



Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

The ONC-Coordinated Federal Health IT Strategic Plan: 2008-2012

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Executive Summary

On April 27, 2004, President Bush issued Executive Order (EO) 13335 “to provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care.” EO 13335 established the position of a National Coordinator for Health Information Technology (IT) within the Office of the Secretary of Health and Human Services. The National Coordinator was charged with coordinating federal health IT policies and programs and relevant executive branch agency outreach and consultation with public and private entities. As such, the National Coordinator provides the day-to-day leadership necessary for the development of a health IT infrastructure for the nation.

EO 13335 also charged the National Coordinator with developing, maintaining, and directing “... the implementation of a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures.”

Accordingly, the Office of the National Coordinator for Health Information Technology (ONC) has worked across the federal government to develop this ONC-coordinated Federal Health IT Strategic Plan (the Plan), which identifies the federal activities necessary to achieve the nationwide implementation of this technology infrastructure throughout both the public and private sectors. The timeframe of the Plan is 2008-2012.

The Plan has two goals, Patient-focused Health Care and Population Health, with four objectives under each goal. The themes of privacy and security, interoperability, IT adoption, and collaborative governance recur across the goals, but they apply in very different ways to health care and population health.

Goal 1) *Patient-focused health care*: Enable the transformation to higher quality, more cost-efficient, patient-focused health care through electronic health information access and use by care providers, and by patients and their designees.

Objective 1.1 – Privacy and Security: Facilitate electronic exchange, access, and use of electronic health information while protecting the privacy and security of patients’ health information

Objective 1.2 – Interoperability: Enable the movement of electronic health information to where and when it is needed to support individual health and care needs

Objective 1.3 – Adoption: Promote nationwide deployment of electronic health records and personal health records that put information to use in support of health and care

Objective 1.4 – Collaborative Governance: Establish mechanisms for multi-stakeholder priority-setting and decision-making to guide development of the nation’s health IT infrastructure

Goal 2) *Population health*: Enable the appropriate, authorized, and timely access and use of electronic health information to benefit public health, biomedical research, quality improvement, and emergency preparedness.

Objective 2.1 – Privacy and Security: Advance privacy and security policies, principles, procedures, and protections for information access and use in population health

Objective 2.2 – Interoperability: Enable the mobility of health information to support population-oriented uses

Objective 2.3 – Adoption: Promote nationwide adoption of technologies and technical functions that will improve population and individual health

Objective 2.4 – Collaborative Governance: Establish coordinated organizational processes supporting information use for population health

Achievement of the eight objectives is tied to measurable outcomes.

The Plan articulates 43 strategies that describe the work needed to achieve each objective. Each strategy is associated with a milestone against which progress can be assessed, and a set of illustrative actions to implement each strategy. As a group, the strategies are characterized by:

- Commitment to the engagement of multiple stakeholders across the public and private sectors;
- Concern for reliability, confidentiality, privacy, and security when exchanging, storing, and using electronic health information; and
- Focus on the consumer of health care as a critical participant in achieving the two overarching goals of the Strategic Plan, as described above.

The goals, objectives, and strategies of the Plan portray the totality of what must be done, in a coordinated manner distributed across the federal government, to achieve an interoperable health IT infrastructure for the nation in support of patient-focused health care and population health. To emphasize the collaborative nature of this initiative, a major component of the Plan is a compilation of relevant federal agency projects, as well as partnerships between those federal agencies and other stakeholders, that are already underway in pursuit of one or more of the specific objectives.

Consistent with ONC's mission and role, the Plan is not limited to the activities and tasks that ONC directly sponsors. This Plan is primarily federally focused with many of the strategies proposed in the Plan designed to harmonize activities in the public and private sectors. This approach is designed to ensure that federal resources allocated to health IT, while supporting the individual and distinct missions of the Departments, are also positioned to realize maximum benefit for the nation as a whole.

In developing the Plan, ONC worked with other federal agencies to solicit input and assure that the full breadth of federal activity was reflected. ONC will periodically update the Plan and actively engage other federal agencies in re-evaluating the strategic objectives and strategies, and in tracking progress toward these goals and objectives.

Strategic Plan Overview

Background, Mission and Vision

On April 27, 2004, President Bush issued Executive Order (EO) 13335 “to provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care,” establishing the position of a National Coordinator for Health Information Technology (IT) within the Office of the Secretary of Health and Human Services. Acknowledging the role of multiple executive branch agencies in addressing the vision of this nationwide infrastructure, the National Coordinator was charged with ensuring coordination of federal health IT policies and programs and of relevant executive branch agency outreach and consultation with public and private entities. Thus, the National Coordinator provides the leadership necessary to support national progression to a health IT infrastructure envisioned to:

- Ensure that appropriate information to guide medical decisions is available at the time and place of care;
- Improve health care quality, reduce medical errors, and advance the delivery of appropriate, evidence-based medical care;
- Reduce health care costs resulting from inefficiency, medical errors, inappropriate care, and incomplete information;
- Promote a more effective marketplace, greater competition, and increased choice through the wider availability of accurate information on health care costs, quality, and outcomes;
- 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
- Ensure that patients’ individually identifiable health information is secure, protected, and available to the patient to be used for medical and non-medical purposes, as directed by the patient, as appropriate.

Upon publication of EO 13335, President Bush also set an ambitious target for the majority of Americans to have access to electronic health records (EHRs) by 2014.

A Coordinated and Collaborative Effort

EO 13335 also charged the National Coordinator with developing, maintaining, and directing “... the implementation of a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures.” The Office of the National Coordinator for Health Information Technology (ONC) has worked with multiple federal agencies to develop this Strategic Plan, which identifies the federal activities necessary to achieve the nationwide implementation of this technology infrastructure throughout both the public and private sectors.

This plan explicitly recognizes that the federal government has a profound role in promoting interoperable health IT – not as an end in itself, but because of the existing federal responsibilities for both the individual health care costs of federal and private beneficiaries and the vast majority of the population health activities and the provision of federal disability benefits in the nation. Because so much of the information necessary to improve population health can be drawn from the clinical information generated in the course of direct health care delivery, there would be considerable duplication of effort and waste of federal resources if two separate

health IT infrastructures were implemented. Thus, this Strategic Plan includes goals for a nationwide health IT infrastructure that is designed to meet the needs of patient-focused health care, population health, and use by the patient. The federal government will receive substantial benefit from the efficiencies that result from federal activities to attain such an infrastructure. Moreover, the health of the nation is a public good in which the federal government has intense interest. This Plan organizes and details a coherent set of goals, objectives, and strategies comprising the nation's health IT agenda. The Plan describes federal activities that are currently underway and address these goals and objectives. Some of these are conducted by ONC. Most are conducted by a broad array of federal agencies and departments, with ONC as one central collaboration and coordinating body amongst these agencies to ensure that they have the opportunity to leverage each others' activities, and that such activities work in harmony. The objectives included in this Plan create an outline for organizing current and future federal initiatives to complement each other and act synergistically to achieve each objective.

The federal government is one of several audiences for this Plan. Given the nationwide reach of the goals and the breadth of resources needed to achieve them, the broader intended audience for this document specifically includes public and private providers of health care, consumers or recipients of health care, the health IT industry, consumer advocates, and population health information users. The Plan outlines, for this full range of stakeholders, how the nation can realize a set of widely endorsed goals and how these stakeholders can become active participants in achieving the vision. It demonstrates how health IT activities in the public sector align with and benefit from activities in the private sector, and vice versa, putting each sector's resources to best use.

Overview of the Federal Health IT Strategic Plan

This federal Strategic Plan has two main goals: 1) transforming care delivery, personal health, and support through the access to and use of electronic health information; and, 2) advancing population health (public health, biomedical research that makes use of health care information, health care quality improvement, and emergency preparedness) through timely access to and use of electronic health information. Underpinning the approach to these goals is a commitment to a public-private, multi-stakeholder approach and a concern for reliability, confidentiality, privacy, and security when exchanging, storing, and using electronic health information.

Goal One: Patient-focused Health Care – supports and builds on EO 13335 by seeking to enable high-quality and efficient patient-focused health care through the use of electronic health information by providers, as well as patients and their designees. The information generated and exchanged through an interoperable infrastructure, with appropriate available tools, will enable health care providers to:

- Better coordinate and personalize care by providing other health care providers access to comprehensive and longitudinal medical records, and providing individuals access to their own records through personal health records;
- Reduce medical errors;
- Support the prevention of illness; and
- Minimize duplicative treatments and tests.

Additionally, individuals will benefit from improved system-wide efficiencies through decreased paperwork, consistent and controlled access to health information, and the ability to securely access and transfer their information for purposes that may extend beyond health care.

Goal Two: Population Health – supports the use of electronic health information—primarily, but not exclusively, generated as a by-product of health care delivery—for critical national needs

relating to public health, biomedical research, quality improvement, and emergency preparedness. Such use would promote early and effective management of infectious disease outbreaks, improved tracking of chronic disease management, the ability to gather data for research purposes, and the evaluation of health care based on value, by way of comparable price and quality information.

The consumer of health care is a critical participant in achieving both goals, as the consumer is at the center of information exchange in support of health care delivery, and a beneficiary of improved population health capabilities and other key activities. In several places, this Plan anticipates the emergence of technologies, generally referred to as “personal health records” or PHRs. These tools support consumers’ (or their designees’) abilities to manage, access, and share their own health information, much of which is generated by care providers.

The Plan for achieving each goal is detailed through objectives, strategies, and illustrative actions that align with a set of four core functional components: 1) policies relating to privacy and security; 2) standards, networking, and interoperability; 3) adoption of technology and information use; and 4) collaborative governance and decision-making. These components are necessary to create an environment in which health information can be exchanged securely and accessed in a timely manner for the purpose of patient care and population health.

1. Policies Relating to Privacy and Security (“Privacy and Security”)

The success of a nationwide, interoperable health IT infrastructure in the United States will require a high degree of public confidence and trust. Careful attention is needed both to ensure the functional capabilities to exchange health information, and to maintain privacy and security. Only by engaging all stakeholders, particularly consumers, in a coordinated effort can health information be protected in a manner that promotes public trust.

2. Standards, Networking, and Interoperability (“Interoperability”)

To advance high-quality, safe and efficient health care and promote population health, information must be readily exchanged among diverse participants. To effectively exchange health information, health IT systems and products must use consistent, specific data and technical standards. These harmonized data and technical standards must be agreed upon and in some instances required. They must be testable in, and applicable to, different systems, types of information, and health care settings.

3. Adoption of Technology and Information Use (“Adoption”)

To transform health care and population health services, relevant health information users must adopt interoperable technologies. To this end, it is necessary to identify and reduce or remove the many existing obstacles to adoption of EHRs in health care settings. Initiatives such as the Centers for Medicare & Medicaid Services (CMS) Electronic Health Record Demonstration, described later in this document, should help advance the adoption agenda. There must be sufficient numbers of trained technical staff within health care and population health systems to enable development and deployment of useful technologies. It is also necessary to support adoption of PHRs, and other direct consumer uses of health IT and networking. As barriers are identified and addressed, the current slow rate of adoption will be followed by a period of rapid uptake, as the beliefs of providers, payers, and consumers shift from “why do we need it?” to “we cannot do without it”. Adoption efforts must ensure that the benefits of health IT reach disadvantaged and underserved populations, and do not widen the often-cited “digital divide”.

4. Collaborative Governance and Decision-Making (“Collaborative Governance”)

Progress toward a nationwide, secure, interoperable health IT infrastructure and the Presidential target for the majority of Americans having access to electronic health records (EHRs) by 2014 requires support and participation from all health care stakeholders and their participation in advancing health IT. The necessary planning, consensus building, priority-setting, and consistent approaches to implementing policies can best be achieved through appropriate structures and mechanisms for collaborative governance. It is essential that such governance occurs across the public and private sectors and involves all individuals and organizations with a stake in health-related activities.

Each of the core functional components of the Plan requires the support of the other components in order to be fully successful. For example, interoperability requires the public trust that derives from privacy and security protections. The incentives that will drive adoption of health IT require the support of all stakeholders that will stem from collaborative governance.

Interwoven (Matrix) Structure of the Plan

Under each of the Plan's two goals, there are four objectives: one addressing privacy and security, one addressing interoperability, one addressing adoption, and one addressing collaborative governance. In this way, and as shown in the table below, the Plan takes on a matrix structure. Attainment of all eight objectives of this Plan will be required to establish and derive maximum value from a sustainable, secure, interoperable health IT infrastructure for the nation, and thus achieve the vision of EO 13335.

	Privacy and Security	Interoperability	Adoption	Collaborative Governance
Goal 1. Patient-Focused Health Care	Objective 1.1: Facilitate electronic exchange, access, and use of electronic health information, while protecting the privacy and security of patients' health information	Objective 1.2: Enable the movement of electronic health information to support patients' health and care needs	Objective 1.3: Promote nationwide deployment of EHRs and PHRs and other consumer health IT tools	Objective 1.4: Establish mechanisms for multi-stakeholder priority-setting and decision-making
Goal 2. Population Health	Objective 2.1: Advance privacy and security policies, principles, procedures, and protections for information access in population health	Objective 2.2: Enable exchange of health information to support population-oriented uses	Objective 2.3: Promote nationwide adoption of technologies to improve population and individual health	Objective 2.4: Establish coordinated organizational processes supporting information use for population health

Objectives and Strategies

In this document, the plan for achieving each goal is detailed through four objectives and multiple strategies to address each objective. To assess progress, each objective is accompanied by one or more measurable outcomes. For some of the objectives—for example, those related to deployment of the National Health Information Network—the measures are labeled as “developmental”. In these cases, the initiatives to execute the objectives have not yet matured and instruments to measure progress do not yet exist. The targets for these

developmental measures will be developed after the baseline studies are conducted. The Plan indicates, where possible, when baseline data are expected for the developmental measures. As in any coordinated effort to achieve strategic goals, the strategies are designed to be mutually reinforcing and will, by necessity, overlap to some extent. Interconnections among strategies that address different goals and objectives are intentional.

The main body of the Plan includes a synopsis of each strategy. Appendix A contains more detailed descriptions of each strategy, along with milestones and the targeted time at which each milestone is expected to be achieved. For each strategy, Appendix A includes component actions that are more specific tasks to be undertaken in pursuit of each milestone. Since this document is a strategic plan, the actions are provided as “illustrative” examples and *do not represent a comprehensive list of the action steps* that would need to occur, by ONC or by other federal offices or entities. In many cases, the action steps reflect federal agency activities currently underway. All such action items should be considered subject to change as they undergo review and evaluation.

The goals, objectives, and strategies of this Plan seek to portray the totality of what must be done, in a coordinated manner distributed across the federal government, to accomplish the health IT agenda and thus realize the vision of the EO 13335. Because the strategies of the Plan coordinate actions across the federal government, many of the strategies are interdependent.

Related Initiatives and Progress to Date

To characterize the collaborative nature of this initiative, relevant federal agency projects, as well as partnerships among those federal agencies and other stakeholders, are cited under the specific objective(s) they address. These activities were either ongoing at the time of, or began after, the signing of EO 13335 in 2004. As new federal activities are developed or initiated, we will periodically update the Strategic Plan to include them.

The appendices provide further explanation of the initiatives cited in this Plan. Appendix B contains a matrix that portrays how these initiatives support the goals and objectives of the Plan, while Appendix C provides a summary for each of the initiatives.

Timeframe

The timeframe for the Plan is five years (FY 2008-2012), so the target dates for all outcomes and milestones are 2012 or earlier. While the President’s 2014 target (mentioned earlier) is technically outside the time span of this five-year Strategic Plan, that target date shapes the timelines for the Plan’s objectives and strategies.

Scope of this Strategic Plan

Consistent with ONC’s mission and role, the Plan is not limited to the activities and tasks that ONC directly sponsors. (Appendix C describes the activities supported by ONC’s FY 2008 and estimated FY 2009 budgets.) The Plan is designed to build upon, leverage, and coordinate the existing and critical roles that many federal, state, local, tribal, and private stakeholders already play in advancing these goals. Many of the strategies proposed in this Plan are designed to harmonize activities in the public and private sectors, to ensure that federal resources allocated to health IT realize maximum benefit for the nation as a whole.

The Plan is also designed to achieve interoperability over time without requiring either substantial replacement of existing health IT solutions or the use by all stakeholders of a single health IT system, thus avoiding the necessity for a large increase in funding for those federal or

non-federal entities that already have robust health IT solutions in place. Rather, the Plan proposes to set up the foundation and infrastructure to support interoperable technologies and automated exchange of health information, in support of the nation's health care system.

This Plan acknowledges that health care is provided by a wide range of professionals, and all health professionals are envisioned as users of health IT. The term "health professional" is explicitly meant to include physicians, nurses, and other health professional groups, including health information management professionals, whose coordinated efforts are essential to an effective and efficient health care system.

This Plan focuses primarily on information collected for purposes of health care delivery and population health, and also contemplates other uses of that information for administrative purposes, including disability determinations. Where and when data elements are useable for purposes beyond care delivery and population health (as is the case with diagnostic or procedural codes), the standards activities integral to this Plan will be coordinated with existing standards that have been identified through the activities related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In those instances where health-related data support financial and administrative activities, the benefits of interoperability described in this Plan will also accrue to these components of the health care system.

The Plan includes, as a component of Goal Two, facilitation of research that makes use of data collected from or about individuals in conjunction with patient-focused health care. Some types of clinical, translational, and health services research therefore fall within the scope of the Plan. Basic research and animal studies are excluded.

Ultimate achievement of the Plan's goals will require a robust biomedical informatics, public health informatics, and health services research enterprise. Such research will be required to address known challenges (such as knowledge management, natural language processing, and the association of health IT with health outcomes) and also respond to new challenges that arise as a result of more widespread deployment of health IT and growing use of health care information in population health. The Plan assumes that such research will continue, but does not include it.

Lastly, this Plan does not propose new policies. The use of new technologies will raise the need for new policies, and this Plan describes specific activities where new policies need to be considered and options evaluated, but does not directly propose them.

Future Steps

In developing this Plan, ONC worked with other federal agencies to solicit input and assure that the full breadth of federal activity was reflected. ONC will periodically update this Plan and actively engage other federal agencies in re-evaluating the strategic objectives and strategies, and in tracking progress toward these goals and objectives.

Reflecting the responsibilities assigned to the National Coordinator, ONC will serve as the coordinator with federal agencies and departments to ensure the timely implementation of the strategies and actions by individual agencies - aligned with their respective mission-specific priorities - that are consistent with or complement this Plan's eight objectives. As a first step, ONC will work with the agencies and departments specifically referenced in this Plan, and others as new opportunities emerge, to delineate which organization(s) are primarily responsible for implementation of each milestone.

Tabular Summary of Plan

The following pages offer a table that summarizes the Plan, with highly abbreviated “shorthand” statements of the objectives, outcome measures for each objective, strategies, and milestones as well as the target date(s) for each listed milestone. Due to space constraints, the “shorthand” statements might not reflect the entire scope of the strategy or outcome covered by the complete statement in the Plan. This table is intended to serve as an overview of the Plan’s structure and a quick reference guide to its components.

Goal 1: Patient-focused Health Care							
Enable the transformation to higher quality, more efficient, patient-focused health care through electronic health information access and use by care providers and by patients and their designees							
Objective	Strategy	Milestone	2008	2009	2010	2011	2012
1.1 - Privacy and Security: Facilitate electronic, exchange, access and use of electronic health information for patients while protecting the privacy and security of their information <i>(Measure: % of organizations with policies and approaches consistent with confidentiality, privacy, and security framework)</i>	1.1.1: Develop a confidentiality, privacy, and security framework.	Publication of framework.					
	1.1.2: Identify best practices to ensure confidentiality, integrity, and availability of information.	Best practices used to develop standards and certification criteria.					
	1.1.3: Facilitate state-based efforts for protected exchange of health information	States work collaboratively to develop approaches for increased commonality.					
	1.1.4: Increase stakeholder trust of health IT through education.	Stakeholder-specific guidance about privacy and security laws.					
	1.1.5: Address apparently inconsistent statutes and regulations for exchange of electronic health information.	Published guidance to promote exchange of electronic health information.					
1.2 - Interoperability: Enable exchange of health information to support patients' health and care needs <i>(Measure: % of providers and organizations using recognized interoperability standards to connect and exchange information.)</i>	1.2.1: Advance use of specified data and technical standards for interoperability	Use by federal government entities of interoperability standards.					
	1.2.2: Identify core capabilities for networks to exchange health information.	Publicly available core service capabilities and data use agreements for networks to exchange health information.					
	1.2.3: Foster the business case for exchange of health information.	An approach for exchange of health information in competitive markets.					
	1.2.4: Increase the volume of standardized exchange of health information to enhance its value.	Providers and provider organizations use NHIN specifications for exchange of health information.					
	1.2.5: Promote processes for testing implementation of recognized standards and policies.	Testing tools and criteria, and certification criteria are available.					
	1.2.6: Encourage provision of electronic personal health information in standardized form.	Consumers have increased access to personal health information through interoperable technologies.					
	1.2.7: Increase the number of competitive health information service providers.	Numerous health information service providers.					
	1.2.8 Use standards to empower use of health information beyond direct patient care delivery.	Standards for a patient's authorized release to a trusted entity for non-health care purposes.					

Goal 1: Patient-focused Health Care							
Enable the transformation to higher quality, more efficient, patient-focused health care through electronic health information access and use by care providers and by patients and their designees							
Objective	Strategy	Milestone	2008	2009	2010	2011	2012
1.3 - Adoption: Promote nationwide deployment of EHRs and PHRs and other consumer health IT tools (Measure: % of physician offices, and small offices, using certified EHR systems)	1.3.1: Remove business obstacles for provider use of EHRs.	Physicians using certified EHRs are eligible for malpractice credit.					
	1.3.2: Make EHRs easy to buy and implement.	Available approaches for provider support for EHR adoption.					
	1.3.3: Increase value of EHRs through technology.	Certified EHRs with clinical decision support.					
	1.3.4: Promote certified health IT products as essential to clinical care.	Majority of products are certified.					
	1.3.5: Develop the workforce for health IT product development and use.	Study quantifies the needed workforce.					
	1.3.6: Identify ways for PHRs to link to useful health and care applications.	Consensus about the components of a certified PHR.					
	1.3.7: Advance PHR and consumer health IT tools.	Creation of a plan to guide PHR development.					
	1.3.8: Minimize provider liability when using health IT.	Increased provider understanding of health IT liability risks as evidenced through research results.					
	1.3.9: Remove barriers to treating patients outside of provider offices.	Published results of public/private collaborations supporting secure messaging pilots.					
1.4 - Collaborative Governance: Establish mechanisms for multi-stakeholder priority-setting and decision-making (Measure: Establishment of self-sustaining AHIC successor)	1.4.1: Establish an entity to advance nationwide exchange of health information.	A public-private entity oversees nationwide exchange of health information.					
	1.4.2: Assure consumer representation in stakeholder governance.	Consumer participation in activities related to the exchange of health information.					
	1.4.3: Promote active and appropriate participation by all relevant government agencies in multi-stakeholder governance entities activities.	Mechanisms enable federal, state, and local governance entities to have input into decision-making processes.					

Goal 2: Population Health
 Enable the appropriate, authorized, and timely access and use of electronic health information to benefit public health, biomedical research, quality improvement, and emergency preparedness.

Objective	Strategy	Milestones	2008	2009	2010	2011	2012
2.1 - Privacy and Security: Advance principles, procedures, and protections for information access in population health (Measure: % of federal organizations adhering to principles expressed in confidentiality, privacy and security framework.)	2.1.1: Employ the privacy and security framework (see Strategy 1.1.1) for population health information.	Publication of privacy and security framework with engagement of population health stakeholders.					
	2.1.2: Address apparently inconsistent statutes or regulations for exchange of population health information.	Identification of conflicts and appropriate actions taken.					
	2.1.3: Facilitate state-based efforts for protected exchange of population health information.	Guidance published for states.					
	2.1.4: Increase stakeholder understanding of current federal privacy and security laws.	Federal agencies work with stakeholders to identify issues and clarify laws.					
2.2 - Interoperability: Enable exchange of health information to support population-oriented uses (Measure: % of population health agencies using recognized interoperability standards to exchange information)	2.2.1: Advance standards to support the merging of comparable population health information.	Population health information users will receive comparable data from clinical sources.					
	2.2.2: Enable flexible models for exchange of population health information.	Three models for exchange of population health information are supported.					
	2.2.3: Assess providers' and networks' implementation of standards.	Electronic verification capabilities will ensure consistent use of standards.					
	2.2.4: Promote availability of population health information in electronic form.	Networks provide population health information using NHIN specifications.					
	2.2.5: Provide population health information needed for emergency response.	Networks using NHIN specifications provide population health information for emergency response.					
2.3 - Adoption: Promote nationwide adoption of technologies to improve population and individual health (Measure: % of population health information that is re-used without manual intervention.)	2.3.1: Optimize exchange of EHR and population health information among users.	Increased automation of clinical information sent and accessed by providers.					
	2.3.2: Minimize provider burden for population health reporting.	Certified EHRs will have automated "upstream" data transmission.					
	2.3.3: Electronic exchange of population health data among various stakeholders.	Pilot projects underway for population health data exchange.					
2.4 - Collaborative Governance: Establish coordinated organizational processes supporting information use for population health (Measure: % of governance entities that comply with consensus-based policies.)	2.4.1: Advance data stewardship models for exchange of population health information.	Data stewardship models supporting pilots of exchange of population health information.					
	2.4.2: Implement quality measures in ways compatible with different models for exchange of health information.	Quality measures are electronically reported to providers.					
	2.4.3: Connect clinical care and public health through exchange of electronic health information.	Public health priorities are advanced through coordinated governance by AHIC Successor.					
	2.4.4: Connect clinical care and research through exchange of electronic health information.	Demonstrated coordination of governance across clinical care and research communities.					
	2.4.5: Create accountability for implementing exchange of electronic health information.	Accreditation criteria for electronic exchange of health information.					
	2.4.6: Develop, implement, and oversee health data sharing strategy across federal agencies.	Federal health data are shared securely across federal agencies.					

Goal One – Enable Patient-focused Health Care

Enable the transformation to higher-quality, more cost-efficient, patient-focused health care through electronic health information access and use by care providers, and by patients and their designees.

Goal One of the Plan focuses on the processes of health care that primarily involve interactions between patients and care providers, but increasingly reflect activities of individuals to promote their own health and well-being. Secure access to information by providers and patients can promote health care that is reflective of best practices, safer, and thus more cost-efficient. Informed patients will be able to make better choices and decisions toward maintaining a healthier lifestyle, potentially preventing debilitating and costly illnesses. Empowering patients to direct their health information, to be used in support of the patient's needs beyond direct health care, will bring far-reaching benefits.

The Plan articulates four objectives that support the accomplishment of this goal. Through the achievement of all four objectives, with progress toward each objective occurring in parallel, the health care system can be transformed. In their simplified form, the objectives are:

Objective 1.1 – Privacy and Security: Facilitate electronic exchange, access, and use of electronic health information, while protecting the privacy and security of patients' health information

Objective 1.2 – Interoperability: Enable the movement of electronic health information to where and when it is needed to support individual health and care needs

Objective 1.3 – Adoption: Promote nationwide deployment of electronic health records and personal health records that put information to use in support of health and care

Objective 1.4 – Collaborative Governance: Establish mechanisms for multi-stakeholder priority-setting and decision-making to guide the development of the nation's interoperable health IT architecture

These objectives work together to achieve the vision of Executive Order 13335 and the vision that most Americans will have electronic health records by 2014.

Objective 1.1 – Privacy and Security: Identify any policy issues, gaps or barriers--and advance the development of approaches--to facilitate the electronic exchange, access, and use of health information, while protecting the privacy and security of patients' health information.

Measure: Percentage of organizations that electronically exchange health information for health care delivery and that develop their policies and implementation approaches consistent with a nationwide confidentiality, privacy, and security framework. (Developmental.)

Target: To be determined, pending review of baseline data collected in 2010.

Method: Annual survey of a scientific sample of health care organizations.

Discussion

To guide evolving technology, careful attention to privacy and security policies, at the federal and state levels, is needed to ensure that nationwide interoperable health IT is achieved with a high degree of public confidence and trust. The adoption of baseline and common confidentiality, privacy, and security protections is essential to building that trust among involved patients and other stakeholders. Application of these protections by entities engaged in electronic exchange of health information can help foster the adoption of health IT. Addressing many of the policy issues regarding electronic disclosure, access, and use of health information, while ensuring that privacy and security protections are in place, will facilitate the electronic exchange, access, and use of health information for health care delivery.

- Assuring the integrity of the health information being exchanged, accessed, and used by providers and patients can lead to higher quality care. Establishing national principles for health information security and stewardship will allow providers to trust that the information they use when assessing and treating patients is as accurate as possible and has not been accessed by unauthorized users.
- Harmonizing privacy and security policies across care settings and communities can help facilitate the appropriate exchange of health information and increase consistent protections for health information. Providers and patients will be able to easily access and use health information when and where it is needed while being assured that only those who are authorized have access to this information.
- Ensuring that all stakeholders are aware of patient privacy rights, and that patient perspectives are included and addressed when organizations develop privacy and security policies and implementation approaches, can promote patient-focused care. By involving patients and patient advocates in the policy development process – at federal, state, local, and organizational levels – all stakeholders will be better informed about patient privacy rights and patient preferences, and this, in turn, will increase trust in nationwide exchange of health information.
- Patient-focused care is dependent on patients having access to their own information. The use of personal health records by health care consumers is expected to increase in proportion to the trust they place in the protections of their information being exchanged electronically.

Strategies

Five strategies work in combination to achieve this objective. The strategies are shaped by the President's Executive Order 13335 which requires the Strategic Plan to address privacy and security issues related to health IT. (Details in Appendix A beginning on Page A1.)

Strategy 1.1.1: Develop a confidentiality, privacy, and security framework for policy development to promote patient and consumer trust in, and advance the electronic exchange of, health information.

Privacy and security policies currently differ between the federal and state levels, across states, across organizations, and among distinct stakeholders and users of information. In addition, new issues raised by electronic exchange of health information are best resolved through a comprehensive framework for all stakeholders to consider these issues and develop consistent policies for exchange of health information. Building from HIPAA and

other existing privacy and security laws, such as the Privacy Act and the Federal Information Security Management Act, a framework of policy principles, developed at the federal level, can guide organizations in establishing policies for the exchange of electronic health information that apply the same baseline protections for patient information, supporting needed exchange across organizations and jurisdictions.

Strategy 1.1.2: Identify best practices for implementing technical solutions to ensure confidentiality, integrity, and availability of electronic health information consistent with the confidentiality, privacy and security framework.

Technical solutions are an important means to put into practice the principles established by the confidentiality, privacy, and security framework. Identifying and implementing best practices and common approaches for technical solutions to ensure confidentiality, integrity, and availability of electronic health information can support higher quality care as providers and patients make decisions based on the most accurate and complete information.

Strategy 1.1.3: Facilitate state-based activities to identify and address challenges to the use of health information technology, and the intra- and inter-jurisdictional exchange of electronic health information, while preserving or enhancing the current level of patient protections.

Many state laws that address or impact the privacy or the disclosure of electronic health information were written before interoperable health IT and the widespread exchange of electronic health information were feasible and, as such, may inadvertently and unnecessarily prohibit or significantly limit the appropriate exchange of electronic health information. In addition, certain conflicts and inconsistencies exist among these various statutes, regulations, and policies, whether perceived or real, that present further challenges to appropriate electronic exchange of health information. These conflicts and inconsistencies can lead to reduced quality of care and inefficiencies in health care delivery when health care providers choose not to share information for treatment purposes because they are reluctant to risk non-compliance with laws or policies they do not fully understand. Through a variety of forums, the federal government has and will continue to foster federal and state collaboration and coordination on patient protections while considering approaches that also enable the exchange of health information to promote greater quality and efficiency of health care delivery.

Strategy 1.1.4: Increase stakeholder understanding of current federal health privacy and security statutes and regulations in order to promote trust in the use of health information technology and the exchange of electronic health information for health care treatment purposes.

Successful transformation to a patient-focused health care delivery system is dependent on public trust in efficient exchange of electronic health information for treatment purposes. This strategy supports educating all stakeholders involved in health care delivery – particularly those that hold patient health information – about the protections afforded by federal health privacy and security policies. This educational effort, in addition to increasing patients' understanding of their privacy rights, should foster patients' trust that their information will remain private and secure.

Strategy 1.1.5: Identify and evaluate approaches to address federal statutes or regulations that conflict or are inconsistent – or are perceived to conflict or be inconsistent -- with the exchange of electronic health information for health care delivery, while preserving or enhancing patient protections.

Some federal statutes and regulations that were written before health IT and exchange of electronic health information were contemplated may inadvertently and unnecessarily limit the electronic exchange of health information for health care delivery. These limitations – actual or perceived – can prevent providers from having all the information they need about a patient at the point of care. This strategy promotes a collaborative approach to crafting solutions that maintain an appropriate level of privacy and security of patient information while enabling appropriate exchange, access, and use of electronic health information.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 1.1 provides a list of these initiatives along with the appendix page where a summary of each can be found. Activities focus on offering guidance and clarifications regarding privacy protections for electronic health data and exchange of health information to support care delivery, identifying variation in states’ privacy and security common approaches and practices, identifying mechanisms to foster compatibility of these common approaches and practices, and ensuring appropriate privacy and security protections are included in emerging infrastructures for exchange of health information.

Table 1.1 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 1.1
Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30)
CMS: HIPAA Security Rule (Page A35)
NIST: Security Technology (Page A55)
OCR: HIPAA Privacy Rule and Health IT (Page A45)
ONC: Anti-Fraud Activities (Page A46), Certification Commission for Healthcare Information Technology (CCHIT: Page A46), Health Information Security and Privacy Collaborative (HISPC: Page A47), Healthcare Information Technology Standards Panel (HITSP: Page A47), Nationwide Health Information Network (NHIN: Page A47), State Alliance for e-Health (Page A48)
SAMHSA: Health IT Initiatives (Page A54)
Federal Advisory Committees
National Committee on Vital and Health Statistics (NCVHS: Page A62)
American Health Information Community (AHIC: Page A63), with its workgroup on Confidentiality, Privacy, and Security (Page A64)

Objective 1.2 – Interoperability: Enable the exchange of interoperable health information among health care providers and organizations, as well as patients and their designees, to support patients’ health and care needs.

Measure: Percentage of providers and provider organizations with EHRs using recognized interoperability standards and NHIN specifications to connect their health information systems and exchange health information in support of care delivery. (Developmental.)

Target: To be determined, pending review of baseline data collected in 2010*.

Method: Annual national survey of a scientific sample of providers and provider organizations.

Discussion

Advancing recognized data and technical standards, policies, and networking is essential to promoting interoperability of health IT solutions. The resulting ability to exchange health information supports progress toward more efficient and informed care delivery, care coordination, communication among providers, and individual care management.

- Sharing health information across multiple care settings can increase care coordination and lead to greater efficiency. Employing recognized data and technical standards facilitates interoperability and the transfer and use of this information. By increasing the number of entities that support these recognized interoperability standards and meet minimum policies and principles, providers and patients will be able to easily access and use health information when and where it is needed. Duplication of services can be reduced as information flows seamlessly across organizational borders. Presidential Executive Order 13410 is an example of efforts to increase the federal government's use of interoperable systems and harmonized standards. This Order seeks to ensure that health care programs administered or sponsored by the federal government promote quality and efficient delivery of health care through the use of interoperable health IT, transparency regarding health care quality and price, and better incentives for program beneficiaries, enrollees, and providers.
- Exchange of health information using interoperable systems can bring about higher quality of care. Secure and reliable access to the most comprehensive and current patient information can help providers and patients make more informed decisions. Providers and patients can be assured that consistent information is shared through the use of standards in health systems. The Nationwide Health Information Network (NHIN) is a public-private endeavor to use standards and information exchange approaches for participating networks and entities, which have been developed by voluntary consensus standards bodies for exchange of health information among all such entities and networks. It is an approach to establishing an interoperable infrastructure among distinct networks that allows for different approaches and implementations, while ensuring secure information exchange as needed for patient care and population health.

Strategies

Eight strategies work in combination to achieve the objective of enabling the exchange of interoperable health information to support patients' health and care needs. Several of the strategies under the two interoperability objectives – 1.2 and 2.2 – are similar due to the needs

* Initial versions of these specifications will be developed by the end of Calendar Year 2008.

for a shared information infrastructure for health care and population health purposes including occupational safety, public health, and emergency preparedness. Health care providers and population health information users also have unique needs that must be addressed by the infrastructure, making certain aspects of these strategies distinct. (Details in Appendix A beginning on Page A4.)

Strategy 1.2.1: Advance the identification, availability and use of specified data and technical standards for interoperability that meet critical provider and individual information needs.

The ability to readily share information among providers and with patients is critical to improving care coordination and quality of care. The infrastructure necessary to support this exchange involves incorporating recognized interoperability data and technical standards into health IT products and systems to support multiple and different care settings (such as an emergency room and a cardiologist's office) as well as personal health records. The ability of providers and individuals to use dissimilar health IT systems and networks to reliably and securely exchange health information is dependent upon these interoperability specifications or standards.

Strategy 1.2.2: Identify core capabilities and governance necessary for networks to work with other networks in support of secure exchange of electronic health information using non-proprietary standards.

If networks employ some common network capabilities, interoperable data and technical standards to support them, and common governance principles, providers will be able to efficiently communicate and share patient information, as appropriate and necessary, regardless of the network they use. However, solutions and networks for exchanging health information have frequently been developed to meet specific, often proprietary, needs. Each solution frequently has had an individualized set of technologies, policies, and governance. Strategy 1.2.2 seeks to increase the number of networks able to easily and securely exchange information with other networks.

Strategy 1.2.3: Foster the business case for self-sustaining exchange of health information in communities, states, and nationwide.

Sustainable exchange of health information among different networks in communities and across regions and states can improve quality, patient-focused health care, and patients' overall health status. A number of challenges to the evolution of interoperable technology, networks, and services exist. To mitigate these challenges, federal and state governments need to consider and evaluate policy options that encourage exchange of health information among federal, regional, state, and specialty networks that use recognized interoperability standards and NHIN specifications. The advancement of business drivers for the exchange of health information will enable quality improvement and efficiencies in care delivery by solidifying the demonstrable outcomes, financial stability, and infrastructure support for the non-proprietary exchange of health information to support care.

Strategy 1.2.4: Increase the amount of health information being exchanged electronically using the specified standards for exchange of health information – to enhance the value for other providers, provider organizations, and networks to adopt the standards.

Achieving a critical mass of providers who use standards-based electronic exchange of health information is important to promoting widespread adoption of interoperable health IT. When few providers are using interoperable health IT, other providers and patients are less

likely to invest in interoperable systems. As a result, the utility of the health information and existing networks, including quality and cost-efficiency improvements in care delivery, are not maximized. The federal government, with support from relevant stakeholders, will enhance health information available for exchange and support a range of approaches and models designed to support shared, standards-based exchange of health information. An NHIN that connects several models of information exchange through the use of interoperability standards and specifications will increase the cost-efficiency of care delivery by enabling greater information exchange across more diverse users and settings.

Strategy 1.2.5: Promote the development of the processes and infrastructure for testing, verification, and implementation of recognized standards and services, and nationwide policies in networks, connected systems, and health IT.

Verification of the accurate implementation and use of data and technical standards is critical to increasing the interoperability of solutions for exchange of health information. Certification of systems, conformance testing capabilities, and on-site verification of the accurate implementation of standards are all necessary components to enhance the capabilities of and achieve continued growth among interoperable networks. As interoperability standards and specifications are established and updated, methods to test and verify their implementation will be critical to ensure that exchange of health information seamlessly evolves. Strategy 1.2.5 seeks to promote the development of processes and infrastructure for testing and verifying that recognized data and technical standards and nationwide policies are being consistently implemented to ensure interoperability.

Strategy 1.2.6: Encourage health care organizations to provide personal health information in useable standardized electronic form to consumers or their designees.

Consumers are being encouraged to take a more active role in managing their own health care. Interoperable health IT can catalyze patient-focused care by increasing consumers' (or their designees') ability to electronically access, accumulate, and manage their personal health information. Greater access to usable, electronic health information in standard formats can yield improvements in health literacy, patient-provider communication, care coordination, and overall quality of care. Strategy 1.2.6 seeks to encourage health care organizations to offer health information to consumers or their designees in standardized electronic form.

Strategy 1.2.7: Increase the availability of health information service providers that compete to support exchange of health information.

The secure exchange of health information can be costly to support. With shared standards there are opportunities for health information service providers to support multiple organizations and markets helping to drive down the costs of exchange. Steady growth in the number of health information service providers must occur to maximize the ability of providers and patients to access and use electronic health information for care delivery. Currently, a number of different models for exchange of health information have emerged; however, most organizations still cannot exchange data with each other. Information service providers that adhere to recognized interoperability standards, specifications, and policies will be able to support an interoperable health information infrastructure nationwide.

Strategy 1.2.8: Through the identification and recognition of standards, empower individuals to use their health data to serve their needs beyond direct patient care delivery.

Medical records play a significant role in many areas of an individual's life beyond direct patient care. Records are needed for everything from preventing illness, to establishing immunizations for school attendance, to determining the impact of a disabling condition in order to obtain services and benefits. Immediately critical in this arena is the need to enable persons with disabilities to authorize the electronic movement of their medical records to key public and private service providers. This strategy seeks to promote the development and recognition of standards necessary to support this type of interoperability, and to encourage providers to take advantage of the benefits it brings.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 1.2 provides a list of these initiatives along with the appendix page where a summary of each can be found. Activities focus on three main areas: support of development of data and technology exchange standards; pilot testing of standards; and adopting standards within the federal government and promoting adoption within the private sector.

Table 1.2 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 1.2
Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30), United States Health Information Knowledgebase (USHIK: Page A31)
CMS: ICD-10 (Page A36), Medicaid Information Technology Architecture (MITA: Page A36), Medicaid Transformation Grants (Page A36), Beneficiary Information Services (Page A35)
FDA: Structured Product Labeling for Products (Page A38)
HRSA: Health IT Electronic Health Record and Innovations Grants (Page A39), Telehealth Grants (Page A39), Regional Genetic and Newborn Screening Service Collaboratives (Page A39)
IHS: Resource and Patient Management System (Page A41)
NIH: Cancer Biomedical Informatics Grid (Page A42), Support, Maintenance, & Dissemination of Standard Clinical Vocabularies (Page A43)
ONC: Planning for AHIC 2.0 (Page A48), Certification Commission for Healthcare Information Technology (CCHIT: Page A46), Federal Interdepartmental Health IT Collaborative [Multi-agency] (Page A46), Federal Health Architecture (FHA) [Multi-agency] (Page A47), Healthcare Information Technology Standards Panel (HITSP: Page A47), Nationwide Health Information Network (NHIN: Page A47), Use Case Development (Page A49)
HHS/OS: Personalized Healthcare (Page A52), Value-driven Health Care (Page A53)
SAMHSA: Health IT Initiatives (Page A54)
NIST: Conformance Testing Infrastructure (Page A55); Security Technology (Page A55)
DoD: AHLTA (Page A56), Memorandum of Agreement with State of Florida (Page A56)
SSA: Medical Evidence Request and Data Use Prototype (Page 59), NHIN "Release of Information to a Trusted Entity" Use Case Funding and Participation (Page 59), Personal Health Record Prototype (Page 59)
VA: Personal Health Record (Page A57)
FCC: Rural Health Care Pilot Program (Page A58)
Inter-Departmental and Inter-Agency Initiatives

Table 1.2 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 1.2
AHRQ, FDA, NLM, NCI, and VA: Data Standards Program (Page A59)
DoD and VA: Exchange of Information (FHIE, BHIE, CHDR, LDSI: Page A60)
DoD and VA: Joint EHR (Page A60)
Federal Advisory Committees
National Committee on Vital and Health Statistics (NCVHS: Page A62)
American Health Information Community (AHIC: Page A63), with its workgroups on Consumer Empowerment (Page A65), Electronic Health Records (Page A65), Personalized Healthcare (Page A66)

Objective 1.3 – Adoption: Promote the nationwide adoption of interoperable electronic health records (EHRs) by providers, and the adoption of personal health records (PHRs) and other consumer health IT tools by consumers and their designees.

Measure: Percentage of physician offices using certified EHR systems.

Target: 40% by 2012

(This outcome targeted for 2012 is consistent with President Bush’s target of the majority of Americans to have access to EHRs by 2014.)

Measure: Percentage of small physician office practices (those with five physicians or fewer) using certified EHR systems.

Target: 12% by 2012

Method: Annual national survey of a scientific sample of physician offices.

Discussion

Adoption of interoperable health information technology by providers and patients and its subsequent routine use are the critical foundations for transforming the current health care system to one that focuses on the patient while providing quality in an efficient manner.

- In its 2001 report - Crossing the Quality Chasm: A New Health System for the 21st Century* – the Institute of Medicine describes *quality care* as safe, timely, effective, efficient, equitable, and patient-centric. The report documents how this might be achieved, including the critical importance of timely access by clinicians to accurate and comprehensive electronic health information about each of their patients.

Adoption of interoperable electronic health records by clinicians throughout the delivery system can improve:

* Crossing the Quality Chasm: A New Health System for the 21st Century. Committee on Quality of Health Care in America, Institute of Medicine. National Academy Press. Washington, DC. 2001. (Full text available at: <http://www.nap.edu>).

1. Safety through provision of warnings and alerts when actions are taken that could injure a patient.
 2. Timeliness by fostering communications between providers and patients to assure that an individual's needs are understood prior to a scheduled encounter and appropriately met.
 3. Effectiveness by providing and assessing comprehensive information about a patient's care against evidence-based guidelines for care.
 4. Efficiency by presenting the comprehensive information necessary to coordinate care across multiple settings and providers, thus eliminating duplication and delays.
 5. Equity as these technologies are made widely available to all populations.
 6. Patient-centeredness by incorporating and presenting information about patient choices, preferences, and values in their clinical record**.
- Widespread adoption of health information technologies will also support more *cost efficient* care – beyond the efficiencies gained from improvements in quality from enhanced patient safety, effective application of preventive processes, and better coordinated care. Through the use of health IT, more robust data will become available about variations in outcomes associated with different care processes. And, as therapies are tailored more specifically to each patient, the health system will become more cost-efficient by employing only those therapies known to be effective for that patient.
 - The health of individuals and of communities is not solely dependent on the health care delivery system. Individuals are in part responsible for their own health, and can affect it through the decisions they make regarding their lifestyle, dietary and exercise habits, accessing preventive health care services, and even pursuit of “good health” according to their own personal, basic beliefs. However, choices and beliefs will lead to better health only if a person is well-informed. Electronic access to one's own clinical information, the ability to communicate electronically with one's clinicians, the ability to ensure that medical information is available to key non-medical service providers, and the ability to access pertinent health information related to one's condition or situation are all critical to well-informed, timely, individual choice and engagement. Personal Health Records (PHRs) are products that can collect, collate, and present the comprehensive data needed by engaged, activated individuals and for tools that can reformat the data in a manner most useful for those individuals.

Strategies

Nine strategies, in addition to those related to privacy, security, and interoperability, work together to achieve the objective of nationwide adoption of EHRs, PHRs and other consumer health IT tools. The initial five of these strategies (1.3.1 through 1.3.5) specifically address EHR adoption in the health care delivery system and the President's goal of making electronic health records available to most Americans by 2014. Strategies 1.3.6 and 1.3.7 focus on the emerging areas of consumers' access to, and use of, electronic health information related to their own health and care. Strategies 1.3.8 and 1.3.9 are designed to advance patient-focused health care by addressing liability, licensure, and other issues that can promote the provision of care

** Patient-centered care is defined as care that takes into consideration the values and preferences of the patient.

when the patient is in a remote setting, not in the same physical setting as the clinician. (Details in Appendix A beginning on Page A8.)

Strategy 1.3.1: Remove business barriers and disincentives for provider and delivery system adoption of EHRs.

Evidence suggests that there are barriers to the adoption and use of EHRs, including the cost of the EHR, changes in workflow processes, and time and effort required for training. This strategy will promote adoption by working to remove business barriers and disincentives.

Strategy 1.3.2: Increase the likelihood of efficient and effective EHR purchase and implementation.

The EHR adoption process is complicated, time consuming, and has been shown to decrease productivity in the short term, before beneficial effects related to health care occur. Sufficient provider training and technical assistance can help health care providers navigate the adoption process so that they better understand the products and can purchase and implement the software successfully. In this way, the benefits of health IT will be realized more rapidly and the number of effective and efficient EHR implementations can be maximized.

Strategy 1.3.3: Increase the value of EHRs through interoperability, clinical decision support, and other technical advances.

Clinicians find value in products and services that decrease their administrative burden, increase their access to comprehensive information about a given patient, and present clinical information in a manner that enables accurate and timely diagnoses, treatments, and care. To the extent that EHRs have these features and these features work well, clinicians will be more inclined to invest in EHR products. This strategy addresses the technical and implementation challenges that must be overcome to assure routine inclusion and use of these features within EHRs.

Strategy 1.3.4: Promote certified health IT products as critical components and standards of clinical care.

The risk of purchasing a product that does not meet the provider's needs is one of the major barriers to widespread adoption of EHRs. Private sector certification processes would minimize this risk by assuring that the certified products meet specific criteria for functionality, security, and interoperability. As such, this process would not only protect the clinician purchaser, but would also allow the federal government, to the extent permitted by law to directly stimulate the adoption of interoperable products in both the public and private sectors through contractual mechanisms that reference use of certified systems.

Strategy 1.3.5: Develop the workforce for health IT product development and use.

Health IT development and implementation require an appropriately trained, highly-skilled workforce to play a wide range of specialized and essential supporting roles. Currently, the numbers of trained health IT professionals are only adequate to support the relatively low rate of health IT adoption. To enable the adoption rate to increase, and thus enable attainment of the 40 percent adoption objective by 2012 (and over 50 percent by 2014), the size of this trained health IT workforce will need to increase substantially.

Strategy 1.3.6: Identify key PHR functions and features that will allow individuals to link their health information to a wide variety of market-driven personal health tools that they and their designees find valuable in managing their health and care.

PHRs have low rates of adoption to date for many reasons. While secure websites that enable patients to access their electronic health records are widely used where available, there is considerable confusion about what constitutes a free-standing PHR that is wholly controlled by the patient or consumer. This strategy seeks to define the key elements of a free standing PHR that will support secure maintenance of an individual's personal health information so that it can link to the myriad of applications being developed in the marketplace to support that individual's ability to manage his or her own health.

Strategy 1.3.7: Design methods to promote the use of PHRs and other consumer health IT tools by consumers and their designees.

Communicating with consumers about the benefits of PHRs and self management of one's own health may require new approaches to be effective. This strategy will expand and increase our understanding of how best to use these new technologies to the benefit of individuals interested in better management of their own health and care.

Strategy 1.3.8: Minimize liability risks and clarify misperceptions of liability risks for providers using health IT, while preserving or enhancing patient protections.

Many providers are concerned about both real and perceived liability risks of using EHRs and participating in the exchange of electronic health information. This strategy will promote clinician adoption of health IT by addressing issues related to state-based licensure and certification criteria that can mitigate liability risk.

Strategy 1.3.9: Remove technical, financial, workflow, and other barriers to diagnosing, treating, and communicating with patients outside the boundaries of traditional health care settings.

Our provider focused health care system is predicated on patients accessing care in the clinical setting. However, actual care is primarily dependent on decisions made in the home, office, or school setting by the patient – often without the guidance of their clinicians. Adoption and use has been very slow of new technologies that can provide data and enable communication between individuals and their clinicians at the time when it is needed. This strategy will promote adoption by helping the industry to understand the sources of the barriers to adoption and by identifying solutions that promote more widespread use of these technologies.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 1.3 provides a list of these initiatives along with the appendix page where a summary of each can be found.

Table 1.3 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 1.3
Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30)
ASPE: Health IT Activities (Page A32)
CMS: EHR Adoption Demonstration (Page A35), E- Prescribing Efforts (Page A35), ICD-10 (Page A36), Medicaid Information Technology Architecture (MITA: Page A36), Medicaid Reimbursement for Telehealth (Page A36), Medicaid Transformation Grants (Page A36), Beneficiary Information Services (Page A35)
FDA: Structured Product Labeling for Products (Page A38)
HRSA: Rural Hospital Flexibility Grant Program (FLEX: Page A39), Health IT Electronic Health Record and Innovations Grants (Page A39)
IHS: Resource and Patient Management System (Page A41), Telehealth (Page A41)
NIH: Cancer and Biomedical Informatics Grid (Page A42), Support for Biomedical Informatics Research Training (Page A43), Health Informatics R & D (Page A43)
OCR: Health IT and Health Disparities/Special Needs Populations (Page A45)
ONC: Certification Commission for Healthcare Information Technology (CCHIT: Page A46), Secure Messaging Pilot (Page A48), Standardized Measures for Adoption of EHRs (Page A48), Use Case Development (Page A49)
HHS/OS: Personalized Healthcare (Page A53), Value-driven Health Care (Page A53)
SAMHSA: Health IT Initiatives (Page A54)
DoD: AHLTA (Page A56)
VA: Electronic Health Record (VistA, CPRS: Page A57), Telehealth (Page 57), Personal Health Record (Page 57)
Inter-Departmental and Inter-Agency Initiatives
DoD & VA: Exchange of Information (FHIE, BHIE, CHDR, LDSI:Page A60), Joint EHR (Page A60)
OIG & CMS: Hospital Donation of Health IT (Page A60)
Federal Advisory Committees
American Health Information Community (AHIC: Page A63), with its workgroups on Chronic Care (Page A64), Consumer Empowerment (Page A65), Electronic Health Records (Page A65), Personalized Healthcare (Page A66)

Objective 1.4 - Collaborative Governance: Establish mechanisms for equitable and balanced multi-stakeholder priority-setting and decision-making to achieve a secure, nationwide, interoperable health information technology architecture.

Measure: Achievement of a self-sustaining AHIC Successor that will have broad representation from public and private sectors and provide coordination and continued development of electronic exchange of health information across the country by 2011

Target: Successor will have balanced public and private stakeholder representation and be self-sustaining

Methods: Financial reports of the AHIC Successor and review of board composition for adequacy of representation

Discussion

Ensuring a mechanism for collaborative governance involving all major stakeholder groups across the public and private sectors will advance the necessary planning, priority-setting, consistent approaches to implementing policies, and consensus building needed to achieve interoperable exchange of health information and, in turn, support the overall transformation of care.

- Governance of the exchange of health information supported by entities with *equitable and balanced multi-stakeholder* representation, will create forums for all interested parties to come together to voice their interests and priorities and develop coordinated solutions to realize interoperability across the health care system. Progress toward the goal of widespread adoption of interoperable health IT requires support from all health care stakeholders, as well as their participation in *priority-setting and decision-making*. Governance entities at regional, state, and national levels facilitate discussion and common solution development toward evolving necessary policies, standards, and infrastructure to support health care transformation. Lack of support from any major stakeholder group could lead to solutions that work for some and not others, or halt progress toward the goal altogether.
- *Multi-stakeholder* governance entities can bridge efforts across the public and private sectors and geographies to ensure coordinated progress towards an electronically connected, patient-focused health care system.
- Consumer representation in these multi-stakeholder entities will support development of a transformed health care delivery system that is patient-focused, with the exchange of health information consumer-controlled.

Strategies

Three strategies will enable equitable and balanced public-private governance for the electronic exchange of health information that will transform health care and engage governmental participation at the federal, state, local, and tribal levels. (Details in Appendix A beginning on Page A12.)

Strategy 1.4.1: Establish a national public-private governance entity to advance interoperability and sustainable exchange of health information nationwide.

Sustainable exchange of health information will require broad inclusion and buy-in from all of the nation's health care stakeholders. The priorities and activities surrounding this exchange must be defined and governed by an objective, equitable, broadly representative and transparent entity. While this strategy recognizes the exchange of health information for care delivery as the first priority for widespread adoption, it also acknowledges that in order to enable most quality improvements and efficiency gains, these care delivery requirements must be coordinated with those necessary to meet population health needs. Strategy 1.4.1 also involves mechanisms to ensure accountability of governance entities across geographies that will reinforce responsible policies and procedures for appropriate use and exchange of electronic health information.

Strategy 1.4.2: Empower consumers through representation in multi-stakeholder governance entities at the national, state, and local level.

For care delivery to truly be patient-focused, consumers' interests must be reflected in policies and governance for the exchange of health information nationwide. Consumer participation in national, state, and local governance entities is necessary to enable health IT initiatives that reflect consumer priorities, ensure public trust, and maximize consumer welfare. Strategy 1.4.2 emphasizes the importance of consumer involvement in developing organizational policies and procedures around the exchange of health information, identifying effective methods for engaging consumers, and working to promote consumer involvement in activities nationwide.

Strategy 1.4.3: Promote participation by federal, state, local, and tribal government representatives in multi-stakeholder governance entities for the exchange of health information, at all appropriate levels: national, state, and local.

Communication and aligned priorities regarding the use and exchange of health information at varying levels of jurisdiction must exist to achieve the care transformation that the exchange of health information can bring. This strategy recognizes the need to promote shared and complementary participation in governance activities and to align goals and organizational policies and practices for the exchange of electronic health information across all geographic levels nationwide. It is also designed to support regular and organized interaction, collaboration, communication, and participation by federal, state, local, and tribal government representatives in such activities.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 1.4 provides a list of these initiatives along with the appendix page where a summary of each can be found. The majority of these activities focus on fostering coordination and building consensus among a broad range of health IT stakeholders on topics including federal health IT policy and decision-making, differences in state policy, how to advance consistent policies for organizations engaged in the exchange of health information, and consistent health IT terminologies and definitions. The American Health Information Community (AHIC) has had a very prominent role since its creation, advising the Secretary of HHS regarding health IT coordination and collaboration across the public and private sectors.

Table 1.4 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 1.4
Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30)
NIH: Cancer and Biomedical Informatics Grid (Page A42), Clinical Translational Science Awards (Page A42)
OCR: Health IT and Health Disparities/Special Needs Populations (Page A45)
ONC: Certification Commission for Healthcare Information Technology (CCHIT: Page A46), Federal Interdepartmental Health IT Collaborative [Multi-agency] (Page A46), Federal Health Architecture (FHA) [Multi-agency] (Page A47), Federal Interagency Health IT Policy Council [Multi-agency] (Page A47),

Planning for AHIC 2.0 (Page A48), State Alliance for e-Health (Page A48), State Level Health Information Exchange Consensus Project (Page A49), Terminology Consensus Project (Page A49)

Federal Advisory Committees

National Committee on Vital and Health Statistics (NCVHS: Page A62)

American Health Information Community (AHIC: Page A63), with its workgroups on Population Health and Clinical Care Connections (Page A66), and Quality (Page A67)

Goal Two – Improve Population Health

Enable the appropriate, authorized, and timely access and use of electronic health information to benefit public health, biomedical research, quality improvement, and emergency preparedness.

Goal Two of the Plan concentrates on enabling the use of electronic health information for critical health improvement activities that promote the health of communities and the population as a whole nationwide. Goal Two envisions the use of interoperable health IT to develop more robust and effective systems for such activities as disease detection and the mobilization of resources to manage outbreaks, generating new knowledge from clinical studies, identifying health care practices associated with best outcomes, and helping communities manage and recover from natural disasters.

Because of their focus on communities and populations, the activities under this second goal differ fundamentally from those of the first goal that focus on the care of individuals. In general, the activities under Goal One anticipate access and use of information about one person at any given time; activities under Goal Two anticipate analysis of information that is frequently combined use for the public good.

The Plan articulates four objectives that support achievement of this goal. The themes of privacy and security, interoperability, adoption, and collaborative governance recur to describe the objectives in Goal Two, but will be seen as well in the descriptions of the objectives; the objectives themselves and the proposed strategies to achieve them are targeted specifically to population health. In their simplified form the objectives are:

Objective 2.1 – Privacy and Security: Advance privacy and security policies, principles, procedures, and protections for health information access and use in population health

Objective 2.2 – Interoperability: Enable the mobility of health information to support population-oriented uses

Objective 2.3 – Adoption: Promote nationwide adoption of technologies and technical functions that will improve population and individual health

Objective 2.4 – Collaborative Governance: Establish coordinated organizational processes supporting information use for population health

Objective 2.1 – Privacy and Security: Advance the development of privacy and security policies, principles, procedures, and protections that facilitate appropriate access to, or transfer and use of, electronic health information for public health, biomedical research, quality improvement, and emergency preparedness.

Measure: Federal agencies involved in the electronic exchange of health information and charged with population health activities adhere to principles for exchanging

electronic health information in a manner consistent with a nationwide confidentiality, privacy, and security framework by 2012.

Target: 80% of agencies by 2012.

Method: Annual survey of federal agencies charged with population health activities.

Discussion

A nationwide, interoperable health IT architecture in the United States must be multi-functional and dynamic – supporting not only the needs of the health care delivery system, but also population health activities. While it is essential that health information be accurate and accessible for this wide-range of health information uses, it is critical that appropriate policies be in place to protect patient confidentiality and privacy when health information is used for purposes outside of direct patient care. Objective 2.1 seeks to advance development of privacy and security policies that protect access to health information in an interoperable electronic environment, in a manner that the public trusts, and through a coordinated effort that engages all stakeholders at the federal, state, local and tribal levels.

- Identifying or establishing policies, principles, procedures, and protections that set parameters on when data may be accessed, by whom, and for what purposes can promote *appropriate and authorized access and use* of electronic health information for population health purposes. Coming to nationwide consensus principles on health information security, stewardship, and access for each of the population health activities – because each has unique data needs – will engender trust among all stakeholders that the information is accurate and confidential.
- Facilitating the exchange of population health data by harmonizing privacy and security policies across jurisdictions can enable the *timely access and use* of electronic health information for population health purposes. By increasing harmonization of the privacy and security requirements that are limiting – or are perceived as limiting – information flow within and across state lines, or between states and the federal government, users of population health information can receive data in a more timely fashion, allowing them to more accurately assess public health/epidemiologic risks, report physician feedback on quality measures, or deploy medical supplies and staff in an emergency.

Strategies

Four strategies work in combination to achieve this objective. (Details in Appendix A beginning on Page A14.)

Strategy 2.1.1: Employ the confidentiality, privacy, and security framework (see Strategy 1.1.1) for policy development to establish patient and consumer trust and advance the exchange of electronic health information for population health purposes.

Privacy and security policies currently differ at the federal and state level, across states, across organizations, and among distinct stakeholders and users of data. This strategy can help guide organizations in developing confidentiality, privacy, and security policies that enable appropriate access to, and use of, electronic exchange of health information for population health purposes such as public health, biomedical research, quality improvement, and emergency preparedness. Building from HIPAA and other existing federal privacy and security laws such as the Privacy Act and the Federal Information Security Management Act, this framework will take into account the information needs for the range of population

health activities, as well as the need to engender consumer trust that information will be kept private and secure.

Strategy 2.1.2: Identify and evaluate federal statutes or regulations that conflict or are inconsistent – or are perceived to conflict or be inconsistent – with the exchange of electronic health information used for population health purposes, while preserving or enhancing patient protections.

Some federal statutes and regulations related to the disclosure of health information for population health uses were written before interoperable health IT and widespread exchange of electronic health information became feasible and were considered, and, therefore, may inadvertently and unnecessarily prohibit or limit the appropriate exchange of such information – or be perceived to do so. This strategy seeks to increase appropriate and timely access to health information across various population health uses, while maintaining an appropriate level of privacy and security, by clarifying the current policies for all users in the context of interoperable health IT.

Strategy 2.1.3: Facilitate state-based activities to identify and address challenges to the use of health IT and the intra- and inter-state exchange of electronic health information to support population health, while preserving or enhancing the current level of patient protections.

Many state laws that address privacy or the disclosure of electronic health information were written before interoperable health information technology and the widespread exchange of electronic health information became feasible. The federal government will promote collaboration and coordination among stakeholders at the state level to advance the electronic exchange of health information for population health while ensuring proper patient privacy and security protections.

Strategy 2.1.4: Increase stakeholder understanding of current federal health privacy and security laws in order to promote trust in the use of health IT and exchange of electronic health information for population health purposes.

All stakeholders involved in exchange of electronic health information for population health purposes – including consumers – should have an understanding of federal privacy and security policies to enable appropriate and timely access and use of health information for population health activities.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 2.1 provides a list of these initiatives along with the appendix page where a summary of each can be found. Activities focus on offering guidance and clarifications to ensure privacy and security protections are maintained or enhanced in electronic health information access and exchange policies related to population health activities. They also focus on how the array of privacy and security standards, policies, and practices across jurisdictions can support authorized population health uses.

Table 2.1 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 2.1

Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30)
CMS: HIPAA Security Rule (Page A35)
NIH: Genome Wide Association Studies Data Sharing Policy (Page A42)
NIST: Security Technology (Page A55)
OCR: HIPAA Privacy Rule and Health IT (Page A45)
ONC: Health Information Security and Privacy Collaborative (HISPC: Page A47), Healthcare Information Technology Standards Panel (HITSP: Page A47), Nationwide Health Information Network (NHIN: Page A47), State Alliance for e-Health (Page A48)
HHS/OS: Personalized Healthcare (Page A52)
SAMHSA: Health IT Initiatives (Page A54)
Federal Advisory Committees
National Committee on Vital and Health Statistics (NCVHS: Page A62)
American Health Information Community (AHIC: Page A63), with its workgroup on Confidentiality, Privacy, and Security (Page A64)

Objective 2.2 – Interoperability: Enable the secure exchange of interoperable health information among health-related organizations – as well as providers, patients and their designees – to support appropriate population-oriented uses.

Measure: Percentage of population health agencies – in the public sector at the federal, state and local levels as well as the private sector – that use recognized interoperability standards and NHIN specifications for exchanging health information. (Developmental.)

Target: To be determined, pending review of baseline data collected in 2010.

Method: Survey of selected samples of agencies or results of automated conformance testing.

Discussion

Public health, biomedical research, quality improvement, and emergency preparedness efforts currently operate in a constrained environment that is largely paper-based, poorly coordinated and inefficient. As electronic health information becomes more robust and more widely available, those engaged in population health activities increasingly see it as a critical resource. The advancement of recognized interoperability standards, policies, and approaches – consistent with those used to support the exchange of health information for direct patient care – can also promote the interoperability of health IT solutions and networks necessary to enable the exchange of health information for population-oriented uses.

- Implementing recognized interoperability standards and policies can promote *timely access and use* of electronic health information for population health purposes. Exchange of electronic health information among such diverse organizations and models requires interoperability standards that are specific and verifiable, and architecture to meet technical demands. The same standards should be used to exchange information among organizations involved in providing clinical care as those organizations that use the information for population purposes. Doing so will further enable such organizations to achieve their population health goals. At times, a higher degree of interoperability will be necessary for these purposes since the comparability, not just exchange of data, is critical to ensure that data can be merged from and used by diverse organizations.
- There are several models for the exchange of health information including: organizationally based (e.g., integrated delivery networks), geographically-based (local, regional, and state-level entities and regional health information organizations), and personally controlled (“health data banks”). Promoting certification criteria for these organizations which address issues relating to *appropriate* access will help ensure *authorized* uses of health information for population health activities. To garner public trust for the use of health information for population health purposes, organizations that exchange health information and other data stewards should have to adhere to interoperability standards and employ common policies for collecting, storing, analyzing, and transmitting health information. Certification for organizations that exchange health information will promote implementation of and compliance with standards and policies on privacy and security, and data use and availability.

Strategies

Five strategies work in combination to achieve the objective of enabling the secure exchange of interoperable health information for population health purposes. (Details in Appendix A beginning on Page A17.)

Strategy 2.2.1: Advance the availability and use of consistent data and technical standards that enable the merging of comparable data originating from multiple organizations and sources in support of population health uses.

Clinical, regional, state, and federal initiatives that promote and protect population health rely on access to aggregate health data from multiple sources. The wide array of organizations and their varying uses for the data has resulted in the emergence of different and often inconsistent data and technical standards. This strategy is critical to reducing the variation in data and technical standards and to promoting the utility of health information for population health purposes. It seeks to ensure that population health data users (public health, biomedical research, quality improvement and emergency preparedness activities) can use comparable information from different sources. It will also advance EHR functionality and interoperability to include standards, technical architecture, and certification requirements that support data sharing and use for population health purposes.

Strategy 2.2.2: Allow for flexibility in the models for the exchange of health information (organizational, geographic, and personally controlled), while still advancing the specific standards and policies necessary to ensure that they all work together to meet population health needs.

Just as a number of different models for exchanging health information have emerged, these entities employ an array of technical architectures, network services, and policies to

satisfy their unique priorities. Consistent standards that support exchange of electronic health information are critical to enabling timely access to and use of population health data. This strategy supports the continued evolution of different models and promotes innovation in developing new capabilities and services. It simultaneously ensures that emerging technical standards support the minimal set of services and policies needed to support population health initiatives. This strategy also seeks to foster the consideration of population health needs as a critical component of the development of these entities.

Strategy 2.2.3: Assess the implementation of recognized standards and nationwide policies in entities that exchange health information.

Testing and verification of the accurate implementation and use of data and technical standards is critical to increasing the interoperability of solutions for the exchange of health information. Certification of systems, conformance testing capabilities, and on-site verification of the accurate implementation of recognized standards and nationwide policies are all necessary components to enhance the capabilities of and achieve continued growth among interoperable networks. This strategy is critical to ensuring that organizations are employing the necessary standards and policies to assure secure and appropriate exchange of health information. It seeks to make certain that the population health capabilities of interoperable networks continue to evolve such that population health users may access and use data in a timely manner.

Strategy 2.2.4: Promote the availability of health information in a useable electronic form for appropriate population health users outside of direct patient care.

Public health, biomedical research, quality improvement, and emergency preparedness activities each have their own distinct population health information needs. This strategy seeks to ensure that interoperable health information networks continue to meet this range of population health information uses and needs. It will promote timely access to useable electronic health information through interoperable health information networks that use recognized interoperability standards and the specifications developed through the NHIN initiative.

Strategy 2.2.5: Advance the availability of needed clinical and resource information for providers and emergency response teams when responding to significant events that affect population health.

Health IT and networks for the exchange of health information, such as the networks that comprise the NHIN, can connect all members of emergency response teams – from the top levels of the federal government to the providers in the field – and enable timely access to comprehensive data. Building on the National Strategy for Public Health and Medical Preparedness established by the recent Homeland Security Presidential Directive, this strategy will ensure that the NHIN can support emergency response needs.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 2.2 provides a list of these initiatives along with the appendix page where a summary of each can be found. Activities focus on development of nomenclature, content, and standards in support of electronic exchange of health information for

population health purposes and on testing and adoption of these standards both within the federal government and in collaboration with the public and private sector.

Table 2.2 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 2.2
Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30), United States Health Information Knowledgebase (USHIK: Page A31)
ASPR: Homeland Security Presidential Directive 21 (Page A32), Pandemic All-Hazards Preparedness Act (PAHPA: Page A33)
CDC: BioSense (Page A33), EPI-X (Page A33), National Healthcare Safety Network (Page A34), Public Health Information Network (Page A34), Public Health Preparedness Systems (Page A34)
CMS: Medicaid Information Technology Architecture (MITA: Page A36), Medicaid Transformation Grants (Page A36)
FDA: Sentinel Network (Page A38), Structured Product Labeling for Products (Page A38)
HRSA: <i>Connections</i> Project (Page A38)
IHS: National Data Repository (Page A40), Resource and Patient Management System (Page A41)
NIH: Cancer Biomedical Informatics Grid (caBIG: Page A42), Health Informatics R & D (Page A43), National Network of Libraries of Medicine (Page A43), Support, Maintenance, & Dissemination of Standard Clinical Vocabularies (Page A43)
ONC: Certification Commission for Healthcare Information Technology (CCHIT: Page A46), Federal Interdepartmental Health IT Collaborative [Multi-agency] (Page A46), Federal Health Architecture (FHA) [Multi-agency] (Page A47), Healthcare Information Technology Standards Panel (HITSP: Page A47), Nationwide Health Information Network (NHIN: Page A47), Planning for AHIC 2.0 (Page A48), Use Case Development (Page A49)
HHS/OS: Personalized Healthcare (Page A52), Value-driven Health Care (Page A53)
SAMHSA: Health IT Initiatives (Page A54)
NIST: Conformance Testing Infrastructure (Page A55); Security Technology (Page A55)
DoD: AHLTA (Page A56), Memorandum of Agreement with State of Florida (Page A56)
FCC: Rural Health Care Pilot Program (Page A58)
Inter-Departmental and Inter-Agency Initiatives
AHRQ, FDA, NLM, NCI, and VA: Data Standards Program (Page A59)
DoD and VA: Exchange of Information (FHIE, BHIE, CHDR, LDSI: Page A60), Joint EHR (Page A61)
Federal Advisory Committees
National Committee on Vital and Health Statistics (NCVHS: Page A62)
American Health Information Community (AHIC: Page A63), with its workgroups on Consumer Empowerment (Page A65), Electronic Health Records (Page A65), Personalized Healthcare (Page A66), Population Health and Clinical Care Connections (Page A67), Quality (Page A67)

Objective 2.3 – Adoption: Promote the nationwide adoption of information technologies that enable the reliable and efficient exchange of electronic health information to continuously improve population health activities and individual health care services.

Measure: Increase the electronic health information transmitted for population health use by ambulatory and inpatient providers that is re-use of information routinely collected in the course of patient care without re-entry or other manual intervention. (Developmental.)

Target: To be determined, pending review of baseline data collected in 2010.

Method: Survey of representative samples of population health agencies

Discussion

Improvements and advances in population health and individual health care services depend on the ability to transmit electronic health information efficiently and securely among data sources and data users. Information can flow in both directions: “upstream” from providers and consumers to authorized population health agencies, and “downstream” from population health agencies to providers, consumers, and their communities. Patients, providers, community agencies, and population health agencies have distinct information to offer one another to serve a wide range of useful purposes.

The increasing availability of individual patient data in electronic form creates enormous potential for enhancing public health, clinical research, health care quality studies, and emergency preparedness. With appropriate protections of security and privacy, information can flow from practice-based or other local systems to population health agencies and be immediately available for analysis. During disease outbreaks or natural disasters, this information can promote all important “situational awareness” that can save lives and make best use of the available resources.

Reporting of patient-specific data for population health purposes – such as disease surveillance, clinical research, or quality studies – can be improved with the adoption of health IT functionalities and standards which will support ‘real-time’ transmission of data. The adoption of technologies and tools that streamline and automate the information flow is an essential step in realizing the full potential of population health through health IT.

Strategies

Three strategies work together to achieve Objective 2.3 of establishing an efficient exchange of information among relevant entities to improve population health activities and individual health care services. (Details in Appendix A beginning on Page A19.)

Strategy 2.3.1: Establish mechanisms to optimize the exchange of information between care providers using EHRs and authorized users of population health data, as well as among authorized users and recipients of population health data.

Health IT and information exchange can facilitate greater access to and use of population health data for all authorized users. This strategy seeks to enable the efficient transmittal of information between EHRs and authorized population health data users, and ensure timely and secure mechanisms for the exchange.

Strategy 2.3.2: Minimize burden on health care providers when reporting clinical data for population health purposes using EHRs and other health IT, while ensuring consistent health information protections.

The increased burden associated with providing clinical data for population health uses may limit participation by providers and other data sources in the exchange of health information. This strategy aims to reduce the burden on the delivery system and increase participation by promoting efficient data collection and reporting and facilitating the automated collection of population health data and use of non-clinical data sources.

Strategy 2.3.3: Establish mechanisms for the electronic exchange of health information among authorized users of population health data, communities, and individual consumers.

This strategy supports the collection of appropriate information directly from consumers as well as community sources, with appropriate privacy protections in place, and the secure transmission of this information to population health agencies that are authorized to receive it. It also embraces dissemination of population health findings from population health agencies to consumers and communities. This mode of information exchange, which connects consumers to population health information without intermediation by health care providers, poses unique challenges that need to be examined and resolved, but the potential benefits are significant.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 2.3 provides a list of these initiatives along with the appendix page where a summary of each can be found. Activities across the government include deployment of systems, infrastructure, and policies that enable secure adoption, use and integration of population based exchange of health information.

Table 2.3 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 2.3
Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30)
ASPR: Homeland Security Presidential Directive 21 (Page A32), Pandemic All-Hazards Preparedness Act (PAHPA: Page A33)
CDC: BioSense (Page A33), Public Health Information Network (Page A34)
CMS: ICD-10 (Page A36), Medicaid Information Technology Architecture (MITA: Page A36)
FDA: Sentinel Network (Page A38), Structured Product Labeling for Products (Page A38)
IHS: National Data Repository (Page A40)
NIH: Health Informatics R & D (Page A43), Clinical Translational Science Awards (Page A42), Support, Maintenance, & Dissemination of Standard Clinical Vocabularies (Page A43)
ONC: Use Case Development (Page A49)
HHS/OS: Personalized Healthcare (Page A52), Value-driven Health Care (Page A53)
SAMHSA: Health IT Initiatives (Page A54)
DoD: AHLTA (Page A56)

Federal Advisory Committees
American Health Information Community (AHIC: Page A63), with its workgroups on Chronic Care (Page A65), Consumer Empowerment (Page A65), Electronic Health Records (Page A65), Personalized Healthcare (Page A66)

Objective 2.4 – Collaborative Governance: Establish coordinated and effective organizational processes—at the federal, state, local, and tribal levels—to promote the availability and management of aggregated clinical information to benefit population health.

Measure: Percentage of governance entities with responsibility related to the exchange and use of information for population health that comply with consensus-based policies and processes. (Developmental.)

Target: To be determined, pending review of baseline data collected in 2010.

Method: Survey of governance entities or results of accreditation process if one is in place.

Discussion

Interoperable exchange of health information enables access to electronic health information for population health uses: public health, biomedical research, quality improvement and emergency preparedness. Numerous needs for population health information exist across all levels of government and in the private sector. Each type of use has unique considerations, requiring tailored mechanisms and organizational policies and practices to aggregate and share electronic health data. Accountability mechanisms are needed to ensure that organizational policies and processes across organizations overseeing the exchange of health information protect consumers while meeting public health needs and goals. Appropriate organization policies and processes, consistent with nationwide policies, will facilitate the building of a common information exchange infrastructure and ensure that all stakeholders participate in and benefit from the exchange of health information for various purposes.

- Coordination of data capture and aggregation across federal, state, local, and tribal levels is critical to ensure the *timely access and use* of electronic health information for population health purposes.
- Collaborative governance entities at regional, state, and national levels will directly engage a wide-range of agencies and other stakeholders to establish policies and processes for the appropriate use of data for population health. While federal agencies directly responsible for public health, biomedical research, quality improvement and emergency preparedness must determine how to use IT to support their missions, collaborative governance involving the public and private sectors will ensure *appropriate and authorized access and use* of data from the exchange of health information for population health purposes.

Strategies

Six strategies combine to achieve Objective 2.4 of facilitating governance and coordination of the availability and management of electronic health information for population health purposes. (Details in Appendix A beginning on Page A21.)

Strategy 2.4.1: Establish and monitor the use of data stewardship models that allow for capture and consistent use of electronic health data for population health purposes through common practices compliant with laws and organizational policies.

Appropriate data stewardship within existing laws and organizational policies is necessary to make needed data available to authorized population health users. This strategy works to establish a foundation of policies and procedures to ensure authorized and appropriate use of electronic health information for public health, biomedical research, quality improvement, and emergency preparedness. This foundation will facilitate a consistent approach to data stewardship across initiatives for the exchange of health information that are also involved with data aggregation and sharing for population health purposes.

Strategy 2.4.2: In concert with federal partners, identify and coordinate priorities, policies, and practices that are needed to develop and implement quality measures in ways that are compatible with different models for the exchange of health information.

There are unique concerns related to the collection and aggregation of electronic health information for defining and evaluating quality of care. This strategy supports the effective use of electronic health data by facilitating standardized data elements aligned across multiple stakeholders' quality measurement initiatives and promotes the use of an automated common set of electronic data elements. The use of this common data set will facilitate collection and aggregation of electronic health data that forms more complex and complete data resources for quality measurement.

Strategy 2.4.3: Identify mechanisms, policies, and practices needed to connect clinical care and public health for public health purposes, including biosurveillance and emergency preparedness.

The exchange of electronic health information can support public health data needs at the federal, state, local, and tribal levels. This strategy will facilitate increased use of automated electronic health information for public health, biosurveillance, and emergency preparedness by promoting coordination and governance across jurisdictions to establish best practices for automated data collection, aggregation, and reporting.

Strategy 2.4.4: Identify priorities, policies, and practices needed to connect clinical care and research for the purpose of advancing basic, clinical, and health services research.

Making comprehensive and timely data available for basic, clinical, and health services research through the exchange of electronic health information can advance medical knowledge. This strategy fosters a collaborative approach to identifying the data needs of researchers, promoting privacy protections for patients and consumers (including informed consent), and establishing best practices for aggregating and sharing clinical data sources for research.

Strategy 2.4.5: Create accountability for organizations responsible for implementing policies and practices for exchange of electronic health information.

Standard policies and procedures for entities that exchange health information can ensure that patient privacy protections are maintained as data are aggregated and shared for population health purposes. This strategy promotes consistent application of those policies and procedures through accountability mechanisms, including accreditation.

Strategy 2.4.6: To the extent permitted by law, develop, implement, and oversee a health data sharing strategy across federal agencies that will leverage available electronic health information from multiple sources to meet the needs of population health programs including public health, biomedical research, quality improvement and emergency preparedness.

Federal and public health programs that utilize population health information could be augmented by a data sharing strategy that enables access and use of standards-based sharing of electronic health information from clinical care providers. This strategy aims to increase federal use of electronic health data, to the extent permitted by law, by identifying programmatic needs and implementing a data sharing strategy to meet those needs. These steps will help federal agencies to analyze data requirements and availability and support standardized procedures for data sharing necessary to realize the full benefit of using electronic health information to support population health programs.

Recent Federal Government Progress

Several federal agencies are involved in multiple initiatives that will advance this objective. This work has at times been informed by certain federal advisory body recommendations that were submitted to the Secretary of HHS. Table 2.4 provides a list of these initiatives along with the appendix page where a summary of each can be found. The majority of their activities focus on coordinating emergency preparedness and other population health oriented initiatives. Activities also seek to build consensus among a broad range of health IT stakeholders on federal and state health IT priorities and policies that affect the range of population health activities including research and quality improvement.

Table 2.4 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 2.4
Federal Agency and Department Initiatives
ASPR: Homeland Security Presidential Directive 21 (Page A32), Pandemic All-Hazards Preparedness Act (PAHPA: Page A33)
NIH: Clinical Translational Science Awards (Page A42)
ONC: Federal Interdepartmental Health IT Collaborative [Multi-agency] (Page A46), Federal Health Architecture (FHA) [Multi-agency] (Page A47), Federal Interagency Health IT Policy Council [Multi-agency] (Page A47), Planning for AHIC 2.0 (Page A48), State Alliance for e-Health (Page A48)
Other Public-Private Sector Initiatives
National Quality Forum (NQF: Page A62)
Federal Advisory Committees
National Committee on Vital and Health Statistics (NCVHS: Page A62)
American Health Information Community (AHIC: Page A63), with its workgroups on Population Health and Clinical Care Connections (Page A66), Quality (Page A67)

Appendix A: Strategies, Milestones and Action Items

Strategies for Objective 1.1

Privacy and Security: Identify any policy issues, gaps or barriers – and advance the development of approaches – to facilitate the electronic exchange, access, and use of health information, while protecting the privacy and security of patients’ health information.

Strategy 1.1.1: Develop a confidentiality, privacy, and security framework for policy development to promote patient and consumer trust in, and advance the electronic exchange of, health information.

Because privacy and security policies currently differ between the federal and state levels, across states, across organizations, and among distinct stakeholders and users of data, this strategy is critical to establishing guidance for policy development relative to the exchange of electronic health information within and across jurisdictions. EO 13335 requires the Strategic Plan to address privacy and security issues related to health IT. The FY 2008 Congressional Appropriations Committee Report (House Report Number 110-231) requested that ONC develop a “confidentiality, privacy and security framework.” Building from HIPAA and other existing Federal privacy and security laws such as the Privacy Act and the Federal Information Security Management Act, a confidentiality, privacy, and security framework will be the result of a federally led effort involving stakeholders community-wide and will serve to promote trust among consumers and users of electronic individual health information and to guide all efforts to advance the exchange of electronic health information for the care and treatment of patients. Confidentiality, privacy, and security principles will serve as a resource for developing organizational and state governmental policies and will aid the further development of federal governmental policies. HHS will explore the possible use of federal procurement and agency programs for these principles to gain traction.

The following illustrative actions supporting this strategy address the need to engender the public’s trust in the exchange of electronic health information for health care delivery. Stakeholders need to be engaged in a transparent and inclusive process to develop a confidentiality, privacy, and security framework:

- Based on common themes identified in published sets of privacy and security principles, develop a draft confidentiality, privacy, and security framework for policy development.
- Obtain federal government and public, which includes consumers, acceptance on the draft framework and develop the final framework.
- Publish the confidentiality, privacy, and security framework.

This framework will take into account *health care delivery system* needs, when addressing privacy and security as they relate to the exchange of electronic health information for health care delivery purposes.

Milestone 1.1.1: In 2008, ONC will publish a confidentiality, privacy, and security framework and engage stakeholders in a dialogue regarding the principles and health care delivery-related

*activities to foster trust in the exchange of electronic health information among patients, consumers, providers and other stakeholders.**

Strategy 1.1.2: Identify best practices for implementing technical solutions to ensure confidentiality, integrity, and availability of electronic health information consistent with the confidentiality, privacy, and security framework.

In order to be accountable to the baseline principles established by the confidentiality, privacy, and security framework, the technical capabilities of EHRs, PHRs and other consumer health IT tools, individually-oriented health data bases, and networks for the exchange of health information will need to be examined and may require adaptations. The following illustrative actions supporting this strategy will leverage existing expert resources to develop guidance on technical solutions:

- Conduct outreach to relevant stakeholders to understand current and emerging practices and technologies for appropriately managing and enforcing the confidentiality, integrity, and availability of electronic health information (e.g., discuss with various types of health care stakeholders the current EHR/PHR systems being used in order to understand what practices may be implemented by using and building on existing technologies).
- Identify the range of best practices for implementing technical solutions for confidentiality, integrity, and availability of electronic health information consistent with the confidentiality, privacy and security framework.
- Collaborate with relevant agencies and offices to publish guidance on best practices for implementing technical solutions for confidentiality, integrity, and availability of electronic health information.

Milestone 1.1.2: By 2010, disseminated best practices for implementing technical solutions for the confidentiality, integrity, and availability of electronic health information are used to inform standards development, as well as recognized certifying bodies' electronic health record and network certification criteria.

Strategy 1.1.3: Facilitate state-based activities to identify and address challenges to the use of health information technology, and the intra- and inter-jurisdictional exchange of electronic health information, while preserving or enhancing the current level of patient protections.

Many state laws that address or impact privacy or the disclosure of electronic health information were written before interoperable health IT and the widespread exchange of electronic health information were feasible and became commonplace and, as such, may inadvertently and unnecessarily prohibit or significantly limit the appropriate exchange of electronic health information. In addition, certain conflicts and inconsistencies exist among these various statutes, regulations, and policies, whether perceived or real, which present challenges to the appropriate electronic exchange of health information. As in the previous strategy, it is important to emphasize the importance of preserving or enhancing patient and consumer protections. The following illustrative actions supporting this strategy highlight ONC's role to facilitate state efforts to reach consensus on how to appropriately address such challenges to both intra- and inter-state exchange of electronic health information:

* All milestone dates should be assumed to refer to the end of the designated year.

- Facilitate the evaluation of relevant state statutes, policies, and practices regarding privacy and security protections and data access restrictions – to identify challenges to the use of health IT and the intra- and inter-state exchange of electronic health information.
- Facilitate the identification of common approaches for addressing challenges to the use of health IT and the intra- and inter-state exchange of electronic health information, while assessing the extent to which those approaches could impact crucial patient and consumer protections.
- Foster the development of guidance for state-based best practices that identify and address challenges to: the use of health IT, the exchange of electronic health information, and opportunities for preserving and enhancing patient and provider protections.

Milestone 1.1.3: By 2009, states work collaboratively to develop approaches for greater commonality to facilitate the exchange of electronic health information and preserve or enhance the current level of protections.

Strategy 1.1.4: Increase stakeholder understanding of current federal health privacy and security statutes and regulations in order to promote trust in the use of health information technology and the exchange of electronic health information for health care treatment purposes.

Misinterpretation and misapplication of federal health privacy and security statutes and regulations result in a reluctance by providers to share patients' personal health information for health care delivery purposes. In addition, patients' lack of understanding of these privacy and security statutes and regulations, and of the rights the laws afford them, contribute to mistrust, which limits the exchange of electronic health information. The following illustrative actions that support this strategy focus on increasing stakeholder trust in the exchange of electronic health information for health care delivery purposes by identifying the areas of greatest concern and providing education:

- Compile misconceptions/misunderstandings about consumer privacy and security protections.
- Develop educational tools to increase stakeholder, including patient and consumer, understanding of federal privacy protections.
- Develop guidance to clarify select federal privacy and security statutes and regulations as they apply to the exchange of electronic health information.

Milestone 1.1.4: By 2009, stakeholder-specific guidance that clarifies select federal privacy and security statutes and regulations as they apply to the exchange of electronic health information is published and made available to all stakeholders.

Strategy 1.1.5: Identify and evaluate approaches to address federal statutes or regulations that conflict or are inconsistent – or are perceived to conflict or be inconsistent --with the exchange of electronic health information for health care delivery, while preserving or enhancing patient protections.

Some federal statutes and regulations that address or impact the disclosure of health information were written before interoperable health IT and widespread electronic exchange of health information were contemplated, and as such, may inadvertently and unnecessarily prohibit or limit the appropriate exchange of electronic health information for care and treatment purposes.

In addition, perceived inconsistencies among these various statutes, regulations, and policies present further challenges to the appropriate electronic exchange of health information. The following illustrative actions supporting this strategy promote an inclusive process for addressing those areas in which federal regulations pose challenges to the exchange of electronic health information, while maintaining or enhancing current levels of patient and consumer privacy protections:

- Work with federal agencies to identify statutes, regulations, or policies that may inadvertently and unnecessarily prohibit or limit the appropriate use of health IT and the exchange of electronic health information and, as authorized, seek changes that would address such restrictions.
- Work with consumer and industry representatives to identify ways to preserve or enhance patient protections.
- Engage in activities (e.g., developing guidance) to address challenges created by federal regulations.

Milestone 1.1.5: Guidance is published by relevant agencies related to the exchange of electronic health information to appropriately improve the consistency and currency of policy by 2011.

Strategies for Objective 1.2

Interoperability: Enable the exchange of interoperable health information among health care providers and organizations, as well as patients and their designees, to support patients' health and care needs.

Strategy 1.2.1: Advance the identification, availability, and use of specified data and technical standards for interoperability that meet critical provider and individual information needs.

This strategy is critical to establishing a foundation of common, recognized interoperability standards and specifications for the exchange of health information. It builds on existing standards harmonization efforts, leverages the provisions of Executive Order 13410 that seek to advance recognized interoperability standards (see Page 15), and supports the development of new health information exchange standards where necessary. The following illustrative action steps will increase the availability and use of highly specified data and technical standards:

- Continue to prioritize and expand a set of common data elements in EHRs, PHRs, and other consumer health IT tools necessary to enable critical provider and patient information needs through interoperable health information networks.
- Promote efforts to ensure inclusion of appropriate and consistent data and technical standards into certification requirements for EHRs, PHRs, and other consumer health IT tools and networks.
- Ensure that standards are used in relevant federal contracts, consistent with the EO 13410, "Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs" (see description of "Value-Driven Health Care," in Appendix C, page A53).

Milestone 1.2.1: By 2009, federal government entities (and their contractors) will have initiated and will continue to facilitate the use of critical data interoperability standards as well as agreements covering electronic data.

Strategy 1.2.2: Identify core capabilities and governance necessary for networks to work with other networks in support of secure exchange of electronic health information using non-proprietary standards.

Health information exchange solutions and networks have frequently been developed to meet specific, often proprietary, needs. Each solution has a unique mission and set of technologies, policies, and governance. As a result, many networks cannot easily exchange information with other networks. This strategy is critical to ensuring that disparate networks are able to communicate with each other. The following illustrative action steps will promote widespread interoperability of health information networks and enable non-proprietary exchange of information:

- Leverage existing electronic data inter-exchange systems that transport sensitive data and work with evolving health information networks to understand the range of network services, policies, and governance structures.
- Promote the development of standards for requisite data and technical needs in the certification of health information exchange networks to support core services, including security, through the NHIN and HITSP.
- Assist in identifying the specifications that support network-to-network exchange for enhanced care delivery and patient self-management.

Milestone 1.2.2: By 2009, core service capabilities and data use agreements for sharing health information through a network will be publicly available for national, state, interstate, local, and tribal health information networks to use when exchanging health information.

Strategy 1.2.3: Foster the business case for the self-sustaining exchange of health information in communities, states, and nationwide.

Sustainable exchange of health information within and across regions and states is essential to improve patient care and health. Federal and state governments need to consider and evaluate policy options to encourage participation in the exchange of health information through regional, state, and other networks that use recognized interoperability standards and NHIN specifications. The following illustrative action steps begin to explore ways to advance the business case:

- Determine mechanisms and approaches to develop sustainable exchange of health information, a market for service providers and products enabled by the exchange of health information.
- Identify the role of government in supporting the development of the exchange of health information nationwide.
- Evaluate the value of the exchange of health information to various stakeholders in communities with operational data exchange across providers.

Milestone 1.2.3: By 2009, an approach is determined for developing a robust, competitive market, informed by emerging evidence related to the value of the exchange of health information.

Strategy 1.2.4: Increase the amount of health information being exchanged electronically using the specified standards for the exchange of health information – to enhance the value for other providers, provider organizations, and networks to adopt the standards.

The electronic exchange of health information has been hindered by a variety of barriers, real and perceived. This strategy is critical to overcoming these challenges by promoting sufficient information availability through provider participation. The federal government, with support from relevant stakeholders, will enhance health information available for exchange and support a range of approaches and models designed to support the exchange of health information. An NHIN that connects several models of information exchange—geographically based entities (RHIOs and regional HIEs), integrated delivery systems, and health data banks for personally controlled health records--through the use of interoperability standards will enable greater information exchange across more diverse users and settings. The illustrative action steps will help gauge participation and promote connectivity:

- Monitor engagement levels and measure growth in the exchange of health information across care settings.
- Identify and address barriers to provider and patient involvement in the exchange of health information.
- Connect standards-based initiatives for the exchange of health information at federal, state, local, and tribal levels that have electronic health information available for providers and provider organizations.

Milestone 1.2.4: By 2010, providers and provider organizations will use recognized interoperability standards and NHIN specifications to connect their health information networks with other providers and provider organizations.

Strategy 1.2.5: Promote the development of the processes and infrastructure for testing, verification and implementation of the recognized standards and services, and nationwide policies in networks, connected systems, and health IT.

The development and harmonization, of data and technical standards and policies into certification requirements is necessary but not sufficient for the continued growth and enhanced capabilities of interoperable networks. The ability to test for and verify the implementation of these standards in deployed systems is critical to ensuring consistent implementation of data standards, services, and policies needed to support interoperable exchange of health information. The following illustrative action steps will help strengthen and enhance verification processes to include testing and validation functions:

- Support efforts to certify the exchange of health information and connected systems.
- Promote the development of the processes and infrastructure for testing and verifying that data and technical standards and policies needed to support interoperability are being implemented.
- Promote processes and the provision of services that enable health information service provider accreditation and network certification consistent with emerging data and technical standards and requisite data policies, including appropriate access policies.

Milestone 1.2.5: By 2010, testing tools and data, as well as testing criteria for certifying standards and services, are available.

Strategy 1.2.6: Encourage health care organizations to provide personal health information in useable standardized electronic form to consumers or their designees.

Many health care organizations do not offer electronic availability of personal health information to consumers or their designees. Strategy 1.2.6 is critical to ensuring that individuals have full electronic access to their health information and can play an active role managing their own health care using tools and services of their choice. This availability will also help with portability across different provider organizations. The action steps supporting this strategy foster the availability of electronic health information (when available in electronic form by the health care organization) to consumers or their designees to enable them to better manage their own health and health care. The following illustrative action steps will help establish a foundation for the development of secure consumer health IT tools and health care providers and organizations to support consumer access:

- Identify and prioritize the electronic personal health information needs of consumers and their designees.
- Demonstrate consumer-oriented uses of electronic personal health information using the NHIN core services.
- Support development of processes to certify the security and portability of personal health records, health data banks, or other consumer health IT tools that could interface with interoperable health information networks.

Milestone 1.2.6: By 2012, consumers and their designees or surrogates have increased access to and use of personal health information via interoperable health information networks or technologies.

Strategy 1.2.7: Increase the availability of health information service providers that compete to support the exchange of health information.

A number of different models for the exchange of health information have emerged across the country, but most organizations still cannot exchange standards-based data with others. Exchange must be supported in many unique ways in many locations. This strategy is critical to supporting interoperable health information networks by encouraging a market for companies supporting standards-based services for the exchange of health information. The following illustrative action steps will help foster a marketplace for accredited health information service providers in many jurisdictions:

- Document the range of health information service providers, their services, and the breadth of their availability.
- Work with voluntary consensus based standards organizations (e.g., HITSP) to identify a minimum set of standards for certification and/or accreditation of health information service providers and foster their use nationwide.
- Work with industry representatives to identify barriers, such as potential liability issues, regulatory uncertainties and inter-state conflicts, to offering health information services.

The ultimate goal is to enable all types of electronic health information, including lab results, prescription histories, medical images and information from health care tools (e.g., blood pressure readings, risk assessment tools and other monitoring devices) and more, to flow into an EHR or PHR to form a comprehensive portrayal of the patient's health.

Milestone 1.2.7: By 2012, a consistent and visible increase in the number of commercial health information service providers to meet the growing demand of health organizations and individuals who desire to exchange information electronically.

Strategy 1.2.8: Through the identification and recognition of standards, empower individuals to use their health data to serve their needs beyond direct patient care delivery.

There are a number of uses for medical data outside of care delivery and population health, such as disease prevention, immunization records required for school attendance, and entitlement determinations for disability benefits. These potential uses present their own unique challenges to data access – including consumer control over how data is used, and by whom. Consumers and their designees must understand the range of possible uses of their data outside of health care delivery and population health in order to make informed choices about permitting access to their data. Additionally, appropriate standards need to be developed to ensure that users of a patient's health information can operate within the parameters authorized by law or by the patient and his/her designees, and so that EHRs and PHRs can support the automated exchange of medical information for non-health care purposes. Moreover, developing the value proposition for exchanging medical information for these purposes will help health care delivery and population health agencies and organizations understand the benefits of supporting these consumer needs. The following illustrative action steps will serve to expand the discussion about standards, to adapt to these needs and to provide benefits to the overall health care system:

- Work with voluntary consensus based standards organizations (e.g., HITSP and HL7) to identify standards gaps and develop appropriate standards.
- Work with consumer representative organizations to educate the consumer on the values and options of using medical information for non-health care purposes.
- Develop a value proposition to inform health care delivery and population health agencies and organizations of consumer benefits of exchanging medical information for non-health care purposes.

Milestone 1.2.8: By 2009, standards exist for handling the patient's authorized release of information to a trusted entity for non-health care purposes.

Strategies for Objective 1.3

***Adoption:* Promote the nationwide adoption of interoperable electronic health records (EHRs) by providers, and the adoption of personal health records (PHRs) and other consumer health IT tools by consumers and their designees.**

Strategy 1.3.1: Remove business barriers and disincentives for provider and delivery system adoption of EHRs.

Current EHR adoption rates remain low among both physicians and hospitals. The high cost of procurement, implementation, and maintenance of both IT hardware and EHR software are a primary barrier to more widespread adoption. Furthermore, evidence suggests that return on EHR investment accrues towards the payers of health care (health insurers, employers, and consumers), more than to providers, even though providers can realize some financial benefit. The relationship of malpractice premiums to EHR use is a complex issue that could be the

source of strong incentives for adoption of EHRs. The following illustrative actions steps are designed to minimize these provider barriers to EHR adoption, better quantify benefits that accrue to various stakeholders when EHRs are fully implemented, and develop promotion programs that leverage these benefits and ultimately drive widespread adoption.

- In coordination with public and private sector efforts, a five year demonstration project to evaluate types of incentives that promote adoption of certified EHRs among providers has been launched. (This is the CMS Demonstration discussed elsewhere in this document.)
- Evaluate the costs and benefits to various stakeholders that promote interoperable health IT.
- Confirm through literature reviews and perhaps studies that use of interoperable health IT reduces medical errors and improves patient care.

Milestone 1.3.1: By 2010, physicians using certified EHRs are eligible for malpractice credit.

Strategy 1.3.2: Increase the likelihood of efficient and effective EHR purchase and implementation.

The EHR adoption process for providers is complicated, time consuming, and includes multiple steps (e.g., readiness assessment, vendor selection, workflow redesign, and contract negotiations). The actual EHR implementation process is also complicated and decreases productivity in the short term. Without sufficient provider training and support during these processes, failure rates can be significant. The following illustrative action steps are intended to lead to a better understanding of these challenges and provide information to physicians and others so that they may confidently invest in and effectively use their EHRs.

- Evaluate various private and public approaches to supporting providers through the EHR adoption process with respect to efficiency, provider satisfaction, and adoption success rates.
- Work with vendors to develop and offer guidance on efficient implementation and effective use as components of their “implementation support package.”
- Collaborate with medical societies and associations to ensure that information on the adoption process is readily available to all interested providers.

Milestone 1.3.2: By 2009, information on low-cost, effective and user-friendly approaches for provider support for the EHR adoption process is available through web linkages from multiple sources.

Strategy 1.3.3: Increase value of EHRs through interoperability, clinical decision support, and other technical advances.

EHR adoption, particularly in the office setting, can be both disruptive and costly. As a result, some providers may be hesitant to invest in such products, which ultimately contributes to low adoption rates. To offset these factors and to stimulate adoption of such products and to improve patient safety and the quality and efficiency of health care, providers must realize a high degree of value from EHRs and related technologies. Such value derives from clinical decision support, workflow enhancements, and access to more complete and better organized information. The following illustrative action steps support this strategy’s focus on the technical aspects of an EHR that can enhance care delivery and thus create value for physicians and other health care practitioners.

- Develop a set of use cases for HITSP harmonization of interoperability standards and certification processes that support the needs of providers in caring for their patients.
- Incorporate EHR functionalities into health IT certification that decrease administrative burden.
- Incorporate EHR functionalities into health IT certification that provide clinical decision support at the point of care.

Milestone 1.3.3: By 2010, certified EHRs include clinical decision support.

Strategy 1.3.4: Promote certified health IT products as critical components and standards of clinical care.

Health IT can increase quality of care and improve efficiency in the delivery system. Certification ensures that IT products have the specific capabilities that enable these benefits. As more patients become aware of and directly experience the related benefits, including better access to and understanding of electronic health information, patients will increasingly expect providers to invest in and regularly use health IT in care delivery. The following illustrative actions signal the federal government's commitment to the adoption of certified EHR products and increase consumer exposure to certified EHRs, thus facilitating a broader general understanding of their benefits.

- Specify that, to the extent permitted by law, certified EHRs and products are necessary components for any federally funded programs, pilots, and demonstrations that include the use of health IT.
- To the extent permitted by law, include language in federal contracts and grants specifying that certified products and services should be used and encouraged in direct patient care purposes and for products and services directed to consumers.
- Evaluate level of support necessary for safety net providers to invest in certified EHRs and develop ways to provide that support.

Milestone 1.3.4: By 2010, the majority of health IT products used by clinicians are certified.

Strategy 1.3.5: Develop the workforce for health IT product development and use.

In order to fully realize the benefit of health IT, a dedicated and well-trained workforce is needed. Providers and staff must be trained to use health IT, while vendors and other relevant stakeholders must be trained to support the implementation of these tools. A wide array of professionals, including care providers, educators, health IT vendors, and standards developers will be required to support the transition to IT enabled health care delivery. The following illustrative action steps facilitate the development of a robust and comprehensive workforce supported throughout the industry.

- Evaluate workforce needs for development, implementation, use, and maintenance within the areas of clinical knowledge, biotechnology, public health, and research.
- Working with OPM, promote designation of Federal health IT positions within the occupational classification system.
- Engage health professional licensing bodies in incorporating informatics competencies in the licensing process.
- Incorporate informatics competencies in Federal academic programs, mentorship/fellowship programs to the extent permitted by law.

Milestone 1.3.5: Study released by 2010 that quantifies the workforce needed to support the near-term and long-term priorities to support national deployment of interoperable health IT.

Strategy 1.3.6: Identify key PHR functions and features that will allow individuals to link their health information to a wide variety of market driven personal health tools that they and their designees find valuable in managing their health and care.

The current low rate of adoption of PHRs and other consumer health IT products, services, and tools may reflect a lack of understanding of what they do and the benefits they provide, what privacy and security protections are in place, how they link to and communicate with other products and services, and the features and functions individuals find valuable in managing their health. The following illustrative action steps supporting this strategy address these issues, and provide opportunities to better meet the needs of multiple and diverse populations.

- Develop clear definitions for constructs and terms related to consumer/patient controlled personal health information products and services.
- Promote certification processes for personal health information products and services regarding interoperability standards, security standards, and consistent privacy policies.
- Develop a standardized “disclosure” statement that informs consumers about the privacy policies of market driven consumer oriented tools and services.

Milestone 1.3.6: By 2009, consensus is reached regarding the basic components of a certified personal health record.

Strategy 1.3.7: Design methods to promote the use of PHRs and other consumer health IT tools by consumers and their designees.

The types of health information important to consumers, how it is protected, how it is presented, and how it will be used are still poorly understood. The role of incentives, both financial and non-monetary, to promote adoption of PHRs is also unclear. The following illustrative action steps supporting this strategy are intended to increase the understanding of consumer use of consumer-oriented health IT products and services, the current incentives in place and their impact, and better support widespread adoption through various promotion strategies, including communication on privacy and security protections.

- Develop appropriate education for consumers on the value of health IT.
- Create consumer guidance tools on issues related to privacy, security, and interoperability.
- Promote the availability of PHRs and other consumer health IT products and services to specific populations, such as individuals in rural areas and the underserved.

These and other steps will also serve to engage other stakeholders in promoting adoption.

Milestone 1.3.7: By 2010, creation of a plan that can guide efforts directed at developing and marketing personal health information tools

Strategy 1.3.8: Minimize liability risks and clarify misperceptions of liability risks for providers using health IT, while preserving or enhancing patient protections.

There are both real and perceived liability risks associated with provider adoption of EHRs and participation in the exchange of electronic health information. Supporting providers in fully and accurately understanding these risks and how best to mitigate those that are real is critical to increasing adoption. This is a market-driven strategy because certification can ensure that the

IT products have the functional features that can mitigate risk. The following illustrative action steps seek to clarify and disseminate information on these real and perceived liability risks, and to identify technical solutions that can be incorporated into EHR products to mitigate risk.

- Engage medical societies, associations, and federations of state licensing boards in disseminating factual information regarding medical liability, health IT, and the exchange of electronic health information.
- Promote in the recognized certification bodies' certification requirements, functional criteria that can improve decision-making (e.g., clinical decision support) and reduce errors.
- Conduct annual surveys of various types of providers that include measures of perceived liability risk.

Milestone 1.3.8: By 2011, providers have increased understanding of liability risks in using health IT and engaging in the exchange of electronic health information.

Strategy 1.3.9: Remove technical, financial, workflow, and other barriers to diagnosing, treating, and communicating with patients outside the boundaries of traditional health care settings.

Health IT, and the electronic exchange of patient information that it enables, are rapidly transforming how health care can be delivered. Remote devices allow providers to deliver care and monitor patients, regardless of the location of the patient. Many technical, legal, financial and workflow barriers, however, prohibit widespread adoption of technologies that support improved communication, diagnosis, and treatment outside of the clinical setting. The following illustrative action steps focus on understanding the sources of these barriers and identifying solutions to promote widespread use of these technologies in the future.

- Support on-going and new programs that evaluate both the cost and quality outcomes associated with the provision of care supported by care using communications and technologies outside of the clinical setting.
- Support the harmonization of standards for interoperability of data generated by remote monitoring devices.
- Remove barriers to electronic communications between patients and their providers as an evidence-based first step in engaging consumers in using health IT to manage their own health.

Milestone 1.3.9: By 2012, results of public/private collaborations supporting secure messaging pilots in three independent sites are published.

Strategies for Objective 1.4

***Collaborative Governance:* Establish mechanisms for equitable and balanced multi-stakeholder priority-setting and decision-making to achieve a secure, nationwide, interoperable health information technology infrastructure.**

Strategy 1.4.1: Establish a national public-private governance entity to advance interoperability and sustainable exchange of health information nationwide.

It is important that the priorities and activities surrounding the nation's health IT agenda be defined and governed by an objective, equitable, broadly representative, and transparent entity. The action steps supporting this strategy are designed to ensure governance at national, state, and local levels to implement policies and procedures for appropriate use and exchange of electronic health information. This strategy recognizes the exchange of health information for care delivery as the first priority for widespread adoption, but as the current AHIC has considered when formulating its recommendations to HHS, these health care requirements must be coordinated with those necessary to meet population health needs. The following illustrative steps in conjunction with other action steps will help ensure the establishment of representative multi-stakeholder governance for the exchange of health information at national, state, local, and tribal levels and help ensure that broad perspective and priorities are considered:

- Establish a successor to the current AHIC (currently being referred to as "AHIC 2.0") that will assume new governance and priority setting responsibilities related to health information standards and interoperability.
- Ensure AHIC 2.0 develops an equitable, balanced, and broadly representative multi-stakeholder approach to identify priorities and key governance issues for automated electronic exchange of health information.
- Support development of accreditation of governance entities for the exchange of health information across national, state, and local levels.

Milestone 1.4.1: By 2009, a fully operational entity with broad representation from the public and private sectors that provides effective oversight of electronic data exchange and uses across the country.

Strategy 1.4.2: Empower consumers through representation in multi-stakeholder governance entities at the national, state, and local level.

Consumer participation in national, state, and local level governance entities is necessary to ensure representation of consumer interest. This level of consumer involvement will enable health IT initiatives to better reflect consumer priorities, ensure public trust, and maximize consumer welfare. The action steps below emphasize the importance of consumer involvement in developing policies and procedures around the exchange of health information, identify and disseminate best practices and models for engaging consumers, and work to promote actual consumer involvement in activities nationwide. The following illustrative steps in conjunction with other action steps will help ensure that perspectives and priorities of consumers are appropriately reflected in policies and governance for the exchange of health information nationwide.

- Encourage multi-stakeholder governance models that incorporate consumer perspectives and preferences in policies and operations for the exchange of health information.
- Identify best practices for multi-stakeholder governance models that promote effective and efficient decision making – and promote consumer engagement in multi-stakeholder governance activities at the federal, state, local, and tribal levels.
- Support development of accreditation of governance entities for the exchange of health information across national, state, and local levels.

Milestone 1.4.2: By 2011, consumers consistently participate in activities related to the exchange of health information and in related oversight bodies across the country, and ensure that consumer perspective is represented and valued in these processes.

Strategy 1.4.3: Promote participation by federal, state, local, and tribal government representatives in multi-stakeholder governance entities for the exchange of health information at all appropriate levels: national, state, and local.

Coordination and mutual participation by federal, state, local, and tribal government representatives is needed to ensure communication and align priorities regarding the use and exchange of health information that supports patient-focused health care nationwide. Participation is needed for government representatives on health IT governance entities at their geographic level and above. The illustrative action steps below are designed to sustain regular and organized interaction, collaboration, communication, and participation in such activities. The action steps also emphasize the need to promote shared and complementary participation in governance activities and to align goals and policies for the exchange of electronic health information across all geographic levels nationwide:

- Identify the range of governance functions for the exchange of electronic health information at the national, state, local, and tribal levels.
- Support communication and collaboration across national, state, local, and tribal activities related to the exchange of health information – to facilitate alignment of activities.
- Support the priority setting process informed by federal, state, local, and tribal perspectives to ensure appropriate alignment and coordination of governance.

Milestone 1.4.3: By 2011, mechanisms enable federal, state, and local governance entities for the exchange of health information to have input into transparent decision-making processes.

Strategies for Objective 2.1

Privacy and Security: Advance the development of privacy and security policies, principles, procedures, and protections that facilitate appropriate access to, or transfer and use of, electronic health information for public health, biomedical research, quality improvement, and emergency preparedness.

Strategy 2.1.1: Employ the confidentiality, privacy, and security framework (see Strategy 1.1.1) for policy development to establish patient and consumer trust and advance the exchange of electronic health information for population health purposes.

Because privacy and security policies currently differ between the federal and state levels, across states, across organizations, and among distinct stakeholders and users of data, this strategy is critical to establishing guidance for consistent confidentiality, privacy and security policy-development relative to the electronic health information exchange within and across jurisdictions. As described under Strategy 1.1.1, Executive Order 13335 requires the Strategic Plan to address privacy and security issues related to health IT. Building from HIPAA and other existing Federal privacy and security laws, such as the Privacy Act and the Federal Information Security Management Act, this confidentiality, privacy and security framework will take into account the information needs for the range of population health activities, including public health, biomedical research, quality improvement, and emergency preparedness.

The following illustrative actions supporting this strategy address the need to engender the publics' trust in the exchange of electronic health information for population health. Stakeholders need to be engaged in a transparent and inclusive process to develop a

confidentiality, privacy, and security framework that provides guidance for policy development and implementation:

- Based on research on existing privacy and security principles, develop a draft confidentiality, privacy, and security framework, as noted in Strategy 1.1.1, that considers the needs of population health in the policy development process.
- Obtain federal government and public acceptance on the draft framework and develop the final framework.
- Publish final framework.

This framework will take into account the information needs for the range of *population health activities*, including public health, biomedical research, quality improvement, and emergency preparedness.

Milestone 2.1.1: By 2008, ONC will publish a confidentiality, privacy, and security framework and engage stakeholders in a dialogue regarding principles around which population health organizations can develop policies that enable appropriate, authorized, and timely access and use of electronic health information, and that foster trust among patients and consumers.

Strategy 2.1.2: Identify and evaluate federal statutes or regulations that conflict or are inconsistent – or are perceived to conflict or be inconsistent – with the exchange of electronic health information used for population health purposes, while preserving or enhancing patient protections.

Similar to Strategy 1.1.5, some federal statutes and regulations related to the disclosure of health information for population health uses were written before interoperable health IT and widespread exchange of health information were considered, and may inadvertently and unnecessarily prohibit or limit the appropriate exchange of such information – or may be perceived to do so. The following illustrative actions supporting this strategy suggest methods for addressing those areas related to exchange of electronic health information used for population health purposes in which federal laws pose – or are perceived to pose – challenges to the exchange of electronic health information, while maintaining or enhancing current levels of patient privacy protections:

- Work with federal agencies to identify regulations or policies regarding access to health care data for population health uses that may be conflicting, inconsistent, or outdated and to identify options for resolving conflicts or inconsistencies and updating those regulations or policies.
- Work with agencies and industry to identify and evaluate approaches, consistent with the framework developed in Strategy 2.1.1, for resolving conflicts or inconsistencies and updating regulations or policies regarding access to health care data for population health uses and enhancing select protections.
- Engage in activities (e.g., developing guidance) to address challenges created by federal regulations.

Milestone 2.1.2: By 2011, relevant agencies will identify any such laws and take appropriate action to facilitate the exchange of electronic health information for population health purposes and preserve or enhance patient protections.

Strategy 2.1.3: Facilitate state-based activities to identify and address challenges to the use of health information technology and the intra- and inter-state exchange of electronic health

information to support population health, while preserving or enhancing the current level of patient protections.

Many state laws that address or impact the privacy or the disclosure of electronic health information were written before interoperable health IT and the widespread exchange of electronic health information were feasible, and as such, may inadvertently and unnecessarily prohibit or significantly limit the appropriate exchange of electronic health information. In addition, perceived inconsistencies among these various statutes, regulations, and policies present further challenges to appropriate health information exchange. As in the previous strategy, an emphasis on the importance of preserving or enhancing patient and consumer protections is also present here. The following illustrative actions that support this strategy highlight ONC's role as a facilitator of state efforts to reach consensus on how to appropriately address such challenges to both intra and inter-state exchange of electronic health information to support population health activities:

- Facilitate the evaluation of relevant state laws, policies, and practices regarding privacy and security protections and data access restrictions to identify challenges to the use of health IT and the intra- and inter-state exchange of electronic health information for population health purposes.
- Facilitate the identification of common approaches for addressing challenges to the use of health IT and the intra- and inter-state exchange of electronic health information for population health purposes, while assessing the extent to which those approaches could impact crucial patient and consumer protections.
- Foster the development of guidance for state-based best practices that identify and address challenges to the use of health IT and the exchange of electronic health information for population health purposes, and opportunities for preserving and enhancing patient and provider protections.

Milestone 2.1.3: By 2011, guidance will be published for states to consider how to incorporate policies related to public health and electronic exchange of health information based on consensus recommendations.

Strategy 2.1.4: Increase stakeholder understanding of current federal health privacy and security laws in order to promote trust in the use of health IT and exchange of electronic health information for population health purposes.

Misinterpretation and misapplication of federal health privacy and security laws result in a reluctance by providers to share patients' personal health information for population health uses. Patients' lack of understanding of these privacy and security statutes and regulations, and of the rights the laws afford them, contribute to mistrust, which limits the exchange of electronic health information. The following illustrative actions that support this strategy focus on increasing stakeholder trust in the exchange of electronic health information for population health purposes by identifying the areas of greatest concern and providing education:

- Compile misconceptions/misunderstandings about consumer privacy and security protections.
- Develop educational tools to increase stakeholder, including patient and consumers, understanding of federal privacy protections.
- Work with relevant agencies and offices to develop guidance to clarify select federal privacy and security laws as they apply to the exchange of electronic health information for population health purposes.

Milestone 2.1.4: By 2011, appropriate federal agencies will work with stakeholders to identify issues and clarify, where appropriate, select federal privacy and security laws as they apply to the exchange of electronic health information for population health purposes.

Strategies for Objective 2.2

Interoperability: Enable the secure exchange of interoperable health information among health-related organizations – as well as providers, patients, and their designees – to support appropriate population-oriented uses.

Strategy 2.2.1: Advance the availability and use of consistent data and technical standards that enable the merging of comparable data originating from multiple organizations and sources in support of population health uses.

The exchange of electronic health information among different kinds of organizations offers great value in enabling population health uses, including public health, biomedical research, quality improvement, and emergency preparedness. This strategy is critical to ensuring the ability of different organizations to share and aggregate comparable electronic health information. The following illustrative action steps seek to advance EHR interoperability to include standards, technical architecture and certification requirements that support data sharing and use for population health purposes:

- Define and prioritize a set of consensus based data and technical standards for EHRs that are needed to enable population health uses through interoperable health information networks.
- Document and communicate identified gaps between available EHR standards and population health needs to relevant standards development organizations to inform their work plans and priority-setting processes.
- Promote efforts to ensure inclusion of appropriate and consistent standards into certification requirements for EHRs and networks.

Milestone 2.2.1: By 2009, population health-oriented users of information will be able to receive comparable data from different clinical sources through the use of consistent standards in clinical care for the exchange of health information.

Strategy 2.2.2: Allow for flexibility in the models for the exchange of health information (organizational, geographic, and personally controlled), while still advancing the specific standards and policies necessary to ensure that they all work together to meet population health needs.

This strategy supports different models for the exchange of health information, and innovation in developing new capabilities and services, while promoting consistency of standards to support interoperable exchange of electronic health information. The strategy also addresses the need to ensure that emerging technical standards for entities that exchange health information support the minimal necessary set of services and policies. The following illustrative action steps will help establish a foundation for the emerging marketplace of entities that exchange health information:

- Work with evolving entities that exchange health information to understand emerging technical requirements, the array of technical architectures, and range of network services, policies, and governance structures.
- Foster a dialogue among the array of population health information users and network providers on underlying reasons for and appropriate range of variation in network services, policies, and governance.
- Monitor emerging marketplace for barriers to innovative health information architectural design.

Milestone 2.2.2: By 2009, the exchange of standards for electronic health information will support at least the three different models for entities that exchange health information (organizationally-based, geographically-based, and personally controlled), while providing data for population health purposes.

Strategy 2.2.3: Assess the implementation of recognized standards and nationwide policies in entities that exchange health information.

Establishing the standards and policies that enable the exchange of health information is the first step to ensuring interoperability and is necessary but not sufficient for the continued growth and enhanced capabilities of interoperable networks. This strategy is critical to ensuring that organizations are able to appropriately and consistently employ those standards and policies. The following illustrative action steps will help strengthen and expand current standards development and certification processes to allow for testing of standards implementation:

- Support efforts to certify the exchange of health information.
- Develop processes and promote services that enable provider accreditation and network certification consistent with emerging data standards and requisite data policies, including appropriate access policies.
- Ensure that standards and terminologies, including value sets, are maintained to support availability and currency of recognized standards.

Milestone 2.2.3: By 2010, electronic verification capabilities will actively ensure that those who exchange health information use consistent standards and certification and, at times, accreditation will ensure the implementation of standards and policies that promote interoperability.

Strategy 2.2.4: Promote the availability of health information in a useable electronic form for appropriate population health users outside of direct patient care.

This strategy is critical to ensuring that electronic health information is available for population health needs, including public health, biomedical research, quality improvement, and emergency preparedness. This strategy builds on the emergence of an interoperable health information network using the standards developed through the NHIN initiative. It addresses the need to ensure that additional appropriate population health uses are defined and enabled as networks evolve. The following illustrative action steps draw on existing initiatives and expertise to specify population health information uses and needs and will help ensure that interoperable health information networks continue to meet these needs:

- Demonstrate population health uses of electronic health information through the NHIN trial implementations.

- Specify the electronic health information needs of research, quality, and public health organizations.
- Conduct ongoing evaluations of interoperable health information networks' ability to meet the evolving data needs of research, quality, public health, and emergency response organizations.

Milestone 2.2.4: By 2010, those who use the Nationwide Health Information Network specifications will begin to make aggregate electronic health information available to appropriate population health entities in a manner that meets their range of data needs.

Strategy 2.2.5: Advance the availability of needed clinical and resource information for providers and emergency response teams when responding to significant events that affect population health.

Health IT and networks for the exchange of health information can connect all members of emergency response teams – from the top levels of the federal government to the providers in the field – and enable timely access to comprehensive data. In particular, this strategy acknowledges the recently issued Homeland Security Presidential Directive (HSPD-21) establishing a National Strategy for Public Health and Medical Preparedness. The cabinet level Task Force and advisory committee established pursuant to this directive will play key roles in determining what automated health information support is needed and identifying current barriers to information availability and access. Other federal agencies working with the disaster response community will coordinate the Task Force efforts with relevant and needed standards and network interoperability development activities to ensure these requirements are addressed. The following illustrative action steps support and will make certain that the capabilities created through the NHIN can support emergency response:

- Work with voluntary consensus standards organizations (e.g., HITSP) to identify needed functionality through development of use cases, standards, and certification requirements to support emergency response.
- Advance critical network functionalities in the NHIN to support:
 - Situational Awareness
 - Emergency care
 - Outbreak management
 - Response management
 - Emergency Communication
- Identify barriers that could inhibit data access during disasters.

Milestone 2.2.5: By 2010, those who use the NHIN specifications will begin to provide information in a manner that meets the needs of emergency response.

Strategies for Objective 2.3

Adoption: Promote the nationwide adoption of information technologies that enable the reliable and efficient exchange of electronic health information to continuously improve population health activities and individual health care services.

Strategy 2.3.1: Establish mechanisms to optimize the exchange of information between care providers using EHRs and authorized users of population health data, as well as among authorized users and recipients of population health data.

The exchange of information between care providers and population health data users enables greater accessibility and utility of population health data for all parties. This strategy supports the efficient transmittal of information between providers using EHRs and authorized population health data users. The following illustrative action steps will enable timely, automated, and secure mechanisms for data transmittal:

- Prioritize information for population health uses that can be readily accessed and shared.
- Collaborate to identify and prioritize population health information, mechanisms to facilitate accessibility and use of electronic data, and technology and applications that support information exchange.
- Identify and address gaps in interoperability standards for applications that electronically transmit population health information to providers.

These and other steps will contribute to best practices for the exchange of health information between providers and population health data users.

Milestone 2.3.1: By 2012, standards will exist that increase the automation of clinical information electronically sent and accessed by providers and authorized population health data users.

Strategy 2.3.2: Minimize burden on health care providers when reporting clinical data for population health purposes using EHRs and other health IT, while ensuring consistent health information protections.

The increased burden associated with providing clinical data for population health uses may limit participation by providers and other data sources. This strategy aims to reduce the burden on the delivery system by promoting efficient data collection and reporting. The following illustrative action steps facilitate automated collection of population health data and use of non-clinical data sources:

- Identify methods to standardize or streamline queries made by authorized population health users to collect data for population health purposes (e.g., use of data brokers, automated data capture from standardized transactions).
- Identify non-clinical sources currently maintaining electronic clinical health information, and determine if they can serve as alternative sources of provider data (e.g., claims databases, registries, labs, and consumers).
- Develop guidance on using the range of alternate electronic data sources and explore the need for accreditation of these sources.

Along with other actions, these steps will encourage increased participation and buy-in from providers and others that serve as data sources. When federal agencies are the recipients of population health data reporting, this strategy supports the intent and stipulations of the Paperwork Reduction Act.

Milestone 2.3.2: By 2012, certified EHRs will have features that enable them to transmit automated data to population health agencies.

Strategy 2.3.3: Establish mechanisms for the electronic exchange of health information among authorized users of population health data, communities, and individual consumers.

Consumers and communities are also sources of electronic health information, and their information exchange with authorized population health data users is subject to unique challenges and benefits. This strategy supports the collection of appropriate information directly from consumers as well as community sources, with appropriate privacy protections in place, and the secure transmission of this information to population health agencies that are authorized to receive it. It also embraces dissemination of population health findings from population health agencies to consumers and communities. The following illustrative action steps are designed to identify and create tools to enable consumers' and communities' transmittal and use of population health data:

- Identify data elements for population health uses for which consumers and communities may be a preferred or unique resource for collection and reporting, as compared to providers or other data sources (e.g., risk assessments or full medication lists including over-the-counter medications).
- Support the development of population health applications that can interoperate with community- and consumer-based health IT tools to transmit population health information.
- Promote education for communities and consumers on how to use population health data.

These actions, along with others, facilitate access and understanding of consumer data by authorized population health data users, communities, and individual consumers.

Milestone 2.3.3: By 2012, one or more pilot projects will be underway to explore the feasibility of the exchange of health information among population health organizations, community-based organizations, and individual consumers.

Strategies for Objective 2.4

Collaborative Governance: Establish coordinated and effective organizational processes—at the federal, state, local and tribal levels—to promote the availability and management of aggregated clinical information to benefit population health.

Strategy 2.4.1: Establish and monitor the use of data stewardship models that allow for capture and consistent use of electronic health data for population health purposes through common practices compliant with laws and organizational policies.

The primary focus of this strategy is to make needed data available to authorized population health users by promoting appropriate data stewardship within existing laws and organizational policies. Action steps supporting this strategy establish a foundation to set data priorities and define electronic health information uses for public health, biomedical research, quality improvement, and emergency preparedness. The following illustrative actions will serve as the basis for a policy framework on the exchange of health information and data stewardship for population health purposes:

- Identify governance mechanisms needed to support the exchange of health information for population health purposes: governance to oversee how information is stored, reported, and/or analyzed.
- Establish a national consensus on the definitions and differences between data capture for public health, biomedical research, quality improvement, and emergency preparedness.
- Support the development of policy guidelines for the exchange of electronic health information and for population health data stewardship, based on the interaction of stewardship efforts at the federal, state, local, and tribal levels.

Milestone 2.4.1: By 2010, data stewardship models will be established that support appropriate use of electronic clinical data for public health, biomedical research, quality improvement, and emergency preparedness priorities.

Strategy 2.4.2: In concert with federal partners, identify and coordinate priorities, policies, and practices that are needed to develop and implement quality measures in ways that are compatible with different models for the exchange of health information.

This strategy addresses unique concerns related to the collection and aggregation of electronic health information for defining and evaluating quality of care. The strategy supports effective use of electronic health data by facilitating standardized data elements aligned across multiple stakeholders' quality measurement initiatives. Federal research and development will be leveraged as needed to advance and improve quality practices. The following illustrative actions promote the use of an automated common set of electronic data elements from electronic health records and entities that exchange health information:

- Facilitate establishment of consistent roles and best practices at the national level that enable the automation of quality measurement and reporting.
- Align federal initiatives to aggregate electronic clinical data for quality measurement and reporting with state, local, tribal, and private sector health care quality policies and activities.
- Work with public and private stakeholders to support efforts to use a common set of nationally prioritized, patient-centric, longitudinal quality and efficiency measures in public reporting and payment, starting with a minimum data set for quality and standardized data elements.

Milestone 2.4.2: By 2012, meaningful and standardized quality measurement and feedback to providers will be reliably and validly reported and disseminated electronically at local, regional, and national levels.

Strategy 2.4.3: Identify mechanisms, policies, and practices needed to connect clinical care and public health for public health purposes, including biosurveillance and emergency preparedness.

Public health data needs at federal, state, local, and tribal levels can be enabled through automated data capture, exchange, and aggregation. This strategy supports coordination and governance of data aggregation at all levels. The following illustrative action steps will help identify unique concerns for this type of data collection, facilitate prioritization and planning, and advance the business case for the exchange of electronic health information for public health, biosurveillance, and emergency preparedness purposes/needs to ensure private sector buy-in and participation:

- In collaboration with tribal, local, state, and federal data stewardship entities, identify the unique challenges in aggregating and sharing electronic health information for public health purposes, including biosurveillance and emergency preparedness.
- Work with states and other stakeholders to support the prioritization and planning for data capture and reporting to address broader public health issues (e.g., monitoring of nosocomial infections and adverse drug event monitoring).
- Enhance the business case for exchanging electronic health information to meet public health needs including biosurveillance and emergency preparedness.

Milestone 2.4.3: By 2010, there will be demonstrated coordination of governance entities by an AHIC Successor (e.g., data use agreements) across jurisdictions, public health agencies, and clinical care for the purposes of advancing public health priorities.

Strategy 2.4.4: Identify priorities, policies, and practices needed to connect clinical care and research for the purpose of advancing basic, clinical, and health services research.

Electronic health information can inform and advance medical knowledge by providing data that enables more comprehensive and timely basic, clinical, and health services research. This strategy intends to increase the availability of aggregated data sources for research by supporting data collected with appropriate patient protections. The following illustrative action steps address the unique concerns of research, including informed consent and Institutional Review Board (IRB¹) approval:

- In collaboration with tribal, local, state, and federal data stewardship entities, identify the unique challenges in aggregating and sharing electronic health information for basic, clinical, and health services research. Identify best practices for obtaining informed consent through paper and automated systems and aggregating data in ways to protect research participants.
- Establish a process for streamlining IRB approvals as more electronic clinical data become available through electronic health records and interoperable networks.

Milestone 2.4.4: By 2010, there will be demonstrated coordination of governance entities across clinical care and research communities for the purposes of advancing research.

Strategy 2.4.5: Create accountability for organizations responsible for implementing policies and practices for exchange of electronic health information.

The ability of entities that exchange health information to effectively aggregate and share data for population health purposes is dependent on the use of appropriate policies and procedures. This strategy promotes the standardization and accountability of data aggregation and transmittal activities. The following illustrative action steps will support capacity building, protocol development, and accreditation for the exchange of health information:

- In coordination with the federal data sharing strategy (Strategy 2.4.6), conduct planning and prioritization activities to build capabilities and establish protocols for data capture

¹ An Institutional Review Board (IRB) is a committee made up of physicians, statisticians, researchers, community advocates, and others that ensures that research done involving human subjects or patient information (such as clinical trials) is ethical and that the rights of the study participants are protected. For HHS-conducted or -supported human subjects research, the human subjects regulations at 45 CFR part 46 require that an IRB must review and approve such research before its inception, unless the research qualifies for a regulatory exemption.

and reporting to meet the many different needs of population health (e.g., registries versus surveys).

- Across the key areas of population health, examine the benefits and risks of aggregation practices at state, local, and tribal levels.
- As appropriate, develop accreditation processes to facilitate consistent governance for exchanging electronic health information and for related data aggregation to support population health uses at a national, state, local, and tribal level.

Milestone 2.4.5: By 2011, there will be established accreditation criteria and processes for all models for the exchange of health information, as appropriate.

Strategy 2.4.6: To the extent permitted by law, develop, implement, and oversee a health data sharing strategy across federal agencies that will leverage available data from multiple sources to meet the needs of population health programs including public health, biomedical research, quality improvement, and emergency preparedness.

Federal and public health programs that utilize population health information could be augmented by a data sharing strategy that encourages access and use of information among them using standards-based exchange of electronic health information. These action steps aim to increase federal use of electronic health data, to the extent permitted by law, by identifying programmatic needs and implementing a data sharing strategy. The following illustrative actions will help federal agencies analyze data requirements and availability and support standardized procedures for data sharing and use:

- Create an inventory of data each agency currently collects and from where it collects that data to meet research and programmatic needs and, ultimately, support each agency's individual mission.
- Develop and prioritize data requirements for federal programs consistent with the agency priority and missions and determine where knowledge gaps exist and what specific new data should be enabled.
- Establish a cross-collaborative team to work with agency representatives to develop, identify, and prioritize policies, practices and protocols around how, consistent with the law, data should be requested, accessed and utilized within and across federal agencies.

Milestone 2.4.6: By 2012, federal data will be shared securely among federal agencies, to the extent permitted by law, for population health purposes, while protecting the privacy of individuals.

Appendix B: Federal Health IT Initiatives and Federal Advisory Committee Activities Related to Strategic Plan Goals and Objectives

(Descriptions of the initiatives listed are found in Appendix C)

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC-Coordinated Federal Health IT Strategic Plan	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
Department of Health and Human Services								
Agency for Healthcare Research & Quality (AHRQ)								
AHRQ: Health IT Portfolio	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
AHRQ: United States Health Information Knowledgebase (USHIK)		<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>		
Assistant Secretary for Planning and Evaluation (ASPE)								
ASPE: Health Information Activities		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Assistant Secretary for Preparedness and Response (ASPR)								
ASPR: Homeland Security Presidential Directive 21						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ASPR: Pandemic All-Hazards Preparedness Act (PAHPA)						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Centers for Disease Control and Prevention (CDC)								
CDC: BioSense						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
CDC: EPI-X						<input checked="" type="checkbox"/>		
CDC: National Healthcare Safety Network						<input checked="" type="checkbox"/>		
CDC: Public Health Information Network						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
CDC: Public Health Preparedness Systems						<input checked="" type="checkbox"/>		
Centers for Medicare & Medicaid Services (CMS)								
CMS: Beneficiary Information Services		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>					
CMS: EHR Adoption Demonstration			<input checked="" type="checkbox"/>					
CMS: E- Prescribing Efforts			<input checked="" type="checkbox"/>					

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC-Coordinated Federal Health IT Strategic Plan	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
CMS: HIPAA Security Rule	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>			
CMS: ICD-10		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	
CMS: Medicaid Information Technology Architecture (MITA)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
CMS: Medicaid Reimbursement for Telehealth Services			<input checked="" type="checkbox"/>					
CMS: Medicaid Transformation Grants		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
Food & Drug Administration (FDA)								
FDA: Sentinel Network						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
FDA: Structured Product Labeling for Products		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Health Resources and Services Administration (HRSA)								
HRSA: <i>Connections</i> Project						<input checked="" type="checkbox"/>		
HRSA: Rural Hospital Flexibility Grant Program – FLEX			<input checked="" type="checkbox"/>					
HRSA: Health IT Electronic Health Record and Innovation Grants		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>					
HRSA: Regional Genetic and Newborn Screening Service Collaboratives		<input checked="" type="checkbox"/>						
HRSA: Telehealth Grants		<input checked="" type="checkbox"/>						
Indian Health Service (IHS)								
IHS: National Data Repository						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
IHS: Resource and Project Management System		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
IHS: Telehealth			<input checked="" type="checkbox"/>					
National Institutes of Health (NIH)								
NIH: Cancer and Biomedical Informatics Grid		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
NIH: Clinical Translational Science Awards				<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
NIH: Genome Wide Association Studies Data Sharing Policy					<input checked="" type="checkbox"/>			
NIH: Health Informatics R & D			<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
NIH: National Network of Libraries of Medicine						<input checked="" type="checkbox"/>		

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC-Coordinated Federal Health IT Strategic Plan	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
NIH: Support for Biomedical Informatics Research Training			<input checked="" type="checkbox"/>					
NIH: Support, Maintenance, & Dissemination of Standard Clinical Vocabularies		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Office for Civil Rights (OCR)								
OCR: HIPAA Privacy Rule and Health IT	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>			
OCR: Health IT and Health Disparities/Special Needs Populations			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
Office of the National Coordinator (ONC)								
ONC: Anti-Fraud Activities	<input checked="" type="checkbox"/>							
ONC: Certification Commission for Healthcare Information Technology (CCHIT)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		
ONC: Federal Interdepartmental Health IT Collaborative [Multi-agency]		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
ONC: Federal Health Architecture (FHA) [Multi-agency]		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
ONC: Federal Interagency Health IT Policy Council [Multi-agency]				<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
ONC: Health Information Security and Privacy Collaborative (HISPC)	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>			
ONC: Healthcare Information Technology Standards Panel (HITSP)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
ONC: Nationwide Health Information Network (NHIN)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
ONC: Planning AHIC 2.0		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
ONC: Secure Messaging Pilot			<input checked="" type="checkbox"/>					
ONC: Standardized Measures for Adoption of EHRs			<input checked="" type="checkbox"/>					
ONC: State Alliance for e-Health	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
ONC: State Level Health Information Exchange Consensus Project				<input checked="" type="checkbox"/>				
ONC: Terminology Consensus Contract				<input checked="" type="checkbox"/>				
ONC: Use Case Development		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Office of the Secretary (HHS/OS)								
HHS/OS: Personalized Healthcare		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC-Coordinated Federal Health IT Strategic Plan	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
HHS/OS: Value-driven Health Care		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Substance Abuse and Mental Health Services Administration (SAMHSA)								
SAMHSA: Health IT Initiatives	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Department of Commerce								
National Institute of Standards & Technology (NIST)								
NIST: Conformance Testing Infrastructure		<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>		
NIST: Security Technology	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
NIST: Conformance and Certification Expertise		<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>		
Department of Defense (DoD)								
DoD: AHLTA		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
DoD: Memorandum of Agreement with State of Florida		<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>		
Department of Veterans Affairs (VA)								
VA: Electronic Health Record (VistA, CPRS)			<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
VA: Personal Health Record		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>					
VA: Telehealth			<input checked="" type="checkbox"/>					
Federal Communications Commission (FCC)								
FCC: Rural Health Care Pilot Program		<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>		
SOCIAL SECURITY ADMINISTRATION (SSA)								
SSA: Medical Evidence Request and Data Use Prototype		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>					
SSA: NHIN Use Case "Authorized Release of Information to a Trusted Entity"		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>					
SSA: Personal Health Record Intake Prototype		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>					
Multi-Agency Collaborative Efforts								
AHRQ, FDA, & NLM: Data Standards Program		<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>		

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC-Coordinated Federal Health IT Strategic Plan	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
DoD & VA: Exchange of Information (FHIE, BHIE, CHDR, LDSI)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
DoD & VA: Joint EHR Analysis Project		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
OIG & CMS: Hospital Donation of Health IT			<input checked="" type="checkbox"/>					
Other Public-Private Sector Initiatives								
National Quality Forum (NQF)								<input checked="" type="checkbox"/>
Federal Advisory Committees								
National Committee on Vital and Health Statistics (NCVHS)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
American Health Information Community (AHIC)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
AHIC Chronic Care Workgroup			<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	
AHIC Confidentiality, Privacy, and Security Workgroup	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>			
AHIC Consumer Empowerment Workgroup		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
AHIC Electronic Health Records Workgroup		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
AHIC Personalized Healthcare Workgroup		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
AHIC Population Health and Clinical Care Connections Workgroup				<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
AHIC Quality Workgroup				<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>

Appendix C: Descriptions of Initiatives, Programs, and Projects

The following descriptions serve as background for the many initiatives, activities, programs, and projects cited throughout the Strategic Plan. Many of these endeavors advance both goals and their underlying objectives, while others are more closely related to one of the two goals. Appendix B lists all of these initiatives and activities, and highlights which objectives are or have been supported by each initiative. Each initiative is listed under the department, agency, or organization that is primarily responsible for sponsoring, funding, staffing, or leading it. The “boxes” included with the descriptions highlight the activities to date and agency’s contributions in addressing the goals and objectives of this plan.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY FOR HEALTHCARE RESEARCH & QUALITY (AHRQ)

AHRQ: Health IT Portfolio

AHRQ has invested in a wide range of projects that form a nationwide learning laboratory of health care systems, hospitals, physician practices, research institutes, nursing homes, and other organizations that are helping to transform clinical practice through health IT.

Technologies such as those used to support electronic health records, the exchange of health information, and telemedicine hold the potential to revolutionize everyday clinical care making it better, safer, and more efficient. Some of the myriad projects funded through AHRQ’s Health IT Portfolio include, but are not limited to:

- Development of electronic clinical decision support
- Enhancement of e-prescribing capabilities
- Development of e-medical records
- Promotion of personalized healthcare
- Evaluation of existing health IT projects and grants throughout the Department
- Development and dissemination of information to help improve health literacy among the American public
- Funding for Health Information Exchange - In October 2004 and 2005, AHRQ awarded contracts to six states (Connecticut, Utah, Indiana, Tennessee, Rhode Island, and Delaware) to support statewide demonstration projects on data sharing and interoperability activities. The goals of these five year demonstrations are to develop organizations that connect local health care providers; allow clinicians access to patient information at the point of care; demonstrate measurable improvements in the areas of quality, safety, efficiency, and effectiveness of health care for patients and populations on a state or regional level; and to identify successful strategies for the sustainability of health information exchanges. Each state can develop its own technical, business, and governance structures.

- National Resource Center for Health IT - The National Resource Center for Health Information Technology (the NRC) is a central national source of information and assistance to help the nation embrace the power and efficiency of health information technology. Currently administered by the National Opinion Research Center, the NRC provides direct technical assistance and consulting services to AHRQ projects and grantees involved in developing, testing, and using health IT applications, with a particular focus on addressing challenges to health IT implementation in rural and small community settings. The NRC has also supported key efforts at other Federal agencies including CMS, HRSA, and IHS. NRC is helping to build the nation's capacity across health care settings for the effective use of health IT. In addition, the NRC serves as a link between the health care community at large and the researchers and experts who concentrate on health IT. As the central repository for lessons learned from AHRQ's health IT initiative, the NRC encourages adoption of health IT by disseminating the latest tools, best practices, and research results from this unique real-world laboratory to the broader health care community and to the public at large.

AHRQ: United States Health Information Knowledgebase

The United States Health Information Knowledgebase (USHIK) is a health metadata registry funded and directed by the Agency for Healthcare Research and Quality. USHIK provides and maintains a metadata registry of health information data element definitions, values and information models that enable browsing, comparison, synchronization, and harmonization within a uniform query and interface environment. USHIK is populated with the data elements and information models of Standards Development Organizations (SDOs) and other health care organizations in such a way that public and private organizations can harmonize information formats with health care standards. USHIK also contains data element information for government initiatives that support the use and implementation of data standards such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Consolidated Health Informatics (CHI) initiative.

Progress on Plan Objectives

AHRQ has invested more than \$216 million in grants and contracts to organizations in 48 states stimulating investment in the exchange of health information, with emphasis on rural and underserved areas. AHRQ has funded six states to demonstrate state-wide interoperability and data sharing.

The National Resource Center currently provides technical assistance to over 200 AHRQ grantees and contractors, six state and regional demonstration projects promoting the exchange of health information, and 33 states and one territory working on a Health Information Security and Privacy Collaboration.

USHIK is built on ISO standard 11179. USHIK can produce columns of attributes for each data element and can present comparisons of similar data elements from different standards organizations. USHIK enables analyses of compatibility/incompatibility and provides a tool for data element harmonization. In 2007 data elements from the bioterrorism use case were added to the registry.

ASSISTANT SECRETARY FOR PLANNING & EVALUATION (ASPE)

ASPE: Health Information Activities

The Assistant Secretary for Planning and Evaluation (ASPE) advises the Secretary of HHS on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy. Integral to this role, ASPE conducts research and evaluation studies, develops policy analyses, and estimates the cost and benefits of policy alternatives related to promoting the adoption and implementation of health IT.

Progress on Plan Objectives

ASPE has funded a number of studies to help inform policies related to health IT such as an analysis of health IT costs and benefits, an analysis of consumer control of personal electronic health information, an economic assessment of small physician practices' adoption of electronic medical records, studies examining the exchange of health information for persons receiving post-acute and long-term care services, and work cooperatively undertaken through the CHI initiative resulting in CHI patient assessment and disability standards accepted by the Secretary. ASPE is currently funding several projects to help inform and promote the Secretary's health IT agenda, such as analyzing and modeling the factors associated with successful EHR adoption in physician offices, supporting the specification of the HL7 EHR-S Functional Profile for Nursing Homes, evaluating a CMS pilot for the use of EHRs by the Medicare fee-for-service population, and application of recognized CHI standards to federally-required assessments.

ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE (ASPR)

ASPR: Homeland Security Presidential Directive 21

On October 18, 2007, the White House released Homeland Security Presidential Directive 21 (HSPD-21). HSPD-21 calls on the HHS Secretary to establish an operational national epidemiologic surveillance system for human health that is predicated on state, regional, and community-level capabilities and creates a networked system for two-way information flow between federal, state, tribal, and local government public health authorities and clinical health care providers. To the extent feasible, the system should be built using electronic health information systems and integrate its data into a national bio-surveillance common infrastructure.

HSPD-21 calls for the creation of cabinet-level Public Health and Medical Preparedness Task Force by February 2008. The Task Force, which has been created, is chaired by the HHS Secretary.

The HHS Secretary, in coordination with the Secretaries of Defense, Veterans Affairs, and Homeland Security, is working to establish an Epidemiologic Surveillance Federal Advisory Committee by July 2008. The Advisory Committee will also include representatives from state and local public health agencies and appropriate private sector health care entities to ensure

that the federal government is properly enabling state and local public health surveillance capabilities.

ASPR: Pandemic and All-Hazards Preparedness Act

The Pandemic and All-Hazards Preparedness Act (PAHPA) calls for the Secretary to establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems. Once established, this capability will allow public health officials to share data and information to enhance early detection of and rapid response to potentially catastrophic infectious disease outbreaks and other public health emergencies. In addition, PAHPA calls for the design of a system to link existing State verification systems to create a single national interoperable network for the purpose of verifying the credentials and licenses of health care professionals during a public health emergency. PAHPA also calls for an inventory of telehealth initiatives in existence on the date of enactment of PAHPA, to include the identification of methods to expand and interconnect health information networks; to evaluate ways to prepare for, monitor, respond to, and manage the events of a public health emergency through the enhanced use of telehealth technologies; and to promote greater coordination among existing Federal interagency initiatives.

Progress on Plan Objectives

Pursuant to Presidential Directive 21: the Cabinet Level Task Force has been established and is developing the implementation plan for the Public Health and Medical Preparedness Strategy. HHS, DoD and VA are working together to establish the Epidemiological Surveillance Federal Advisory Committee.

Consistent with PAHPA, the Secretary of HHS has delegated responsibility to ASPR. ASPR has completed the telehealth initiatives inventory and is working with sister agencies and states to develop the interoperable network of systems for situational awareness capability.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC: BioSense

BioSense is a national program intended to improve the nation's capabilities for conducting near real-time biosurveillance, enabling health situational awareness through access to existing data from health care organizations across the country. The primary objective is to expedite event recognition and response coordination among federal, state, and local public health and health care organizations by providing each level of public health access to the same data at the same time.

CDC: Epi-X

Epi-X is a web-based communications network created by the CDC for public health professionals. Through Epi-X, CDC officials, state and local health departments, poison control centers, and public health professionals can access and share health surveillance information in a secure platform. The 4,200 users receive notifications on breaking public health news as they occur. These real time public health alerts, reports, discussions, and comments are continuously moderated by medical epidemiologists and clinical laboratory professionals at CDC. Epi-X is accessible only to public health officials designated by each regional agency. These experts engage in rapid outbreak reporting, peer-to-peer consultation, postings and

discussions about disease outbreaks and other public health events that may involve multiple jurisdictions.

CDC: National Healthcare Safety Network

Launched by the CDC in 2005, the National Healthcare Safety Network (NHSN) was created to integrate and supersede three existing surveillance systems, the National Nosocomial Infections Surveillance System, the Dialysis Surveillance Network, and the National Surveillance of Healthcare Workers. NHSN facilitates voluntary reporting of health care-associated infection information and aggregates the data for use by health care facilities and public health agencies through its two surveillance areas: patient safety and health care personnel safety. The goal is to create a knowledge system for accumulating, exchanging, and integrating relevant information on adverse events associated with health care delivery. NHSN will soon allow for the collection of health care worker influenza vaccination data, multi-drug resistant organism data, central line insertion practices, and high-risk patient influenza vaccination data.

CDC: Public Health Informatics Fellowship Program

The CDC Public Health Informatics Program is a two-year applied training program for professionals interested in the application of information and computer science and technology to public health practice, research and learning. Applicants to the program typically have backgrounds in public health and information and computer science and technology, as well as related domains (engineering, medicine, nursing, library science). Since 1996, the program has produced 58 graduates, 70 percent of which have remained working in public health. The program also offers technical assistance (Info-Aids) to an increasing number of states.

CDC: Public Health Information Network

In 2002, CDC launched the Public Health Information Network (PHIN) initiative to improve the capacity of public health agencies to use and exchange information electronically by promoting the use of standards and defining technical requirements. The standards and technical requirements are determined by best practices related to efficient, effective, and interoperable public health information systems that support both routine public health activities and emergency preparedness and response.

CDC: Public Health Preparedness Systems

CDC distributes resources to support public health preparedness activities, ensures that electronic and other systems are in place to monitor performance and manage accountability, and coordinates the communication efforts among key stakeholders. CDC also oversees the administration of the Cooperative Agreement for Public Health Emergency Preparedness to state and local health departments.

Progress on Plan Objectives

BioSense has begun focusing on the following:

- Catastrophic public health emergencies
- Enhancing biosurveillance capabilities across cities and states
- Data feeds from acute care hospitals to Federal, state and local public health departments
- Evaluating cost-effectiveness of different configurations for connecting health care information sources
- Field testing the biosurveillance Minimum Data Set

Epi-X has supported 6,700 reports related to local and national responses to terrorism, SARS, Hurricane Katrina, and influenza surveillance.

In 2005, CDC initially opened NHSN enrollment to a limited number of facilities. In 2007, CDC launched a national open enrollment for hospitals and outpatient hemodialysis centers.

Current PHIN activities involve educating members of the PHIN community, evaluating best practices, encouraging policy discussion, and creating both vocabulary and messaging standards.

The Centers for Public Health Preparedness (CPHP) was created to strengthen terrorism and emergency preparedness. CPHP major activities include education and training and activities that are needed for the general support of preparedness education, outreach, partnership, and program evaluation.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

CMS: Beneficiary Information Services

One of CMS' priorities, as indicated in its most recent Strategic Plan, is to empower beneficiaries to make more informed decisions about their health and health care. To support this priority, CMS has implemented an online Medicare account management tool for beneficiaries, the Medicare Beneficiary Portal, and has begun to explore the use of personal health records for beneficiaries.

CMS: EHR Adoption Demonstration

CMS is implementing a new demonstration project in which up to 1,200 small to medium sized primary care practices in up to 12 different locations will be eligible to receive additional Medicare payments for using EHRs to improve care. Under the demonstration, primary care doctors who use certified EHRs to coordinate and provide care to Medicare beneficiaries and achieve certain clinical quality measures will be eligible to earn up to several thousand dollars per year in incentive payments. By design, the demonstration will be budget neutral by requiring that the associated costs be offset by savings resulting from more efficient health care delivery.

CMS: E-Prescribing Efforts

The Medicare Prescriptions Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub.L. No. 108-173) directed the Secretary to promulgate uniform standards for the electronic transmission of prescription and certain other information for covered Part D drugs prescribed for Medicare Part D eligible individuals. CMS adopted a set of foundation standards for e-prescribing under Medicare Part D, worked in collaboration with AHRQ to pilot test additional e-prescribing standards, published a required report to Congress on the results of that pilot, and issued a final rule that will require the use of the successfully tested standards and the National Provider Identifier in e-prescribing Part D covered drugs for Part D eligible individuals under specified circumstances.

CMS: HIPAA Security Rule

CMS administers the Security Rule, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which establishes security protections for electronic

protected health information. With delegated authority to implement and enforce the HIPAA Security requirements, CMS regularly issues guidance in the form of educational papers, FAQs, enforcement statements, and other documents, to assist the industry in complying with the HIPAA Security Rule requirements.

CMS: International Classification of Diseases (ICD-10)

International Classification of Diseases (ICD) code sets were developed for statistical reporting of worldwide mortality data. Currently, the United States uses ICD-10 (tenth version) codes for mortality reporting and uses ICD-9 (ninth version) for its morbidity reporting. The tenth version of the code sets vastly expands the number and complexity of both diagnosis and procedure codes, making the codes more precise and comprehensive. Consequently, this increased granularity and precision would increase the quality of information collected and could have many potential benefits to the US health care system.

CMS: Medicaid Information Technology Architecture

The Medicaid Information Technology Architecture (MITA) is an IT initiative intended to foster and stimulate an integrated business and IT transformation across the Medicaid enterprise. The overall goal of the MITA project is to facilitate an improved process for design and implementation of information systems that improves the quality and efficiency of health care delivery, which in turn will improve beneficiary and population outcomes. The overall goal of the MITA project is to establish a national framework for enabling technologies and processes that support improved program administration for the Medicaid enterprise and stakeholders dedicated to improving health care outcomes and administrative procedures for Medicaid beneficiaries. MITA guidelines will ultimately serve as the basis for states' requests for federal financial participation for the Medicaid Management Information System (MMIS).

CMS: Medicaid Reimbursement for Telehealth Services

States may decide to reimburse Medicaid services provided through telemedicine applications. Telemedicine is not formally defined for the Medicaid program and Medicaid law does not recognize telemedicine as a distinct service; however, states can reimburse services given through telemedicine to supplement or enhance the more traditional ways of providing medical care.

CMS: Medicaid Transformation Grants

In 2005, the Deficit Reduction Act authorized \$150 million in new grant funds to states for the adoption of innovative methods to improve effectiveness and efficiency in providing medical assistance under Medicaid. CMS encouraged states to look at how health IT and the exchange of health information could be leveraged to improve Medicaid services (e.g., reduce medical errors through the implementation of EHRs, clinical decision support tools, or eRx.) The funds also could be used for other Medicaid improvement programs, including efforts to reduce Medicaid fraud and abuse.

Progress on Plan Objectives

CMS launched the Medicare Beneficiary Portal in 2004. Currently, the Medicare Beneficiary Portal offers administrative information, such as claims, eligibility, and benefit structure. Some clinical services are also available. In June 2007, CMS launched an 18-month pilot project to examine PHR use by Medicare beneficiaries. CMS will determine the features that are most attractive to

beneficiaries, identify the minimum content and functionality for the PHR tool, and assess the best methods for outreach and education to encourage adoption and ongoing use.

The CMS EHR Adoption Demonstration was announced on October 30, 2007. The five-year demonstration is projected to start recruiting practices in late summer 2008 and begin operations in 2009.

In 2005, CMS published a final rule establishing three “foundation” eRx standards that cover certain transactions between prescribers and Medicare Part D sponsors as well as dispensers and Medicare Part D sponsors, and eligibility queries between dispensers and Medicare Part D sponsors. In 2006, CMS initiated a pilot project in five locations to test six initial standards for E-prescribing. In 2007 CMS published a proposed rule consistent with the results of the pilot that proposed to adopt additional e-prescribing standards. CMS published a final rule in April 2008 that will require the use of the successfully tested standards and the NPI in e-prescribing Part D covered drugs for Part D eligible individuals.

CMS’ activities related to Health IT include:

- Participation on the American Health Information Community Workgroups for Confidentiality, Privacy, and Security and Consumer Empowerment;
- Staff participation on the National Committee on Vital and Health Statistics (NCVHS) Standards and Security Subcommittee;
- Collaboration with ONC in its efforts to develop a confidentiality, privacy, and security framework for exchange of electronic health information, including participation on the ONC-sponsored inter-agency health IT policy council;
- Collaboration with OCR on security and privacy initiatives and HIPAA enforcement;
- Collaboration with the National Institute of Standards and Technology on technical guidance;
- Collaboration with outside stakeholder groups to develop appropriate education on the Security Rule and its implementation.

To test the technical feasibility of using ICD-10 for HIPAA covered transactions, ICD-10 was tested by CMS’s Clinical Data Abstraction Centers. CMS is studying the cost and time necessary for converting its own systems and is evaluating alternatives to support Industry migration to ICD-10 if and when a rule is proposed and finalized.

Many states reimburse Medicaid services made available through telemedicine to improve access to specialists for rural communities and to reduce transportation costs. Most of these states reimburse physician consultations provided through interactive video conferencing.

In 2007, CMS awarded Medicaid transformation grants to 34 states and one territory, totaling \$150 million, the majority of which were for health IT-related initiatives. Medicaid transformation grants were limited to FY’s 2007 and 2008.

FOOD & DRUG ADMINISTRATION (FDA)

FDA: Sentinel Network

The Food and Drug Administration is creating a national, integrated, electronic system for monitoring medical product safety. This system will be developed and implemented in stages, and will ultimately enable FDA to access the capabilities of existing, remote data systems to augment the Agency's current capability. Such a system will enable FDA to query distributed data sources quickly and securely for relevant de-identified product safety information.

As envisioned, the system would facilitate targeted queries, within the bounds of established privacy and security safeguards, across remote systems. The Sentinel Network will build on existing systems and data, to the extent practicable, rather than create a new system. The system will follow scientific principles of surveillance, using health IT standards harmonized by HITSP, recommended by the AHIC to the HHS Secretary, and recognized by the HHS Secretary, as well as ensure the protection of privacy and security of personal health information.

FDA: Structured Product Labeling

Structured Product Labeling (SPL) is part of the FDA initiative to improve patient safety through better access to product information. It is an electronic file in XML format that includes both the content of the labeling that accompanies the drug and specific data elements describing the product including the National Drug Code and Unique Ingredient Identifiers (UNII). The latest release of SPL includes products other than drugs, such as medical devices.

Progress on Plan Objectives

The public meeting on the Sentinel Network yielded consensus to build upon existing data resources/programs in both the public (CMS and Medicare) and private (HMO Research Network) sector.

Currently, FDA makes SPL for approved human prescription drugs available for download for no cost through the National Library of Medicine DailyMed web site. FDA plans to make SPL available for all drugs marketed in the United States. SPL is a Health Level Seven standard accredited by the American National Standards Institute.

HEALTH RESOURCES SERVICES ADMINISTRATION (HRSA)

HRSA: *Connections* Project

Through a cooperative agreement with HRSA, the Public Health Informatics Institute has established several activities to facilitate communities of practice. A community of practice involves the collaboration of a group of people with a common interest who work together over an extended period of time to share ideas and find solutions to a problem. *Connections* serves as a community of practice, providing technical assistance to public health agencies as they develop strategies and activities to integrate information systems essential to improving the health of children. *Connections* was launched in June 2001. Participants collaborate on issues specific to the integration of early child health information systems, including newborn screening, newborn dried blood spot screening, vital records, immunization registries, and lead screening programs.

HRSA: Rural Hospital Flexibility Grant Program – FLEX

Under the HRSA-supported Rural Hospital Flexibility Grant Program, known as FLEX, 16 Health Information Technology Network Implementation grants were awarded to states to help critical access hospitals (CAHs) set up EHRs and other health information technology. Funds will enable CAHs, which receive Medicare reimbursement for acute inpatient and outpatient services, to improve monitoring of patient information and increase the safety, quality and efficiency of rural health services.

HRSA: Health IT Electronic Health Record and Innovations Grants

HRSA has awarded over \$30 million in grants to help networks of health centers prepare to adopt and implement Electronic Health Records (EHR) and other health information technology (health IT) innovations. EHRs, critical tools in improving the quality of care, provide health care professionals the ability to monitor and analyze health information for their patients. EHRs are widely considered to be essential in improving the safety and quality of health care delivery and cutting waste and duplication of care. The grants fund the purchase, planning and implementation of EHRs and other health IT innovations such as electronic prescribing, physician order entry, personal health records, community health records, exchange of health information, smart cards, and interoperability with outside partners.

HRSA: Regional Genetic and Newborn Screening Service Collaboratives

The Regional Collaborative Program consists of seven Regional Genetic and Newborn Screening Collaboratives (RCs) and a National Coordinating Center (NCC). There are several projects that the RCs and the NCC for the RCs have undertaken. The NCC is assessing various aspects of the integration of clinical and laboratory medical genetics into electronic health systems for the integration and adoption of genetic information in the electronic health record system

HRSA Telehealth Grants

The Health Resources and Services Administration (HRSA) offers a number of telehealth grant programs).

The Telehealth Network Grant Program (TNGP) awards 3-year grants to networks of providers to demonstrate how telehealth technologies can be used to: expand access to, coordinate, and improve the quality of health care services; improve and expand the training of health care providers; and/or expand and improve the quality of health information available to health care providers, patients, and their families. In 2006, HRSA initiated a special focus on evaluating the costs and effectiveness of tele-homecare and home monitoring services through three 3-year grants.

HRSA supports six Telehealth Resource Centers under a grant program to assist health care organizations, networks, and providers in the implementation of cost effective telehealth programs to serve rural and medically underserved areas and populations.

The Licensure Portability Grant Program (LPGP) provides support for State professional licensing boards to carry out programs under which state licensing boards cooperate to develop and implement State policies and systems that will reduce statutory and regulatory barriers to telemedicine.

Progress on Plan Objectives

Ongoing *Connections* activities include: defining the business processes of the newborn dried blood spot screening (NDBS) system in providing a blue-print for developing information systems that support the information needs of all the stakeholders involved in the overall NDBS system, and developing a Health Level 7 implementation guide for the electronic transmission of NDBS results in compliance with national standards.

Under FLEX, 16 Health Information Technology Network Implementation grants were awarded to states to help CAHs set up electronic health records and other health information technology. Funds will enable CAHs, which receive Medicare reimbursement for acute inpatient and outpatient services, to improve monitoring of patient information and increase safety, quality and efficiency of rural health services.

In August, 2007 HRSA announced \$31.4 million in health IT Electronic Health Record and innovations grants to help health centers prepare to adopt and implement EHRs and other health information technology innovations. Of the total, \$8 million was earmarked for planning activities, and the remainder was for implementation and support for EHRs at health centers and in networks that link multiple health center grantees.

Four regional genetic and newborn screening collaboratives are participating in collaborative studies using health information technology and information exchange including the creation and use of regional and national information systems designed to monitor health outcomes of infants and children identified with heritable disorders in newborn screening programs, evaluate newborn screening program performance and evaluate treatment protocols.

HRSA is providing funding to 16 grantees across the nation to develop, implement, and evaluate telehealth programs in a variety of settings from primary care clinics, nursing homes, and hospitals to individuals' homes. Five centers distributed across the country have been awarded Telehealth Resource Center Grants to provide multistate services through a network of regional centers that provide technical assistance services locally but collaborate nationally.

INDIAN HEALTH SERVICES (IHS)

IHS: National Data Repository

The purpose of the Indian Health Service's national data repository, National Patient Information Reporting System (NPIRS), is to provide a broad range of clinical and administrative information to managers at all levels of the Indian health care system to allow them to better manage individual patients, local facilities, and regional and national programs. NPIRS has recently completed an upgrade to a new, state-of-the-art, enterprise-wide national data warehouse (NDW) system. This system provides a more accurate, timely, and broader scope of information to clinical and administrative managers throughout the Indian health system.

IHS: Resource and Patient Management System

The Resource and Patient Management System (RPMS) is a componentized electronic health care information system that provides Practice Management functions for IHS-direct, tribal and urban Indian health care delivery facilities throughout the United States. RPMS provides accurate, timely, and comprehensive clinical and administrative information to local health care providers and program managers and provides administrative information at the regional and national levels. The ultimate purpose of the RPMS is to improve the availability of medical information on American Indian and Alaska Native patients, thereby improving the diagnoses, decision making, and health care recommendations of IHS physicians and other IHS health care providers.

The Clinical Reporting System (CRS) is an RPMS software application designed for national reporting as well as local and Area monitoring of clinical performance measures. CRS produces on demand from local RPMS databases a printed or electronic report for any or all of over 300+ clinical performance measures, representing 55 clinical topics. CRS is intended to eliminate the need for manual chart audits for evaluating and reporting clinical measures that depend on RPMS data.

iCare is a component of the RPMS that presents diverse patient data in one user-friendly view. IHS initiated this population health care management project to provide an easy-to-use tool with multiple uses to a wide variety of wide variety of providers. iCare also supports critical care coordination capabilities.

IHS: Telehealth

The IHS telehealth program supports a broad range of activities in four strategic directions: innovation, resource/infrastructure development, business modeling, and collaboration. These activities occur in partnership with IHS Areas and individual IHS/tribal facilities already engaged or planning to be engaged in telehealth service delivery. Specifically, the telehealth program works to:

- Support national Indian health initiatives and priorities;
- Identify and disseminate information on emerging telehealth applications and experience;
- Provide on-site and remote consultation and support to facilities and programs in the 12 IHS Areas;
- Propose/implement new models of service delivery based on telehealth;
- Develop business modeling specific to telehealth sustainability;
- Enhance distance education via emerging tele-education tools;
- Extend collaborations specific to telehealth service delivery among Indian health stakeholders and with state, federal, university, and other health organizations.

Progress on Plan Objectives

NPIRS (National Patient Information Reporting System) is the national data warehouse (NDW) for IHS statistical health care data on patient registration and visit encounters occurring at either IHS facilities or contracting facilities that provide care. NPIRS Monthly exports to the NDW typically contain data from over 2.2 million patient encounters at approximately 293 IHS and Tribal health care facilities in 35 states and supports enhance care-coordination capabilities

RPMS, CRS and iCare enable interoperability of data and support automated quality care reporting and population health monitoring.

Telehealth tools play an important role in the evolving model of service delivery for Indian health care. These tools support access to multi-specialty services, consultation, and training for facilities and communities in all 12 Areas of the Indian Health Service (IHS). Leading clinical telehealth applications include tele-radiology, tele-cardiology, tele-behavioral health, tele-dermatology, and tele-ophthalmology.

NATIONAL INSTITUTES OF HEALTH (NIH)

NIH: The Cancer Biomedical Informatics Grid (CaBIG)[™]

The National Cancer Institute's (NCI) caBIG[™] (cancer Biomedical Informatics Grid[™]) initiative serves as the cornerstone of NCI's biomedical informatics efforts to transform cancer research into a more collaborative, efficient, and effective endeavor, and establish interoperability between research and care. The infrastructure, tools, and policies of caBIG[™]— including activities around data sharing and security— could serve as a model to support applications beyond the cancer community, and the initiative collaborates with health and biomedical information technology efforts in other domains and other countries. The underlying service oriented infrastructure that supports caBIG[™] is referred to as caGrid. Driven primarily by scientific use cases from the cancer research community, caGrid provides the core enabling infrastructure necessary to compose the grid of caBIG[™]. CaGrid[™] provides the technology that enables collaborating institutions to share information and analytical resources efficiently and securely, and allows investigators to easily contribute to and leverage the resources of a national-scale, multi-institutional environment.

NIH: Clinical Translational Science Awards

A national consortium, funded through Clinical and Translational Science Awards (CTSAs), is focused on transforming clinical and translational research to enable researchers to more quickly and efficiently develop new patient treatments. One goal of the program is widespread utilization of health and research information technology to increase understanding of disease, facilitate clinical studies and trials, and advance adoption of effective treatments. CTSA training programs for development of new clinical and translational researchers will incorporate knowledge of informatics.

NIH: Genome Wide Association Studies Data Sharing Policy

The NIH is interested in advancing the use of data obtained through genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. The goal of the GWAS policy is to facilitate broad and consistent access to NIH-supported GWAS data in order to speed the translation of basic genetic research into therapies, products, and procedures that benefit the public health. The full value of GWAS to the public can be realized only if the resulting datasets are made available as rapidly as possible to a wide range of scientific investigators by means of information technology under conditions that provide appropriate protections for research participants and respect the conditions under which they consented to participate.

NIH: Health Informatics R&D

NIH's informatics research grants and contracts and its intramural research programs have supported pioneering research and development in bioinformatics, artificial intelligence in medicine, clinical decision support, biomedical ontology, imaging, electronic medical records, regional health data exchange (including both health care and public health organizations), health applications of advanced telecommunications networks, automated biosurveillance, and emergency management systems.

NIH: National Network of Libraries of Medicine

The National Network of Libraries of Medicine is comprised of 8 Regional Medical Libraries, 120 "resource libraries" primarily at schools of the health sciences, and nearly 6,000 hospital libraries, public libraries, and community-based organizations that serve as health information portals. Under the direction of NIH's National Library of Medicine, the electronic network is an efficient way to ensure that published research results are easily and efficiently accessible by scientists, health professionals, and the public. Member institutions staff exhibits at public and professional meetings, conduct orientation and training courses, and develop partnerships with community organizations to improve access to health information for underserved populations. The Network is a key player in the MedlinePlus "Go Local" feature, which provides information about local health and emergency services as an adjunct to the nationally applicable health information in MedlinePlus, available online at <http://www.nlm.nih.gov/medlineplus/>.

NIH: Support for Biomedical Informatics Research Training

Informatics requires knowledge of a biological, medical, or public health domain as well as computer and information sciences, statistics or mathematics, engineering, and human behavior. Developing a cadre of cross-trained researchers is especially important as advancement of health care and biomedical research requires investigators who understand biomedicine as well as knowledge representation, decision support, translational research, and human-computer interface.

NIH: Support, Maintenance, and Dissemination of Standard Clinical Vocabularies

As the designated HHS coordinating body for clinical terminology standards, the National Library of Medicine supports the development, enhancement, coordination, and distribution of clinically specific vocabularies to facilitate the exchange of clinical data and improve retrieval of health information. NLM funds the ongoing maintenance of LOINC (Logical Observation Identifiers, Names, Codes), pays for a U.S.-wide license for the use of SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms) serves as the U.S. member of the recently formed International Health Terminology Standards Development Organization, and is the developer of the RxNorm clinical drug vocabulary. These three vocabularies are available separately and also within the Unified Medical Language System (UMLS), where they are integrated in a common format with more than 100 other biomedical and health terminologies and classifications. Data from the UMLS provide a foundation for the caBIG Enterprise Vocabulary Server, which provides vocabulary services tailored for the research community. NLM leads efforts to align clinical vocabularies with messaging standards and to map clinically specific vocabularies to administrative code sets, and works with many other government and private organizations to promote use of standard terminologies.
<http://www.nlm.nih.gov/healthit.html>

Progress on Plan Objectives

The caBIG™ community has developed and released bioinformatics tools and capabilities that span the entire continuum of clinical research, pathology, imaging, and genomics and are being deployed at 43 major cancer centers. Over a dozen community cancer centers are working toward interoperable electronic health records to enable information exchange with caBIG compatible tools. CaGrid 1.1 released in September, 2007, includes important security features. CaBIG provides a metadata registry, terminology server, and many open source software tools useful in the development of research and health information systems. The caBIG website provides access to current inventory of open source caBIG tools and infrastructure (<https://cabig.nci.nih.gov/>), along with information and tools to assist in achieving and certifying caBIG compatibility.

The Clinical Translational Science Awards consortium is currently comprised of 24 academic health centers in 18 states and ultimately will link 60 institutions together to support clinical and translational science.

The NIH data sharing policy for Genome Wide Association Studies was released in August 2007 and its implementation guidance in November 2007, providing useful models for policy development in other population health arenas.

NIH grants and contracts support significant research that informs how health information is gathered, generated, stored, protected, and made available when and where it is needed to improve decision-making and translate research results into improved clinical practice.

The National Network of Libraries of Medicine, supported by the National Library of Medicine has successfully provided access to health information for clinicians and patients displaced by disasters and rapid backup and assistance for affected health science libraries. The Network is the backbone of NLM's strategy to promote effective use of libraries and librarians in local, state, and national disaster preparedness and response efforts. <http://www.nlm.nih.gov/network.html>.

The National Library of Medicine supports biomedical informatics research training through 20 university-based training centers with approximately 250 pre-doctoral and post-doctoral trainees across the U.S. In 2009, three other NIH institutes provided funds to support additional trainees. <http://www.nlm.nih.gov/ep/GrantTrainInstitute.html>.

NIH/NLM has played a key role in establishing stable support and distribution mechanisms for key clinical terminology standards. In 2007, NLM helped to establish the International Health Terminology Standards Development Organization, which assumed ownership of SNOMED CT in April 2007, with membership and licensing terms favorable to U.S. interests.

CMS and NIH recently signed a memorandum of understanding under which NLM is providing technical advice on design and planning and tailored vocabulary subsets to support the implementation of the Continuity Assessment Record & Evaluation (CARE) to promote compliance and compatibility health data standards, including LOINC, RxNorm, and HL7.

The “Go Local” links on the Medline Plus website’s health topic pages are linked to information about health services in local geographic areas including hospitals, physician offices, nursing homes, support groups, and health screening providers. “Go Local” now covers geographic areas where more than two-thirds of the U.S. population resides.

OFFICE FOR CIVIL RIGHTS

OCR: HIPAA Privacy Rule and Health IT

OCR administers the Privacy Rule, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which establishes a federal floor of privacy protections and individual rights with respect to certain individually identifiable health information. OCR provides expertise to assist the Department and industry in building upon the baseline protections HIPAA provides to establish a privacy framework appropriate for exchange of electronic health information nationwide. OCR activities include:

- Participation on the American Health Information Community (AHIC) Workgroups for Confidentiality, Privacy, and Security, and Consumer Empowerment;
- Staff participation on the National Committee on Vital and Health Statistics (NCVHS) Privacy and Confidentiality Subcommittee;
- Collaboration with ONC in their efforts to develop a confidentiality, privacy, and security framework for electronic exchange of health information, including participation on the ONC-sponsored inter-agency health IT policy council;
- Collaboration with CMS on e-prescribing and other CMS health IT programs and initiatives; and
- Collaboration with outside stakeholder groups to develop appropriate data stewardship and other principles.

OCR also provides education and guidance to address misconceptions and misapplications of the Privacy Rule, and to explain how the HIPAA Privacy Rule applies to the electronic exchange of health information in various circumstances.

OCR: Health IT and Health Disparities/Special Needs Populations

OCR is an active participant in the Department’s efforts to ensure that the benefits of health IT reach underserved and special needs populations and help to improve access to care and reduce health disparities.

Progress on Plan Objectives

OCR led a national teleconference explaining how the HIPAA Privacy Rule applies to Personal Health Records (PHRs). OCR participated in the development of Health IT recommendations from the AHIC Confidentiality, Privacy, and Security, and Consumer Empowerment Workgroups, as well as from the National Committee on Vital and Health Statistics.

OCR participates in the Consumer Empowerment Workgroup, including its Special Populations Subgroup, which is working to identify and address health IT issues unique to special populations, such as persons with disabilities, underserved residents of rural areas, and racial and ethnic minorities, to maximize their access through personal health information. OCR is a member of the HHS Workgroup on Health IT and Underserved Populations, led by the HHS Office of Minority Health, which seeks to ensure that Departmental health IT activities address and do not exacerbate health disparities.

OFFICE OF THE NATIONAL COORDINATOR (ONC)

ONC: Anti-Fraud Activities

In late 2006, ONC contracted with RTI International to develop recommendations for functional requirements for EHRs that would enhance data by reducing the incidence of improper payment and assisting in fraud management. The recommendations were developed by a team of experts and reviewed by more than 75 health care industry leaders, practitioners, and organizations. RTI researchers also worked with American Health Information Management Association and leading statistical software companies SAS and SPSS.

ONC: Certification Commission for Healthcare Information Technology

The Certification Commission for Healthcare Information Technology (CCHIT) is a certification body for EHRs and their networks that has been recognized by the Secretary. Formed in July 2004 by the American Health Information Management Association, the Health Information Management and Systems Society, and the National Alliance for Health Information Technology, CCHIT was established as an independent, nonprofit organization. In October 2005, CCHIT was awarded a contract by the U.S. Department of Health and Human Services (HHS) to develop and evaluate the certification criteria and inspection process for EHRs. Pursuant to the HHS contract, CCHIT takes the AHIC recommendations that have been accepted by the Secretary into account in its activities. CCHIT also collaborates with the organizations awarded HHS contracts for standards harmonization, and collaboratives participating in the NHIN trial implementations.

CCHIT is supported by five workgroups and several expert panels. The five workgroups are charged with developing certification criteria and tests for their particular focus areas, including EHR foundation, network foundation, inpatient EHRs, ambulatory EHRs, and emergency department EHRs. The expert panels are tasked with recommending to the workgroups criteria and test scripts on interoperability, security, privacy and compliance, cardiovascular, and child health.

ONC: Federal Interdepartmental Health Information Technology Collaborative [Multi-agency]

The purpose of the Collaborative is to bring together top leaders in the federal departments engaged in health IT programs so they may use their resources in ways that are consistent with the health IT initiatives being promoted to achieve the President's goal. Federal departments that are members of the Collaborative include: Department of Agriculture, Department of Commerce, Department of Health and Human Services, Federal Communications Commission, Federal Trade Commission, National Aeronautics and Space Administration, and National Science Foundation.

ONC: Federal Health Architecture [Multi-agency]

The Federal Health Architecture (FHA) Program supports federal health IT needs by providing a collaborative forum for creating a federal framework that is interoperable within the federal government, as well as between other public and private sector organizations. The FHA is managed by ONC with input from OMB. Lead partners are HHS, DoD, and VA; more than 20 federal agencies that have a health care line of business participate.

ONC: Federal Interagency Health IT Policy Council [Multi-agency]

The interagency Health IT Policy Council was established to coordinate federal health IT policy decisions across federal departments and agencies. The aim is to drive the necessary federal action to realize the goal of widespread health IT adoption. They also focus on the breakthrough areas arising out of AHIC recommendations that have been adopted by the HHS Secretary. The breakthrough areas address consumer empowerment, EHRs, biosurveillance, and chronic care.

ONC: Health Information Security and Privacy Collaborative

The Health Information Security and Privacy Collaborative (HISPC) is a collaborative of 34 states and territories that sought to review variations in organization-level business policies and state laws that affect the exchange of health information. Based on that review, the HISPC states identified solutions and developed implementation plans to alleviate challenges created by variations in policies and laws. ONC, in collaboration with AHRQ, contracted with Research Triangle Institute International (RTI) to create HISPC.

ONC: Healthcare Information Technology Standards Panel

Healthcare Information Technology Standards Panel (HITSP), a public-private partnership, is sponsored by the American National Standards Institute and funded by ONC. HITSP is composed of more than 300 health related organizations that work together to identify and harmonize data and technical standards for health IT. In response to a 2005 RFP on evaluation of the standards harmonization process for health IT, the Standards Harmonization Collaborative, a collaborative of 18 independent standards development organizations (SDOs), recommended the creation of HITSP. HITSP is composed of technical committees that assist in identifying and analyzing gaps in harmonized standards.

HITSP harmonizes standards for specific priorities, described in "Use Cases," identified in AHIC recommendations that the Secretary has adopted, or for other industry consensus processes. HITSP works with SDOs to ensure that standards meet existing health needs, ensures specific guidance exists to unambiguously implement the harmonized standards, and fosters the availability and use of health IT standards nationally.

ONC: Nationwide Health Information Network (NHIN)

The Nationwide Health Information Network (NHIN) is comprised of a set of exchange standards and specifications, and data use and reciprocal support agreements intended to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and health care. These exchange standards and agreements will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of health care information beyond direct patient care. ONC is advancing the NHIN as a "network of networks," formed when geographically-based, organizationally-based, or person-controlled HIEs use the standards and agreements to exchange health information among one another (and in many

cases, even internally), promoting interoperability and connectivity of these networks and the systems they, in turn, connect.

ONC: Planning for AHIC 2.0

Plans are underway, through an HHS cooperative agreement, to establish a successor to the AHIC that is a public-private partnership based in the private sector. The planned AHIC successor (to be known as "AHIC 2.0") would assume new governance and priority setting responsibilities regarding health IT standards and interoperability while bringing resources from both the public and private sectors.

Progress on Plan Objectives

During the summer of 2007, ONC produced a White Paper on the formation of AHIC 2.0 to serve as an illustrative example of what the new organization could look like which included AHIC 2.0 as an independent and sustainable entity that would include a variety of stakeholder representation, including consumers. In August of 2007, a Notice of Funding Availability was released to begin a competition to award a cooperative agreement to an organization to design and establish AHIC 2.0. The competition concluded in January 2008 with an award to LMI, working in collaboration with The Brookings Institution. During Stage One the grantee will design and launch AHIC 2.0 and this activity is expected to take about four (4) months. The AHIC 2.0 will begin its activities in the fall of 2008, and AHIC will meet for the last time near the end of CY 2008.

ONC: Secure Messaging Pilot

In January 2006, the AHIC advanced a recommendation to the Secretary that originated from the Chronic Care Workgroup, to establish an evidence base for informed reimbursement policy with respect to secure messaging. Upon acceptance by the Secretary, it was determined that this work would be conducted through ONC. The purpose of this project is to identify and work with three pilot sites to test the value of secure messaging between patients and their clinicians. The value of secure messaging technology will be evaluated both qualitatively and quantitatively.

ONC: Standardized Measures for Adoption of EHRs

Many studies on EHR adoption have had limited findings due to lack of consistent EHR definition and variability in the extent to which the technology is actually being used. A standardized approach for physician adoption was first presented in the October 2006 report from the Robert Wood Johnson Foundation on the state of adoption among physicians, titled *Health Information Technology in the United States: The Information Base for Progress*. The report also provided a base level of outpatient adoption based on this methodology of 9.2 percent. ONC is supporting work to develop standardized methods for measuring adoption. A consistent and standardized approach to measuring adoption and use of EHRs are critical to monitoring progress and to assessing the effect of various initiatives taken to increase the rate of adoption.

ONC: State Alliance for e-Health

The State Alliance for e-Health was designed to build state government consensus across jurisdictions on many issues related to HIE, including privacy and security. Launched in October 2006 by the National Governors Association Center for Best Practices, under a contract

with ONC, the State Alliance is composed of state governors, legislators, high-level officials, and technical experts.

The State Alliance has three taskforces devoted to discrete issues. The Health Information Protection Taskforce is focused on privacy and security and development of solutions identified by the HISPC. The Health Care Practice Taskforce is focused on licensure issues, state laboratory laws, and liability concerns. The Health Information Communication and Data Exchange Taskforce is focused on opportunities for publicly funded programs (e.g., Medicaid) to participate in health information exchanges.

ONC: State Level Health Information Exchange Consensus Project

In March 2006, ONC contracted with the American Health Information Management Association to gather information from existing state-level HIE initiatives to determine successful governance and legal, financial, and operational characteristics, and to develop consensus on guidance for developing state-level HIE initiatives. Nine states were selected to participate in the first phase, which included the development of consensus on best practices for state-level HIEs. The final report detailing findings from phase was completed in September 2006. The second phase, which focuses on the roles in ensuring governance and advancing interoperability of HIEs, will be completed with a final report in 2008.

ONC: Terminology Consensus Project

The multiple and often overlapping meanings health care has attributed to health IT terms poses a barrier to communication and has long been an obstacle to progress in IT adoption. By establishing a basic definition for all to use, the following actions will become achievable:

- Creating legislation that is understandable, consistent with industry efforts and does not work at cross-purposes with other policy, lawmaking, or regulation.
- Explaining IT concepts in language that the American public can comprehend and that is relevant to what they consider important to their health.
- Establishing a dialogue between IT vendors and their customers on expectations for the features of electronic record products and the elements of information sharing.
- Holding both sides of a contract accountable for performance and acceptance of well-understood agreements on general components of an IT product or service.
- Promoting the benefits of health information creation and responsible sharing with one clear voice and a minimum of conflicting messages.

ONC: Use Case Development

Use cases are descriptions of events that detail what a system (or systems) needs to do to achieve a specific mission or stakeholder goals. The use cases – based in part on recommendations from the AHIC that were accepted by the HHS Secretary – describe relevant stakeholders, information flows, issues, and systems needs that apply to the multiple organizations participating in these specified data exchanges. The use cases strive to provide enough detail and context for standards harmonization, architecture specification, certification consideration, and detailed policy discussions to advance the national health IT agenda.

Progress on Plan Objectives

In reference to Anti-Fraud Activities, RTI released a report in August 2007 that included 14 functional requirements that would serve to increase efficiency and improve billing accuracy for clinicians using EHRs. Many of the

recommendations are designed to improve existing standards for electronic health record systems

In July 2006, CCHIT announced its first certified ambulatory EHR products, which meet recognized criteria for functionality, security, and interoperability. The number has increased to almost 100 certified products, covering 75% of the installed market. In November 2007, CCHIT announced the certification of the first six inpatient EHR products, representing 25% of the market. CCHIT incorporates privacy and security provisions into their certification criteria. In 2008, CCHIT plans to expand certification to include interoperable health information networks that will include privacy and security technical criteria.

The Federal Interdepartmental Health IT Collaborative meets on a regular basis to discuss, coordinate, and collaborate on existing health IT programs.

FHA accomplishments to date include:

- FHA has created the first investment, planning and health information reporting guide, for use by agencies for planning health IT implementation and reporting progress.
- FHA has created the Federal Consortium to connect agencies within the federal government and with state, local, and tribal governments, as well as the private sector, to enable the secure exchange of interoperable health information.
- The Consolidated Health Informatics (CHI) Initiative put forward and received endorsement from the Secretary of HHS along with DoD and VA for over 20 standards for health IT which focused on medical vocabularies, messaging, EHRs and health care imaging.
- FHA has defined five federal health service domains: Access to Care, Population Health and Consumer Safety, Health Care Administration, Health Care Delivery Services, and Health Care Research and Practitioner Education.
- FHA's Food Safety Work Group has defined better business processes to protect the nation's food supplies.
- FHA has coordinated federal input into the health IT standards harmonization, interoperability specifications and gap analysis of standards for initial HITSP activities and nationwide health information network (NHIN) processes.

The Federal Interagency Health IT Policy Council meets biweekly to coordinate Federal health IT activities, disseminate information about agency activities related to health IT, and discuss health IT policy issues raised by Policy Council members or that are being discussed by the American Health Information Community, NCVHS, and others.

In July 2007, the Health Information Security and Privacy Collaborative (HISPC) released three reports: (1) the final assessment of variations; (2) a summary of the individual states' plans for implementing solutions to resolve conflicts or inconsistencies among state and federal privacy and security laws; and (3) a nationwide summary that presents a comprehensive overview of the project and recommendations for future directions. HISPC also produced a tool kit to help

states conduct similar assessments of variations in state privacy laws that affect the exchange of health information and foster multi-stakeholder collaborative approaches to identifying and implementing appropriate solutions.

The Health Information Technology Standards Panel has completed three sets of interoperability specifications that include 30 consensus standards and more than 800 pages of specific implementation guidance that describes how these 30 standards need to be used. They have released initial drafts of four other sets of interoperability specifications that will be finalized shortly. In October 2007, HITSP released a set of privacy and security standards intended to ensure the privacy and security of electronically transferred patient information. The standards will serve as an overarching technical foundation that will be incorporated into all interoperability specifications.

As of November 2007, ONC awarded contracts to nine geographically-based health information exchange organizations to begin trial implementations of the Nationwide Health Information Network. A tenth HIE has been formed across federal health care delivery programs (DoD, VA, IHS). The HIEs will participate in the NHIN Cooperative, which is a collaborative to test and demonstrate core technical services to enable basic exchange of health information between the different HIE networks, patients, and other stakeholders. In addition, each of the contractors will test two of the seven breakthrough use cases, as recommended by the AHIC and accepted by the Secretary.

The Secure Messaging Pilot Project was awarded to Abt Associates. Abt Associates has subcontracted with three pilot sites to establish secure messaging between clinicians and their patients.

In August 2005, ONC contracted with George Washington University and Harvard/Massachusetts General Hospital to develop a standardized methodology to measure the rate of adoption of EHRs among physicians and hospitals. A 2007 outpatient survey was conducted using this methodology to determine outpatient rate of adoption. The CDC (through its Center for National Health Statistics) will conduct ongoing surveys in the future. A 2008 survey by the American Hospital Association will be conducted to measure inpatient adoption.

In August 2007, the State Alliance accepted recommendations from the two taskforces devoted to privacy and security issues. The Health Information Protection Taskforce recommendations focused on methods to facilitate greater state-federal interaction on important health IT issues. The Health Care Practice Taskforce recommendations dealt with resolving telehealth barriers created by a lack of uniformity in the licensure process. A critical pathways report will be developed, which will include the recommendations from all three taskforces. This report will be published in 2008.

In September 2007, the American Health Information Management Association, (AHIMA) through a contract with ONC, released a preliminary report detailing state-level HIEs' roles in ensuring governance and advancing interoperability. Recommendations from the report include that each state should support and participate in a public-private entity that would take on a distinct HIE governance

role, and that each state should designate a formal leader who will foster coordination within state government to facilitate HIE participation, investments, and strategies across executive agencies.

The contract “Reaching Consensus: Defining Key Health Information Technology Terms” was awarded in September 2007 to develop a consensus definition for EMR, EHR, PHR, HIE, and RHIO. This report has been released.

In December 2005, ONC developed use cases on laboratory results reporting, registration and medication history, and visit, utilization, and lab result data. In May 2007, HITSP completed harmonized interoperability specifications for these data exchange scenarios. CCHIT has also incorporated aspects of the use case into their certification criteria for ambulatory and inpatient EHRs.

In August 2006, ONC developed use cases on emergency responder EHRs, consumer access to clinical information, medications management, and quality. HITSP has begun harmonizing relevant standards to the use cases and has released draft interoperability specifications for comment. The harmonized use cases should be finalized in 2008.

In January 2007, ONC developed use cases in the areas of remote monitoring, remote consultation, personalized healthcare, consultation and transfers of care, immunizations and response management, and public health case reporting. Once ONC has finalized more developed versions of the use cases that incorporate stakeholder comments, HITSP will begin harmonizing standards and developing interoperability specifications that pertain to the use cases.

OFFICE OF THE SECRETARY (HHS/OS)

HHS/OS: Personalized Healthcare

The Secretary of HHS launched The Personalized Healthcare Initiative to improve the safety, quality, and effectiveness of health care for every patient in the US. The initiative is based on the principle of tailoring medicine to each person’s needs through the use of “genomics,” or the identification of genes. HHS seeks to advance this initiative through two guiding principles:

- Provide federal leadership supporting research addressing individual aspects of disease and disease prevention with the ultimate goal of shaping preventive and diagnostic care to match each person’s unique genetic characteristics
- Create a “network of networks” to aggregate anonymous health care data to help researchers establish patterns and identify genetic “definitions” to existing diseases

HHS has formed four building blocks or goals to guide the implementation of the Personalized Healthcare Initiative. The first goal seeks to establish a secured electronic system to exchange, aggregate and analyze key data from a large number of existing secure health care databases. Secondly, HHS looks to support the science and health IT base and enable it to expand, as well as support efficient and effective drug development partnerships between public and private sector leadership. Lastly, HHS will help to integrate through various efforts the Personalized Healthcare Initiative into the mainstream of clinical practice.

HHS/OS: Value Driven Health Care

President Bush's Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs ("Executive Order 13410"), issued August 22, 2006, called for increased transparency in health care.

This Executive Order established the four "cornerstones" of Value-driven Health Care:

- Interoperable health information technology (health IT)
- Transparency of price
- Transparency of quality
- Use of incentives to promote high-quality and cost-efficient health care

The Executive Order directs federal agencies that sponsor or administer federal health plans (e.g., Medicare, Medicaid, the Federal Employees Health Benefit Program (FEHBP), and TRICARE) to take steps to implement these cornerstones to the extent permitted by law. The Executive Order is available at <http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html>.

Private Sector Initiatives

Secretary Leavitt announced on November 17, 2006, the corresponding non-federal initiative of Value-driven Health Care as a critical component of nationwide health IT interoperability. To achieve this goal initiatives have been launched in several arenas.

Communities

Communities are encouraged to form collaborations among purchasers, health plans, providers, and consumers to transform health care at the local level through quality improvement and public reporting. Two types of community collaborations are being recognized by HHS: Community Leaders and Chartered Value Exchanges. In recognizing collaboratives as Community Leaders, the Secretary is looking for multi-participant organizations that are able to foster multi-stakeholder collaboration within a community including health care providers, health plans, employers and consumers. Community Leaders should have the support and participation of leading business, civic and health care organizations and serve as a convener to advance the four cornerstones of value-driven health care. Recognized Community Leaders who have more fully developed their capacity to achieve the four cornerstones are eligible to become chartered as a Value Exchange. A Chartered Value Exchange (CVE) is a multi-stakeholder organization that has taken clear action in their community to convene industry stakeholders and advance the four cornerstones of Value-driven Health Care. In addition to the imprimatur that comes with being recognized as a Community Leader, CVEs will be invited to participate in a nation-wide Learning Network.

Employers

Employers provide the majority of health insurance coverage for Americans. Employers are encouraged to sign a statement of support and request information from their health plans, third party administrators, providers, and others with which they contract about how they are supporting the four "cornerstones." Employers are also encouraged to use a request for information/proposal (RFI/RFP) as a way to assess the extent to which health plans are consistent with the principles of value-driven health care. A sample RFI is available for employers as a guide to inform their discussions with plans.

Insurer Programs

A number of private insurers, including Blue Cross and Blue Shield Plans, Aetna, UnitedHealthCare, Humana, and Cigna, have launched programs to provide members with information about health care quality and promote measurement of provider performance. Tools allow consumers (either patients or employers) to compare physicians and hospitals.

State and Local Governments

State and local governments are one of America's largest employers and purchasers of health care and have also joined in the value-driven health care initiatives. The Secretary works in partnership with states and local governments to implement the principles of value-driven health care. HHS works with the National Governors Association (NGA) in educating governors and their staff about the importance of health care transparency. Through a series of issue briefs, conference calls, Web casts, and roundtables, NGA has engaged policymakers in dialogue about issues relating to advancing value-driven health care.

Progress on Plan Objectives

In reference to Personalized Healthcare, HHS issued a request for information (RFI) to solicit input from the public and private sectors on plans for developing and using resources involving health IT and genetic and molecular medicine, with specific reference to incorporating these capacities in evidence-based clinical practice, health outcomes evaluations, and research.

In reference to Value Driven Health Care, over 800 employers have signed on to support the four cornerstones and will help advance both interoperable health IT and population health information uses for quality and cost reporting. Similarly, 11 states and 12 cities, counties, or local government agencies have either signed statements of support or taken other significant steps in support of Value-driven health care.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

SAMHSA: Health IT Initiatives

SAMHSA aims to ensure that an electronic health record system includes features specifically designed for behavioral health consumers, caregivers, and providers. SAMHSA's goal is to empower individuals receiving and providing behavioral health care to take full advantage of the opportunities created by the rapidly approaching era of electronic health information and also to receive the protection they deserve for their highly sensitive health information. Projects to support this goal include the development of a behavioral health functional model for certification of EHRs, technical assistance for development and reuse of an open source EHR by state and county behavioral health agencies, an HL7 messaging standard for consumers to transmit privacy consents that control who can access their personal data, a structured vocabulary for privacy consents, a white paper on e-consent mechanisms in other countries, privacy FAQs on the Federal Confidentiality of Alcohol and Drug Abuse Patient Records regulation in the electronic environment, as well as the development of a secure system for sharing opioid addiction treatment protocols in emergency situations when treatment records are not accessible.

Progress on Plan Objectives

The HL7's Electronic Health Record System Functional Model was adopted as an ANSI standard in February 2007. SAMHSA is currently working on the Behavioral Health Conformance Profile for the functional model. Three HL7 version 3 models pertaining to consumer control of their health information have almost reached normative status and are planned for use in an upcoming interoperability demonstration led by VA security experts. SAMHSA has also produced a white paper, "The Implementation of E-consent Mechanisms in Three Countries: Canada, England, and the Netherlands (The ability to mask or limit access to health data)", which was disseminated in February 2007.

DEPARTMENT OF COMMERCE

NATIONAL INSTITUTE OF STANDARDS & TECHNOLOGY

NIST: Conformance Testing Infrastructure

The National Institute of Standards and Technology (NIST) develops conformance test suites, tools, methods, and prototypes to achieve high-quality, interoperable implementations that conform to standards and meet users' needs. New test generation techniques are also developed. NIST partners with ONC and the health IT industry to develop standards, tests, tools, and prototypes to advance the use of information technologies in health care systems and achieve an interconnected electronic health information infrastructure.

NIST: Security Technology

NIST engages the health IT community in technical security implementation assistance through publication of resource guidance on federal implementation of the HIPAA security rule and through outreach and awareness activities such as the CMS/NIST joint workshop on HIPAA Security Rule implementation which included presentations from ONC, HITSP, and CCHIT. For federal agencies, NIST also has a series of Special Publications and Federal Information Processing Standards, which detail information security requirements and guide federal implementation of the Federal Information Security Management Act and other federal information security and privacy policies and laws.

NIST: Conformance and Certification Expertise

NIST consults with emerging health IT certification bodies to help move them toward the implementation and accreditation to ISO standards for certification bodies. Also, NIST provides guidance on conformance topics, including how to specify conformance and communicate requirements for claiming conformance in specifications, as well as how to develop conformance test suites and tools.

Progress on Plan Objectives

NIST has continued to provide technical expertise for standards development. In the area of conformance and interoperability testing, NIST developed: a testing toolkit to validate HL7 messages for use with DICOM (radiology imaging) testing and Certification Commission for Healthcare Information Technology (CCHIT) interoperability testing; and, a tool to validate Continuity of Care Document messages for conformance to HITSP specifications. To assist with standards harmonization, NIST developed a health IT web portal providing interactive, electronic access to HHS Secretary-recognized and accepted use cases, HITSP specifications, and related test materials. NIST served as a technical advisor to the CCHIT for other matters such as testing methods, security, selection of jurors, and statistical tests of juror bias. In the area of security technology, NIST provided subject matter expertise to the CCHIT Security Workgroup and jointly sponsored in January 2008 with CMS a workshop on HIPAA Security Rule implementation and is currently updating guidance.

DEPARTMENT OF DEFENSE

DoD: AHLTA

AHLTA is a secure, standards-based, and patient centric EHR for use in garrison-based medical facilities and forward-deployed medical units. AHLTA provides military physicians with decision support and builds a single encounter document out of a team effort, linking diagnoses, procedures, and orders into one record. It creates a life-long, computer-based patient record for each and every military health beneficiary, regardless of their location, and provides seamless visibility of health information across the entire continuum of medical care. This gives military providers unprecedented access to critical health information whenever and wherever care is provided to our service members and beneficiaries.

DoD: Memorandum of Agreement with the State of Florida

On April 4, 2007, DoD signed a Memorandum of Agreement with the State of Florida establishing an unprecedented partnership to pursue the cross network exchange of health care information that will enhance the quality and efficiency of medical care for our mutual beneficiaries. This pilot collaboration between DoD and Florida is a model initiative to create a mechanism to share and exchange personal health information and data.

Progress on Plan Objectives

DoD AHLTA serves as a test bed for EHR standards and improved clinical support tools. The Florida initiative will help pilot interoperability and population health information use activities.

DEPARTMENT OF VETERAN AFFAIRS

VA: Electronic Health Records (VistA, CPRS)

VistA supports quality health care with an integrated health information and management system that is available in all VA health care facilities. The VistA framework consists of more than 100 programs that support the day-to-day clinical, financial, and administrative functions of the Veterans Health Administration (VHA). VHA developed the Computerized Patient Record System (CPRS) to provide a user interface for the information captured in VistA. With CPRS, VHA health care professionals can access patient information at the point of care across multiple sites and clinical disciplines.

VA: Personal Health Record (My HealtheVet)

My HealtheVet is a nationwide initiative intended to improve the overall health of veterans. The My HealtheVet portal provides a secure, online environment where veterans can view and manage their personal health record, access clinically relevant and objective health information perform health assessments and use electronic services such as prescription refill. My HealtheVet gives veterans an active role in their health care planning.

VA: Telehealth

The VA has several Telehealth initiatives, both internal to the Department and in conjunction with DoD. These initiatives draw on general telehealth, health informatics, and disease management, and include:

- National care coordination home telehealth program (CCHT). Patients are connected to Care Coordinators, who take assessments and receive electronically transmitted health readings from instruments placed in the veterans' homes. Early detection of possible health crises and helping veterans negotiate their way across the continuum of care are two of the major benefits.
- Specific telehealth programs focus on: retinal imaging for diabetes, mental health, rehabilitation, dermatology, and surgery.

Progress on Plan Objectives

In reference to Health IT adoption, VA has fully implemented its Computerized Patient Record System (CPRS) as a longitudinal record available wherever the Veteran seeks care from the Veterans Health Administration. CPRS provides VHA with a great deal of clinical health IT functionality, including clinical decision support and the capture of data in an electronic format, as well as an effective and efficient method for population health reporting.

My HealtheVet was a top-five winner of the 2007 Excellence.Gov awards for IT innovation and collaboration. My HealtheVet is an important test bed for assessing data access and translation for PHRs. The national system has over 500,000 registrants, and veterans have filled over 4.5 million prescriptions using the system. Veterans routinely record their health readings (e.g., blood glucose, blood pressure, pulse oximetry, etc.), health histories (self, family, military), and other pertinent health information, such as medications and medical visits. In addition, they routinely use activity and food logs to record their intake and physical activities, and are printing health summaries to take to their appointments with health care providers.

FEDERAL COMMUNICATIONS COMMISSION

FCC: Rural Health Care Pilot Program (RHCPP)

In September 2006, the FCC adopted an order, pursuant to section 254(h)(2)(A) of the Telecommunications Act of 1996, to establish the RHCPP to examine how the rural health care funding mechanism could be used to enhance public and nonprofit health care providers' access to advanced telecommunications and information services. Specifically, the RHCPP provides funding to support up to 85 percent of the costs associated with: (1) the construction of a state or regional broadband network and the advanced telecommunications and information services provided over that network; (2) connecting to Internet2¹ or National LambdaRail (NLR²); and (3) connecting to the public Internet. These networks will be designed to bring the benefits of innovative telehealth and, in particular, telemedicine services to those areas of the country where the need for those benefits is most acute. Where feasible, participants are required to implement health IT standards identified by HHS. The health care facilities participating in RHCPP include hospitals, clinics, universities and research centers, behavioral health sites, correctional facility clinics, and community health centers.

Progress on Plan Objectives

On November 19, 2007, the FCC awarded more than \$417 million for the construction of 69 statewide or regional broadband telehealth networks in 42 states and three U.S. territories. The RHCPP will support the connection of more than 6,000 public and non-profit health care providers nationwide to broadband telehealth networks.

¹ Internet2 is a U.S. advanced networking consortium, led by the research and education community since 1996, which promotes the missions of its members by providing both network capabilities and partnership opportunities that together facilitate the development, deployment and use of Internet technologies.

² The National LambdaRail (NLR) seeks to advance the research, clinical, and educational goals of members and other institutions by establishing and maintaining a unique nationwide network infrastructure that is owned and controlled by the U.S. research community.

Social Security Administration

SSA: Medical Evidence Request and Data Use Prototype

SSA requests approximately 15-20 million medical records each year from providers all over the country on behalf of, and with the authorization of, millions of individuals applying for disability benefits. In some cases, medical sources have difficulty providing medical records, oftentimes due to the labor costs associated with the pulling, extracting, printing and handling of the records. These delays and response failures can have a significant affect on the timeliness of claims processing for disability benefits. Disability benefits provide a monthly income and may also lead to certain types of health insurance coverage through Medicare and Medicaid. Not only does the applicant benefit through timely decisions, but the provider benefits through such things as the receipt of payment for records. Developing electronic methods of communication which relieve the provider of the burden currently associated with delivering records, will provide benefit for all parties. Work is underway to establish a standards-based request and receipt process which will streamline the disability claims development process. Included in this effort is the development of computer-based intelligent analysis of the data being returned by the provider which will identify potential areas of the disability listings which the examiner may focus on to expedite review and processing. The prototype will be operational by October, 2008.

SSA: NHIN “Release of Information to a Trusted Entity” Use Case Funding and Participation

The Medical Evidence Prototype referenced above will be furthered through the NHIN efforts. SSA has funded the use case to work toward formalizing the standards effort begun in the Medical Evidence Prototype. Standards for the handling of the patient’s authorization for the release of medical records and for the content of the medical record delivered will be vetted with the NHIN participants and submitted to the HITSP for consideration. In 2008, the NHIN Trial Implementations will employ these standards to demonstrate a nationally scalable exchange using test data. In 2009, SSA plans to put this process into production with interested NHIN participants.

SSA: Personal Health Record Prototype

Individuals filing for Social Security disability benefits start the process by providing a comprehensive list of conditions, medications, treating sources, and treatments. This can represent a significant effort on the part of the individual, and frequently critical information affecting the claims process is overlooked. The type of information individuals need to provide to SSA is represented in the typical PHR, whether populated through claims data, or by the patient or providers. SSA will develop a prototype in 2009 to study the ways through which a standards-based communication could gather information already existing in the PHR, with the patient’s authorization, and more simply and effectively begin the disability claims process.

MULTI-AGENCY COLLABORATIVE EFFORTS

AHRQ, FDA, NLM, NCI, and VA Data Standards Program (also known as Federal Medication Terminologies)

Collaboration among AHRQ, FDA, NLM, NCI, and VA resulted in standardizing the flow of drug information from drug manufacturers to FDA (for labeling information approval) to NLM (for assignment of RxNorm codes and display on NLM’s DailyMed web site)—with standardized terminology and use of HL7’s SPL standard. Additionally, this program supported the

development of the Unique Ingredient Identifier (UNII) by FDA and the development of RxNorm by NLM. The goal is to improve drug safety and quality of care by making federally approved drug information available in a uniform, standardized, computer-retrievable manner in real time.

DoD & VA: Exchange of Information

The collaborative federal partnership between Department of Defense (DoD) and Department of Veterans Affairs (VA) has resulted in increased integration of health care services to military service members and veterans. There are multiple initiatives that support timely transfer of data, real-time data sharing, shared data resources and sharing of critical test data to support more efficient use of resources and appropriate care coordination. The initiatives are called:

- Federal Health Information Exchange (FHIE)
- Bidirectional Health Information Exchange (BHIE)
- Clinical Data Repository/Health Data Repository (CHDR)
- Transfer of Radiology Images and Scanned Medical Records from DoD to VA Polytrauma Centers
- Laboratory Data Sharing Initiative (LDSI)

DoD & VA: Joint Inpatient Electronic Health Record Analysis Project

The Joint project will have two phases. The first phase will document and assess DoD and VA inpatient clinical processes, workflows, and requirements. The second phase will be an analysis of alternatives, a business case, and a recommendation for achieving a joint inpatient electronic health record solution with associated cost and schedule.

OIG & CMS: Hospital Donation of Health IT

The Anti-Kickback Statute, a criminal statute, enacted over 30 years ago prohibits any knowing or willful solicitation or acceptance of remuneration to induce referrals for health care services that are reimbursable by the Federal Government. The Department of Justice is responsible for criminal enforcement of the statute and the HHS Office of the Inspector General (OIG) is authorized to impose administrative sanctions such as program exclusion and civil monetary penalties when the statute has been violated. The statute sets forth certain voluntary “safe harbors” which, if fully complied with, insulate an arrangement from enforcement. The OIG is authorized to promulgate additional “safe harbors” by regulation.

The physician self-referral prohibition, commonly referred to as the “Stark” law, prohibits a physician from referring Medicare patients for inpatient and outpatient hospital services and certain other “designated health services” an entity with which the physician (or an immediate family member of the physician) has a financial relationship unless an exception applies. The Stark law prohibits the entity from submitting claims to Medicare for designated health services that are furnished as a result of a prohibited referral. The statute enumerates various exceptions and grants the Secretary the authority to establish additional exceptions by regulation for financial relationships that do not pose a risk of program or patient abuse. Violations of the statute are punishable by denial or payment for all designated health services claims, refund of amounts collected for designated health services claims, and civil money penalties (imposed by OIG) for knowing violations of the prohibition.

Because financial arrangements designed to assist physicians with the acquisition of health information technology implicates these statutes, both laws were believed to inhibit the use of health information technology. In recognition of this impact, the Medicare Modernization Act of

2003 required OIG to promulgate an anti-kickback safe harbor and CMS to promulgate a Stark exception in order to foster the donation and use of e-prescribing technology tools.

Progress on Plan Objectives

(Referring to all multi-agency collaborative efforts described above)

Some of the significant accomplishments in the Data Standards Program in 2007 include: increasing the pipeline of valid drug labeling information to NLM's DailyMed website; a significant reduction in distinct NDC drug package codes inaccurately linked to RxNorm; and an increase in the number of unique drug ingredients in the UNII code system

DoD and VA have been exchanging health information since 2001. Progress includes:

FHIE: As of September 2007, DoD has transferred health information for over 4.0 million patients to the FHIE data repository. As of September 2007, over 2.5 million patient messages (i.e. laboratory results, radiology reports, pharmacy data, and consults) have been transmitted on VA patients treated in DoD facilities.

BHIE: In July 2007, DoD made data viewable to VA from AHLTA, DoD's electronic health record. Data are viewable to DoD from all VA facilities.

CHDR: In September 2006, the Departments established interoperability. The exchange of computable outpatient pharmacy and medication allergy data enables drug-drug interaction checking and drug-allergy checking using data from both departments.

LDSI: LDSI for laboratory chemistry tests is available for use throughout DoD, and is actively being used daily between DoD and VA at several sites where one Department uses the other as a reference laboratory. LDSI is now operational at more than 9 joint VA/DoD sites.

DoD & VA are working on assessing the requirements and best approach for a joint inpatient electronic health record.

On August 8, 2006, OIG and CMS published final regulations under the Anti-Kickback Statute and Stark Law concerning the donation of eRx and EHR technologies. In addition to promulgating the MMA-mandated anti-kickback safe harbor and Stark exception for eRx technology, OIG and CMS promulgated a safe harbor and an exception, respectively, for certain arrangements involving the donation of electronic health records (EHR) technology. The EHR safe harbor and exception protect certain arrangements in which hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage Plans provide interoperable EHR software and information technology as well as training services to physicians (and under the Anti-Kickback Statute, other individuals and entities, such as pharmacists). The EHR safe harbor and exception sunset December 31, 2013; the eRx provisions do not. In response to a November 2006 request for guidance from a provider association, the IRS issued a memorandum

clarifying that 501(c)(3) hospitals may donate health IT software to physicians under specified conditions without risking their tax-exempt status.

Other Public-Private Sector Initiatives

National Quality Forum National Priorities and Goal Setting Project

The National Quality Forum (NQF) is conducting a project to develop a measurement framework to assess value over episodes of care for chronic conditions. The goal of this project is to move towards a better alignment of measurement development and reporting activities within national priorities and goals. The project steering committee has identified national priorities and corresponding three to five year goals. Two priority conditions, acute myocardial infarction and lower back pain, will serve as operational examples. The scope of the project includes:

- development of a measurement framework for chronic care episodes;
- identification of a starting subset of priority conditions;
- assessment of efficiency in the priority areas, including quality measurement and data collection;
- establishment of national performance goals; and
- development of a research agenda for continued measurement and monitoring focused on value across episodes of care.

The project to assess quality over episodes of care relies on the ability to collect longitudinal data in an efficient fashion. NQF is working to assess the availability of the needed data and develop methods to address gaps and areas of need. These data needs will help to inform the research agenda for an evolving quality measurement and monitoring system.

Progress on Plan Objectives

In 2007, AHRQ, CMS, and NQF released a draft report outlining a measurement framework for evaluating efficiency in episodes of care. The group accepted public comments until December 2007. Subsequently they will use the comments to finalize the report. The framework is intended to provide guidance to help key stakeholders move towards a higher performing health care system that is patient-focused and focused on quality. It will also serve to help define needed quality information that can be supported through health IT.

FEDERAL ADVISORY COMMITTEES

National Committee on Vital and Health Statistics

The National Committee on Vital and Health Statistics (NCVHS), established by Congress, serves as a Federal Advisory Committee Act (FACA) committee to provide recommendations to the Secretary of the Department of Health and Human Services on health data, statistics, and national health information policy and also has statutory responsibilities under HIPAA. NCVHS's 18 person membership possesses expertise in a wide array of health IT related fields including electronic data exchange, privacy and security, public health and health services research, health care delivery, health care financing, computerized health information systems,

and health data standards. NCVHS is supported by several standing and ad hoc subcommittees and working groups that address relevant health IT issues:

- Subcommittee on Privacy and Confidentiality
- Subcommittee on Standards and Security
- Executive Subcommittee's Work Group on National Health Information Infrastructure
- Subcommittee on Populations' Work Group on Quality
- Work Group on Uses of Health Data (formerly the Work Group on Secondary Uses of Data)

Progress on Plan Objectives

In October 2007, NCVHS released draft recommendations on "Enhanced Protections for Uses of Health Data: A Stewardship Framework for 'Secondary Uses' of Electronically Collected and Transmitted Health Data. In June 2007, NCVHS sent a letter to the Secretary of HHS recommending that HHS and Congress move expeditiously to establish laws to ensure that all entities that create, compile, store, transmit, or use personally identifiable health information are covered by a federal privacy law. In November 2006, NCVHS released a draft paper that described the critical privacy and security elements for connecting to the NHIN. In June 2006, NCVHS released a report, "Privacy and Confidentiality in the Nationwide Health Information Network."

American Health Information Community

The American Health Information Community (AHIC), a Federal advisory committee, was created by the Secretary of Health and Human Services (HHS) in June 2005. The AHIC provides recommendations which seek to advance the President's goal calling for most Americans to have access to secure, interoperable electronic health records (EHRs) by 2014. To achieve this goal, the AHIC provides recommendations to the HHS Secretary on how to accelerate the development and adoption of health information technology (health IT) and to ensure the privacy and security of electronic health records. The AHIC is composed of no more than 18 public and private health care stakeholders representing cross-cutting health interests, including hospitals, health care providers, health plans, employers, consumers, and federal and state agencies. The group is chaired by the Secretary of HHS.

The AHIC was originally chartered for two years, with the option to renew for the duration of no more than five years. The AHIC is supported by seven workgroups that address specific health information topics and provide recommendations to the AHIC on advancing progress in specific areas. Each workgroup has a short- and long-term charge, and has made progress in the form of recommendations related to those charges. Detailed information on the workgroups, their charges, and many of the recommendations they have made to the AHIC are available at <http://www.hhs.gov/healthit/ahic/>.

Progress on Plan Objectives

The AHIC serves as an example of a federal advisory committee that has successfully created a set of consensus recommendations for the HHS Secretary from varied and often disparate stakeholders. It has provided critical advice to

the Secretary of HHS, which has helped the Department to set the agenda for the advancement of health IT interoperability and adoption. AHIC has identified priority focus areas and created workgroups to explore them in greater detail. Subsequently, the AHIC reviewed, vetted, and fully considered the workgroup draft recommendations before advancing its own recommendations to the HHS Secretary. Finally, the AHIC provided feedback to the Secretary regarding the next steps for the AHIC as a whole, including the development of a plan for AHIC 2.0.

Each workgroup is described in greater detail below. The dates indicated reflect the year the workgroup was formed.

- **AHIC Chronic Care Workgroup (2005):** The Chronic Care Workgroup focuses on identifying and recommending ways to the AHIC to facilitate the deployment of widely available, secure technology solutions, such as secure messaging, for remote monitoring and assessment of chronically ill patients, and for communication between clinicians about patients. The workgroup is comprised of 20 members who represent an array of health care sectors such as health plans, federal agencies, employers, academic research centers, and disease advocacy groups.

Progress on Plan Objectives

In May 2006, the AHIC advanced to the Secretary recommendations intended to foster the widespread use of secure messaging as a means of communication between patients and providers. In June 2007, the AHIC advanced additional recommendations related to enabling the deployment of widely available, secure technology solutions for remote monitoring and assessment of patients and for communication between clinicians about patients. As a result of the Secretary's adoption of these recommendations:

- Interoperability standards are being developed for remote monitoring devices; and
- Options for reimbursing care outside the boundaries of the health care setting are being explored.
- Federal Communications Commission (FCC) is supporting wide availability of broadband so that both providers and patients can access interoperable health care information and use advanced telemedicine applications;
- A pilot study is underway to demonstrate the value of reimbursement for secure messaging;
- Medical licensure across state lines is being addressed by the State Alliance for e-Health;

- **AHIC Confidentiality, Privacy, and Security Workgroup (2006):** The Confidentiality, Privacy, and Security (CPS) Workgroup was established to advance draft recommendations to the AHIC after exploring in greater depth the cross-cutting nature of confidentiality, privacy, and security issues related to exchange of electronic health information. The CPS Workgroup's members consist of privacy, security, clinical, and technology experts, and also members from other AHIC workgroups.

Progress on Plan Objectives

In January 2007 and March 2007, the AHIC advanced recommendations to the HHS Secretary on patient identity proofing and protections needed for entities that support the exchange of health information but may not be covered under HIPAA. The objective of the latter recommendations was to ensure that all entities engaged in the exchange of electronic health information meet common baseline privacy and security standards that are at least equivalent to HIPAA requirements for covered entities.

- **AHIC Consumer Empowerment Workgroup (2005):** The Consumer Empowerment Workgroup was created to advance draft recommendations to the AHIC as it examines the challenges to increasing PHR utilization by consumers and propose strategies for addressing those challenges. The workgroup is composed of 28 members who exhibit a diverse set of professional expertise, especially in the areas of privacy and security, insurance plans, public sector leadership, mental health, standards and development, and consumer advocacy.

Progress on Plan Objectives

The AHIC has advanced 15 recommendations to the HHS Secretary, including:

- Development of a PHR certification process for interoperability, portability, privacy, and security;
- Privacy and security processes and protections for patient oriented products;
- Studies to assess consumer and patient needs with respect to PHRs for identifying incentives for adoption; and
- Education and outreach to increase consumer awareness of PHRs.

- **AHIC Electronic Health Records Workgroup (2005):** The Electronic Health Records (EHR) Workgroup has advanced draft recommendations to the AHIC as it explores and analyzes the barriers to widespread EHR adoption. The workgroup is composed of 20 members who represent a variety of sectors such as health IT vendors, hospitals, federal agencies, and private sector health informatics management associations.

Progress on Plan Objectives

Over the course of the past 18 months, the EHR Workgroup of the AHIC has heard extensive public testimony on the barriers to and enablers of EHR adoption in the delivery system. Recommendations the AHIC has advanced to the HHS Secretary, and the Secretary has adopted, include:

- CLIA guidance to allow the flow of historical laboratory results to clinicians other than the ordering physician;
- Interoperability standards for key laboratory results;
- Pay for performance programs that include structure and process measures, as well as outcome measures;
- On line educational programs to guide adoption and implementation;
- Privacy and security actions with respect to patient identity proofing, authentication, and authorization; and
- Opportunities to support mandated use of e-prescribing.

- **AHIC Personalized Healthcare Workgroup (2006):** The Personalized Healthcare Workgroup advances draft recommendations to the AHIC regarding its four main priority areas: genetic/genomic tests; family health history; confidentiality, privacy, and security; and clinical decision support. The workgroup is composed of 24 members and 17 senior advisors who represent a variety of health care sectors such as health care providers, health plans, pharmaceutical and diagnostics industry groups, academic research institutions, patient advocates, and federal agencies.

Progress on Plan Objectives

In July 2007, the AHIC advanced to the Secretary of HHS recommendations intended to guide the process for developing consensus-based standards to facilitate the incorporation of interoperable, genetic/genomic information and analytical tools into EHRs. The recommendations supported the continued implementation of the Personalized Healthcare Use Case and called for the creation of a multi-stakeholder workgroup comprising of private sector, federal health care providers and federal public health service agencies to determine the types of information that should be generated when performing genetic/genomic tests and to identify standard metrics, terminology, language and processes.

- **AHIC Population Health and Clinical Care Connections Workgroup (2005):** The Population Health and Clinical Care Connections Workgroup initially began as the Biosurveillance Workgroup. Its focus was to advance draft recommendations to the AHIC regarding a minimum data set that would aid in the transmission of essential ambulatory care and emergency department visit, utilization, and lab result data to authorized public health agencies within 24 hours of an emergency. The workgroup was then restructured to keep making progress through draft recommendations to the AHIC to facilitate the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health. The workgroup is composed of 24 members and 4 ex-officio members, who represent a variety of health care sectors such as hospital associations, health care providers, state and local public health agencies, and federal agencies.

Progress on Plan Objectives

In October 2006, the AHIC recommended a minimum data set for biosurveillance and public health reporting, which had originated from its Biosurveillance Workgroup.

In March 2007, the AHIC advanced to the HHS Secretary the recommendations crafted by the Population Health and Clinical Connections Workgroup in the areas of the process and business case for data/information exchange between public health and clinical care entities, case reporting and collaboration to develop a list of “nationally notifiable” conditions that would be reported to all levels of public health agencies, and proposed initial steps toward standardizing alerting and the exchange of contact information across public health and clinical care.

- **AHIC Quality Workgroup (2006):** The Quality Workgroup concentrates on drafting recommendations to the AHIC regarding how health IT can be used to support quality measurement and improvement. The workgroup is composed of 20 members who represent a variety of health care sectors such as hospitals, health plans, quality measure developers, employers, and federal agencies.

Progress on Plan Objectives

The AHIC advanced a recommendation to the HHS Secretary to enhance quality measurement development with improved coordination of reporting efforts.

Appendix D: Planned ONC Fiscal Year 2008 and 2009 Spending Aligned to the Strategic Plan Goals and Objectives

(Descriptions of the initiatives listed are found in Appendix C)

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC Program Funding	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
Department of Health and Human Services - ONC								
STANDARDS	√	√	√	√	√	√	√	√
National Institute of Standards and Technology (NIST) – Standards Harmonization (HITSP)								
Technology Certification (CCHIT)								
Federal Data Standards Initiative								
AHIC Operations								
AHIC Successor								
State Level HIE Consensus Project								
PRIVACY AND SECURITY	√			√	√			
Health Information Security and Privacy Collaborative								
State Alliance for e-Health								

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC Program Funding (continued)	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
Department of Health and Human Services - ONC								
ARCHITECTURE AND ADOPTION Technical Infrastructure Support Use Case Development/ Priority Projects Secure Messaging Pilot – [FY08 only] Nationwide Health Information Network (NHIN) Architecture EHR Adoption Survey Terminology Consensus Project	√	√	√	√	√	√	√	√
OPERATIONS ONC Staff Operations Support *Federal Health Architecture (FHA) – multi-agency *Anti-Fraud Activities *AHIC Workgroups *Federal Interdepartmental Health IT Collaborative – multi-agency *Federal Interagency Health IT Policy Council – multi-agency [*These activities are supported by ONC Operations Funds or ONC permanent staff]	√	√	√	√	√	√	√	√

Appendix E: Acronym List

AHIC	American Health Information Community
AHIC CPS Workgroup	AHIC Confidentiality, Privacy & Security Workgroup
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
AHLTA	Armed Forces Health Longitudinal Technology Application
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPR	HHS Office of the Assistant Secretary for Preparedness and Response
BHIE	Bidirectional Health Information Exchange
BISTI	Biomedical Computation Science and Technology Grants
CaBIG	The Cancer Biomedical Informatics Grid
CaGrid	Infrastructure that supports caBIG
CAH	Critical Access Hospitals
CARE	Continuity Assessment Record & Evaluation
CCHIT	Certification Commission for Healthcare Information Technology
CCHT	National Care Coordination Home Telehealth Program
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CHDR	Clinical Data Repository/Health Data Repository
CHI	Consolidated Health Informatics initiative
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CPHP	The Centers for Public Health Preparedness
CPOE	Computerized Physician Order Entry
CPRS	Clinical Patient Record System/ Computerized Patient Record System
CRS	Computerized Registration System
CPS	AHIC Confidentiality, Privacy, and Security Workgroup
CTSA	Clinical and Translational Science Awards
CVE	Chartered Value Exchange
DEA	Drug Enforcement Agency
DHS	Department of Homeland Security
DoD	US Department of Defense
EHR	Electronic Health Record
EMR	Electronic Medical Record
eRX	Electronic Prescribing
ESFAC	Epidemiological Surveillance Federal Advisory Committee
FACA	Federal Advisory Committee Act
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FEHBP	Federal Employees Health Benefit Program
FHA	Federal Health Architecture

FHIE	Federal Health Information Exchange
FMT	Federal Medical Terminology
FAQ	Frequently Asked Questions
GWAS	Genome-Wide Association Studies
Health IT	Health Information Technology
HHS	US Department of Health and Human Services
HHS/OS	Office of the Secretary
HIPAA	Health Insurance Portability and Accountability Act of 1996
HISPC	Health Information Security and Privacy Collaboration
HITSP	Healthcare Information Technology Standards Panel
HRSA	Health Resources and Services Administration
HSPD-21	Homeland Security Presidential Directive 21
ICD	International Classification of Diseases
ICD-10-PCS	International Classification of Diseases 10 Procedure Coding System
IHS	Indian Health Service
IRB	Institutional Review Board
IRS	Internal Revenue Service
ISO	International Organization for Standardization
LDSI	Laboratory Data Sharing and Interoperability
LOINC	Logical Observation Identifiers, Names, Codes
LPGP	Licensure Portability Grant Program
MCMP	Medicare Management Performance Demonstration
MMIS	Medicaid Management Information System
MITA	Medicaid Information Technology Architecture
NCI	National Cancer Institute
NCVHS	National Committee on Health and Vital Statistics
NDBS	Newborn Dried Blood Spot Screening
NGA	National Governors Association
NHDSE	National Health Data Stewardship Entity
NHIN	Nationwide Health Information Network
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NCC	National Coordinating Center
NDW	National Data Warehouse
NLC	Nurse Licensure Compact
NLM	National Library of Medicine
NPIRS	National Patient Information Reporting System
NRC	The National Resource Center for Health Information Technology
NQF	National Quality Forum
OAT	Office for Advancement of Telehealth
OCR	US HHS Office for Civil Rights

OIG	Office of the Inspector General of HHS
OMB	US Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OPM	US Office of Personnel Management
PAHPA	Pandemic All-Hazards Preparedness Act
PHIN	Public Health Information Network
PHR	Personal Health Record
PHS Corps	Public Health Service Corps
RFI	Request for Information
RFP	Request for Proposal
RHCPP	Rural Health Care Pilot Program
RHIO	Regional Health Information Organization
ROI	Return on Investment
RPMS	Resource and Patient Management System
RTI	Research Triangle Institute International
SAMHSA	US Substance Abuse and Mental Health Services Administration
SARS	Severe Acute Respiratory Syndrome
TNGP	Telehealth Network Grant Program
SDO	Standards Development Organizations
SPL	Structured Product Labeling
SSA	Social Security Administration
UMLS	Unified Medical Language System
UNII	Unique Ingredient Identifiers
US	United States of America
USHIK	United States Health Information Knowledgebase
VA	US Department of Veteran Affairs
VHA	Veterans Health Administration (within the US Department of Veteran Affairs)
XML	Extensible Markup Language