulfilling specific Meaningful Use requirements. Some vendors began specializing in specific areas of health IT, offering individual capabilities that meet specific requirements in the Meaningful Use program.
single certified system capable of fulfilling all requirements would be ideal but not many systems are capable even today. There are vendors offering standalone direct secure messaging, master patient indexes, and other health IT components that need to be implemented in conjunction and with reliance on other systems. The ones that are capable of doing everything, are simply too expensive for smaller organizations to afford. The development of standards, governing framework, and policies have not been fully aligned with the technical capabilities of health IT vendors. This is the main reason why niche health IT companies were founded that offer specific elements of health IT to fulfill one or more Meaningful Use requirements. The larger companies like Epic, AllScripts, eClinicalWorks, NextGen, GE, and Cerner, etc. currently offer the most all-inclusive suite of health IT applications but are oftentimes not scalable for smaller practices (Richards, 2013). These types of systems were designed for large implementations such as entire hospital systems, not small and medium organizations. The overall lack of scalability has hurt the smaller health organizations and hindered their ability to implement health IT products.

When a hospital system or healthcare organization selects a vendor that provides solutions for a targeted niche, it is another node added to an already complex network forcing users to deal with multiple vendors, interfaces, and systems which further hinders the mission of the Executive Order. Single, simplified, and unified systems that are capable of all of the technological functionalities mentioned in chapter 3 are limited in number and very expensive to implement. These enterprise-level systems are not scalable for small clinics and individual practices, leaving them at a disadvantage. Because of the lack of available scalable health IT products, it causes the smaller hospitals, clinics, and
practices to piecemeal their implementations together resulting in a more fragmented environment.

It is not in the interest of the ONC to put vendors out of business, so mandating a policy disallowing any vendors from offering a specialized niche service or product would not be feasible. The industry has already begun alleviating this issue through mergers and acquisitions that have been actively taking place, but the process has been sluggish. The maturation of the industry may ultimately resolve the issue, but a faster method would be to incentivize and empower the smaller health organizations through a financial matching program in order to entice more vendors to enter into the smaller-scale health IT market. The current for-profit stakeholders include multi-billion dollar corporations like Epic, AllScripts, eClinicalWorks, NextGen, GE Healthcare, etc. They are also some of the most technologically-complex systems on the market and are specifically targeted for large implementations like Kaiser Health Systems, state hospital systems, regional clinics, etc. Through a federally-funded financial matching program, it would allow small health organizations to double their financial resources, which would in turn attract the large health IT vendors to build scalable products designed for them.

To stay consistent with the existing EHR Incentive Program, the financial matching program could be capped at $44,000 through Medicare or $63,750 through Medicaid. That would empower the smaller organizations the ability to expend up to $88,000 or $127,500 respectively in order to procure a single system capable of the technological sophistication the large vendors offer. Public-private partnerships have been a consistent funding model across all levels of government and private organizations.
Another potential option could be for the federal government to place the financial burden onto the state-designated entities. The cost associated with interfacing an EHR to a state or even national HIE can be expensive. If individual states funded the interfacing, the smaller organizations could then seamlessly participate in the national initiatives for achieving HIE. State appropriated funding would need to be identified on an individual basis but if feasible through each state sector, it would take away a large financial burden from these providers.

5-3 Address the Lack of Participation from Non-Eligible Providers that have No Medicare/Medicaid Patients

The Meaningful Use program is specifically for providers that see Medicare or Medicaid patients. If a provider’s clientele is strictly patients with private insurance, they do not qualify for the EHR Incentive Program. They would not be able to qualify for the financial incentive payments through the Meaningful Use program and also would not be penalized the percentage deduction starting in 2015 for not implementing certified health IT products. There are no financial incentives to adopt and implement any type of health IT for this group of providers. In a study conducted by the American Health Information Management Association (2013), there are over 344,000 ineligible providers delivering services to 51 million patients across the U.S. Due to lack of information regarding ineligible providers, the study estimated between 4-65% had implemented an EHR system.

In order to achieve full participation from all practicing providers across the nation, the ONC needs to collaborate with the private insurers at the state and national levels. Private insurers would be unwilling to institute a financial incentive program
similar to the EHR Incentive Program but instituting changes in reimbursements could be enough incentive for providers to implement health IT.

The health insurance industry is highly complex. Reimbursement rates by health insurers for services rendered by providers are done on an individual basis with each provider or organization. Through reform initiatives like the Affordable Care Act (ACA), changes in the reimbursement process are being instituted across the healthcare landscape. Historically, providers were reimbursed through a fee-for-service model which rewarded inefficient and ineffective care strategies. Reform, through the ACA, places a much higher emphasis on reimbursing for the long-term health of the patient population. Increasing the reimbursement rates for services rendered based on the technical capabilities of health IT products would entice the non-eligible providers to implement. Each insurer can develop a timeline for when reimbursement rates are at the higher level, and also institute a policy change to decrease the reimbursement rate after a specified amount of years have lapsed and the provider has not implemented health IT. By implementing health IT, the quality of care for the patient is increased and the process becomes more streamlined and efficient with the insurer because the claims generated from the health IT products would be able to be created and submitted electronically. The savings from a more streamlined process would be realized by the insurer and defray the cost of increasing the reimbursement rates for each provider. Getting the private insurers involved would result in reaching all providers across the nation and helping achieve nationwide health IT implementation. If all the goals in the Executive Order are achieved, the overall increase in efficiency and streamlining of the medical process will result in less financial waste which could potentially lead to a decrease in the cost of healthcare.
5-4 Timeliness of ONC Initiated Programs

The EHR Incentive Program launched in the fall of 2010 and is scheduled to run until 2021. The goal of the program is to get widespread implementation of certified EHR systems across the U.S. Implementing a certified EHR system is the precursor to obtaining HIE functionality in that the EHR digitizes the patient record and gets all protected health information into an electronic format. Once the protected health information is in the EHR, it is then able to be exchanged through the utilization of the various health IT elements discussed in chapter 3.

The main issue is that the ONC launched the EHR Incentive Program and the state HIE programs in the same year, even though the EHR phase precedes HIE functionality from a workflow perspective. Recipients for ONC’s state HIE program were announced in March 2010 and the program was set to last four years. Obtaining HIE capabilities is dependent upon the success and widespread implementation of certified EHR systems. In order to achieve fully-functional HIE capabilities, EHR systems need to be capable of specific technological requirements before the exchange of protected health information can be fully realized. The state HIE programs could have been more successful with a phased roll-out based on a state’s readiness. States across the US were at different phases of health IT implementation in 2010. A tiered roll out with specific goals for each state would have been more effective than a single rollout for all states because realistically, the degree of difference between each state in terms of readiness varied greatly.
Chapter 6
SCENARIOS

The health IT landscape is very young compared to other industries. Many industry experts are eagerly anticipating what will happen once all of the federal monies run out and whether the industry will be able to survive on its own. The future of the health IT industry in the context of job creation, stability moving forward, and overall growth appear to be trending upward since the technologies being utilized in healthcare are leading to a stable of new skill sets being desired. There are several questions yet to be answered, like what will become of the ONC once money from the HITECH Act runs out? What are the sustainability models to ensure funding streams continue upon the expiration of federal monies? Without federal incentive monies, what mechanism will be around to ensure the ongoing development of health IT continues so as not to become stagnant?

6-1 Future of the ONC

The ONC was created by Executive Order and funded through the HITECH Act via the ARRA. To date, monies dedicated for RECs and HIEs have already been expended. The money dedicated to the EHR Incentive Program is expected to end in 2021. The mission of the ONC has always been to coordinate the efforts to implement and use the most advanced health IT in order to achieve electronic exchange of health information (ONC, 2013a). One of the biggest questions looming is what will happen to the ONC once the grant monies are expended or nationwide HIE is achieved. The role of the ONC will need to be redefined by 2021 if there is a desire by the DHHS to continue the existence of the agency. One of the potential shifts in responsibilities for the ONC would be for them to provide oversight on the continued governance of the health IT
landscape and become more of a standards-governing body instead of focus on implementation of health IT.

The current organizational structure of the ONC would need to be revised because there would no longer be a need for managing grants and overseeing state community programs. A shift towards forming a closer partnership with the nonprofit organizations tasked with providing oversight in certain areas of health IT would need to be made to ensure interoperability and advancement occurs within the industry. The roles of personnel from the Office of Grants Management and the Office of State and Community Programs would need to be redefined and geared towards coordinating activities to maintain interoperability and advancing the technical capabilities.

With the implementation of health IT throughout the nation, data will be available to be queried and analyzed from a public health perspective. Regulations on how the data can and should be used will become a very real national issue with multiple agencies, companies, and stakeholders vying for access to the large data troves. The potential for advancement and discoveries within healthcare due to the analysis of the data could be revolutionary. At the same time, guidelines and policies would need to be developed to ensure the protected health information remains safe and secure.

6-2 HITECH Act Funds Dry Up

The EHR Incentive Program is set to end in 2021, once the final Medicaid payment is made. Upon the conclusion of the incentive program, adopters of health IT will need to determine how to subsidize the ongoing maintenance, support, and perpetual costs associated with the technologies. Providers will need to view health IT as a business expense necessary to perform their job functions in order to improve the overall quality
of healthcare. The costs for health IT will come out of providers’ and organizations’ pockets, which may be passed downstream to the patient. The goal of the ONC through the EHR Incentive Program and other initiatives is to assist financially in the transition towards adopting health IT and to provide support in the early adoption stages.

When monies from the federal incentive programs and state/community programs run out, it remains to be seen how the health IT industry will react. Health IT is a highly subsidized industry and without that funding stream, there is no clear indication of what will happen. New revenue streams would need to be identified in order to sustain the current levels of the industry.

Many vendors of health IT products have maintenance and support costs as part of their sustainability plans but without the funding from the federal government once the ONC programs end, the maintenance and support costs will come out directly from the revenues generated by hospitals, physician practices, and other healthcare organizations. In the future, health IT will need to be budgeted and accounted for as an ongoing annual expense as part of the core infrastructure for healthcare organizations.

6-3 Transformation of the Industry

Another alternative scenario that has the potential of materializing would be that once the federal monies run out, the health IT industry could transform seamlessly into a profit-driven sector capable of being self-sufficient. While no documentation exists on what will happen with the ONC, extensive research has led to the belief that the agency may eventually dissolve. The actions taken up to this point, such as appointing non-profit organizations to oversee certain aspects of health IT paint a picture of the future in which
the ONC is not around to provide oversight. In that scenario, the industry would need to be self-sustaining in order to survive.

Under the assumption that all this occurs, the dynamics of the market will change drastically because most organizations will have already implemented health IT systems and committed resources to it either financially or with time in order to learn how to use it. There would a low amount of new implementations so the focus from the perspective of the vendors would be to add more technical sophistication and functionality in order to improve the capabilities of what the health IT applications can accomplish. Focusing on obtaining new customers would become a lower priority than retaining the existing ones and releasing upgrades to allow more advanced capabilities to further healthcare.
Chapter 7
CONCLUSION

If the success of the ONC is based on the widespread implementation of EHR systems nationally, then they have succeeded because, at the time of this writing, over 70% of providers are currently using some form of an EHR system. From a practical perspective, the widespread implementation of EHR systems is one of the first steps prior to achieving a national health information network. The success or failure of the ONC should be based on whether the goals in President Bush’s Executive Order were achieved.

It is premature to provide a critique of the federal government’s health IT initiatives because the programs have not concluded and is still ongoing. However, the strategy of the federal government for implementing widespread health IT can be analyzed based on what has been accomplished so far like the REC programs, EHR Incentive Program, state HIE programs, and workforce development programs. How these programs helped to meet the goals outlined in President Bush’s Executive Order can be analyzed.

The REC Program was essential in order to provide information regarding health IT to current medical professionals and increase their awareness as well as understanding. The goals outlined by the REC programs were to provide technical assistance and overview to enrolled providers regarding all health IT inquiries. For the enrolled providers, the REC accomplished those goals and was able to disseminate the information to the providers. The program however, had enrolled only 43% of primary care providers in one of the 62 RECs across the U.S. (ONC Data Brief, 2013). One of the

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most prevalent deficiencies was the amount of primary care providers enrolled in the program. Reaching less than half the providers nationally leaves out a large number of providers that could have benefited from the REC services. More providers could potentially have been reached through increased outreach, a more effective marketing campaign, or grassroots efforts to generate awareness. From the onset, the REC programs were geared towards primary care providers, excluding all specialists and providers not providing primary care services. Those left out include: dentists, optometrists, ophthalmologists, surgeons, radiologists, cardiologists, oncologists, neurologists, etc. These providers were able to participate in the EHR Incentive Program but were not allowed access to the REC as a resource. Leaving out any group of providers creates inequality in the landscape, and the ONC should have allowed for all providers to be able to enroll with an REC. The way in which the RECs were contracted to provide assistance was everything until Meaningful Use stage 2. The Meaningful Use program consists of three stages and, for much of the time, stage 2 was not finalized during the period RECs were offering assistance, creating a gap between the services of the RECs and the goals of the Meaningful Use program.

The purpose of the EHR Incentive Program was to ensure a large amount of providers across the U.S. adopt and implement an EHR system. The program helped get over 70% of providers nationally to use some form of an EHR system. As of 2012, the EHR Incentive Program monies tallied $4.5 billion (Mosquera, 2012). The payment schedule was front-loaded with most of the money paid out after achieving stage 1 of Meaningful Use. By making the payments front-heavy, it indirectly put less importance on the later stages of Meaningful Use, even though they were just as important for
achieving nationwide interoperability. If the payments were distributed evenly, or were even back-heavy, it would have ensured providers follow through with the implementation all the way through the process.

The goal of the state HIE program was to rapidly build capacity for exchanging health information across the health care system and across geographic boundaries. The program lasted four years and ended on February 7th, 2014, without having achieved a nationwide health information network. One of the goals from President Bush’s Executive Order was to, “improve the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers” (Executive Order No. 13,335, 2004, p. 1). The state HIE program did not achieve the goal within the four-year window. At the conclusion of the state HIE program for the Pacific, the final requirement was to implement direct secure messaging, and, as mentioned before, is only the first step towards achieving full HIE functionality.

The final ONC initiative, the workforce development program, was created to provide training and education for future health IT professionals. While the workforce development program did not directly address any part of the Executive Order, it was imperative in order to build a capable workforce for an emerging industry. Programs at all levels of academia have become available across the nation offering degrees and certificates in health IT. Universities across the country now offer academic programs that range from associates through doctorate level for health IT. There are no metrics available in terms of the number of students going through these programs, but a key indicator is that an increasing number of colleges and universities are offering a health IT curriculum, which shows a demand for the skill set needed to work in the industry.
Overall, the federal government’s strategy for health IT has been effective. The programs established through the ONC have all contributed either directly or indirectly towards achieving the goals outlined in President Bush’s Executive Order. Health IT as an industry has a long way to go before reaching its full potential. As the industry matures, the work to achieve a nationwide health information network will be realized. What the ONC has done is lay the groundwork for the health IT landscape so all stakeholders can benefit and thrive.
### Appendix A

<table>
<thead>
<tr>
<th>Amount allocated</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>$18 billion</td>
<td>Center for Medicare and Medicaid Services EHR Incentive Payments.</td>
</tr>
<tr>
<td>$2 billion</td>
<td>Health Information Exchange.</td>
</tr>
<tr>
<td>$1 billion</td>
<td>Renovation and repair of health centers and for the acquisition of health IT systems.</td>
</tr>
<tr>
<td>$550 million</td>
<td>Improving the Indian Health Services facilities.</td>
</tr>
<tr>
<td>$400 million</td>
<td>Research on how electronic data impacts treatment and strategies.</td>
</tr>
<tr>
<td>$300 million</td>
<td>Regional and sub-national efforts towards health information exchange.</td>
</tr>
<tr>
<td>$40 million</td>
<td>Social Security Administration to use EHRs to submit disability claims.</td>
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</tbody>
</table>

Information derived from HITECH Answers (2013).
Appendix B
Meaningful Use Stage 1 – Eligible Provider

<table>
<thead>
<tr>
<th>Core Objectives</th>
<th>Menu Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Use Computerized Provider Order Entry (CPOE) for medication orders.</td>
<td>1 Implement drug formulary checks.</td>
</tr>
<tr>
<td>2 Implement drug-drug and drug-allergy interaction checks.</td>
<td>2 Incorporate clinical lab-test results into EHR as structured data.</td>
</tr>
<tr>
<td>3 Maintain an up-to-date problem list of current and active diagnoses.</td>
<td>3 Generate list of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.</td>
</tr>
<tr>
<td>4 Generate and transmit permissible prescriptions electronically (eRx).</td>
<td>4 Send patient reminders per patient preference for preventive/follow-up care.</td>
</tr>
<tr>
<td>5 Maintain active medication list.</td>
<td>5 Provide patients with timely electronic access to their health information within 4 days of being available to the EP.</td>
</tr>
<tr>
<td>6 Maintain active medication allergy list.</td>
<td>6 Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.</td>
</tr>
<tr>
<td>7 Record the following demographics: preferred language, gender, race, ethnicity, DOB.</td>
<td>7 The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.</td>
</tr>
<tr>
<td>8 Record chart changes in the following vital signs: height, weight, blood pressure, BMI, plot/display growth charts for children 2-20 yrs.</td>
<td>8 The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.</td>
</tr>
<tr>
<td>9 Record smoking status for patients 13 years or older.</td>
<td>9 Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.</td>
</tr>
<tr>
<td>10 Report ambulatory clinical quality measures to CMS or states (Medicaid).</td>
<td>10 Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.</td>
</tr>
</tbody>
</table>
### Core Objectives

| 1 | Use Computerized Provider Order Entry (CPOE) for medication, laboratory, and radiology orders. |
| 2 | Generate and transmit permissible prescriptions electronically (eRx). |
| 3 | Record the following demographics: preferred language, sex, race, ethnicity, DOB. |
| 4 | Record and chart changes in the following vital signs: height, weight, blood pressure, BMI, plot/display growth charts for children 2-20 yrs. |
| 5 | Record smoking status for patients 13 years or older. |
| 6 | Use clinical decision to improve performance on high-priority health conditions. |
| 7 | Provide patients the ability to view online, download and transmit their health information within 4 days of information being available to EP. |
| 8 | Provide clinical summaries for patients for each office visit. |
| 9 | Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities. |
| 10 | Incorporate clinical lab-test results into Certified EHR Technology as structured data. |
| 11 | Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach. |
| 12 | Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminders, per patient preference. |
| 13 | Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient. |
| 14 | The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation. |
| 15 | The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide a summary care record for each transition of care or referral. |
| 16 | Capability to submit electronic data to immunization registries or immunization information systems except where prohibited. |
| 17 | Use secure electronic messaging to communicate with patients on relevant health information. |

### Menu Objectives

| 1 | Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited. |
| 2 | Record electronic notes in patient records. |
| 3 | Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT. |
| 4 | Record patient family health history as structured data. |
| 5 | Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited. |
| 6 | Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited. |

Information derived from the *CMS Meaningful Use Program (2013b).*
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