I. Background

As a nation, we are transforming health care delivery into a system that is patient-centered and value-based. Existing Medicare and Medicaid programs and initiatives, as well as new programs authorized by the Patient Protection and Affordable Care Act (Affordable Care Act), focus on new service delivery and payment models that encourage and facilitate greater coordination of care and improved quality. These new initiatives include accountable care organizations (ACOs), bundled payments, health and medical homes, and reductions in payment for hospital readmissions. Critical to the success of these programs and the ultimate goal of a transformed health care system is real-time interoperable HIE among a variety of health care stakeholders (clinicians, laboratories, hospital, pharmacy, health plans, payers and patients) regardless of the application or application vendor. Greater access to person-level health information is integral to improving the quality, efficiency, and safety of health care delivery.1

Interoperability is generally accepted to mean the ability of two or more systems or components to exchange information and use the information that has been exchanged.2 That means that there are two steps to interoperability: 1) the ability to exchange information; and 2) the ability to use the information that has been exchanged. The Department of Health and Human Services (HHS) recognizes that the actual exchange of health information needs to be both interoperable and electronic across a myriad of information systems for us to realize a patient-centered, value-driven health care system. In this document our references to HIE include the concepts of interoperability and the actual electronic exchange of information. HIE encompasses a broad array of strategies, technologies, types of exchange, and is enabled through common standards. The use of HIE facilitates better communication and enables more coordinated and connected care across the full continuum of health delivery and payment settings. Effective communication

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and information sharing is essential to improving the quality of care, bettering health of communities, and lowering per capita costs.

Since the enactment of the Health Information Technology for Economic and Clinical Health Act (HITECH), as part of the American Recovery and Reinvestment Act of 2009, adoption and use of electronic health records (EHRs) in the United States has dramatically increased. However, gaps and challenges still remain for the widespread use of interoperable systems and HIE across providers, settings of care, consumers and patients, and payers. Both providers and their vendors do not yet have a business imperative to electronically share person-level health information across providers and settings of care that exceeds the cost of doing so. For example, in 2011, four in ten hospitals electronically sent laboratory and radiology data to providers outside their organization; however, only 25% of hospitals could exchange medication lists and clinical summaries with outside providers. In addition in 2011, only 31 percent of physicians were electronically exchanging clinical summaries with other providers. There is even more limited HIE involving post-acute and institutional long-term and post-acute care (LTPAC), most behavioral health (BH), and laboratory providers who are not eligible for incentive payments under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs). Only six percent of long-term acute care hospitals, four percent of rehabilitation hospitals, and two percent of psychiatric hospitals have a basic EHR system. Close to 40% of Medicare beneficiaries discharged from acute care hospitals are discharged to post-acute care settings such as rehabilitation hospitals and skilled nursing facilities (SNFs), but there is little capacity in the system today to support HIE across these settings. Similarly, consumers and patients are not actively engaged in accessing and using their personal health information and requesting that their providers do the same.

Both the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) are working to close some of these gaps and overcome these challenges. CMS has instructed states on the use of the enhanced Medicaid

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4 ONC analysis of data from the 2011 American Hospital Association Survey Information Technology Supplement.
5 ONC analysis of data from the 2011 National Ambulatory Medical Care Survey Electronic Health Record Supplement.
6 Wolf L, Harvell J, Jha A. Hospitals Ineligible for Federal Meaningful-Use Incentives Have Dismally Low Rates of Adoption of Electronic Health Records http://content.healthaffairs.org/content/31/3/505.full.
Federal Medical Assistance Percentages (FMAP) at the 90/10 matching level to support HIE activities, as authorized by HITECH. This includes HIE efforts tied to EHR adoption, linking laboratory or other data sources for Medicaid eligible through HIE, and supporting hardware and software EHR/HIE linkages at the provider site that will support Medicaid providers’ meaningful use of Certified EHR Technology. As part of Stage 2 of the EHR Incentive Programs, CMS introduced many concepts of HIE that eligible professionals and hospitals must meet as part of the “meaningful use” requirements. We expect Stage 3 of the EHR Incentive Programs will also include requirements for advanced HIE. CMS continues to leverage longstanding relationships with the National Committee on Vital and Health Statistics (NCVHS)\(^8\) and industry partners such as the Workgroup for Electronic Data Interchange (WEDI)\(^9\) and Council for Affordable Quality Healthcare (CAQH)\(^10\) on HIE issues via the Health Insurance Portability and Accountability Act (HIPAA) transaction standards and operating rules. CMS’ strategic, enterprise implementation of e-health standards and services aligns the requirements of HIPAA Administrative Simplification including ICD-10, the EHR Incentive Programs, electronic quality reporting, and privacy/information security across its existing and innovative payment programs. CMS’ administration and enforcement of HIPAA Administrative Simplification regulations also promote interoperable data exchange via standards and operating rules. ONC has been advancing standards-based HIE through a variety of programs and initiatives including the Standards and Interoperability Framework, the State HIE Cooperative Agreement Program, the Direct Project, the Nationwide Health Information Network Exchange (NwHIN), and the ONC Health Information Technology (HIT) Certification Program.\(^11\)

II. Synthesis of RFI Questions and Comments

On March 7, 2013, CMS and ONC jointly issued a request for information, “Advancing Interoperability and Health Information Exchange” (RFI), which specified some of the potential

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\(^8\) NCVHS is a federal advisory body to the HHS on health data, statistics and national health information policy, i.e. shared, uniform standards for health data and the confidentiality of health information. It is subject to the Federal Advisory Committee Act.

\(^9\) WEDI is an authority on the use of Health IT to improve healthcare information exchange. Formed in 1991 by the HHS Secretary, WEDI was named in the 1996 HIPAA legislation as an advisor to HHS.

\(^10\) CAQH is a non-profit alliance of health plans and trade associations, working to simplify healthcare administration through industry collaboration on public-private initiatives. Through its Committee on Operating Rules for Information Exchange (CORE), CAQH is working to enhance interoperability between providers and payers through CORE-certified operating rules.

\(^11\) For more information on these initiatives, please visit healthIT.gov.
options to accelerate the existing progress in HIE and enhance the market environment. These options could increase HIE across providers, thereby improving the likelihood of successful delivery and payment reform. More than 200 submissions were received from a broad range of stakeholders, including a wide spectrum of providers, including LTPAC and BH providers and their trade associations; payers; state-based organizations and agencies; and consumers.

Stakeholders provided broad comments on advancing HIE and responses to the questions we posed in the RFI. Most comments received on the RFI were general in nature (e.g., “we support increasing HIE and the use of Blue Button”), while some comments offered discrete actionable options for accelerating HIE. A summary of comments received in response to the RFI follows.

**Accelerating HIE through Payment Models**

A significant number of commenters supported, and recommended extending, many current CMS efforts through the Center for Medicare and Medicaid Innovation (Innovation Center) to develop new processes and support “outside of the box” policy approaches in areas where current regulations restrict access and funding. Many commenters recommended adding specific requirements for HIE in the new payment models. The Health IT Policy Committee recommended in their comments that CMS require HIE in all advanced payment programs and Medicaid waivers. Commenters also expressed support for the CMS State Innovation Models Initiative to incorporate incentives in areas such as LTPAC and BH (including mental health and substance abuse treatment).

The vast majority of comments recommended that there be methods to support the adoption of interoperable EHRs among providers ineligible for incentive payments under the EHR Incentive Programs. These commenters requested direct incentives for LTPAC and BH providers. Commenters also recommended that CMS explore additional codes to reimburse for care coordination, including via telehealth, e-visits, radiology queries, and evaluation and management within fee for service (FFS) and as a part of new care models. Some commenters recommended including an adjustment in fee-for-service payment methods for the use of EHRs and HIE.

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13 The Health IT Policy Committee is a federal advisory committee under the Federal Advisory Committee Act. It is charged with providing policy recommendations to HHS related to, among other things, HIT and HIE. [http://innovation.cms.gov/initiatives/state-innovations/](http://innovation.cms.gov/initiatives/state-innovations/)
While a number of comments suggested that CMS focus on collaboration and innovation instead of additional regulation and/or revised conditions of participation, almost an equal number supported requiring HIE in regulatory requirements for quality measurement. The majority of commenters favoring regulation and/or revised conditions of participation thought it most appropriate for SNFs, nursing homes, and home health agencies. For example, several commenters suggested that survey and certification processes could be leveraged as a mechanism to accelerate HIE and adoption of interoperable EHRs in the SNF and nursing home settings. There was far less support for regulation and revised conditions of participation for the hospital setting, with concerns expressed about the maturity of the HIE market.

Other prominent recommendations included: provide technical assistance for providers that are not eligible for incentive payments under the EHR Incentive Programs (e.g., certain LTPAC and BH providers), including through the expansion of the Regional Extension Center (REC) program; extension of the expiration date for the safe harbor to the anti-kickback statute and the exception to the physician self-referral (Stark Law) for donated EHR software, information technology, and training services; and expansion of the Health Resources and Services Administration (HRSA) Health Center Control Networks to support BH providers.

**HIT Certification**

Commenters made multiple recommendations for the use of certification and the expansion of the ONC HIT Certification Program, including: establishing a voluntary certification program for HIE functions needed for value-based purchasing activities; developing an HIE certification process to ensure improved security of patient data; establishing certification of personal health records in a way that promotes standardization, privacy, and cross-provider utilization; requiring compliance certification of EHRs and HIE systems to reduce the variability of system exchange standards and the costs of implementation; adopting LTPAC and BH setting-specific certification criteria by the Secretary for use in certification under the ONC HIT Certification Program; and developing an EHR certification program for all health care providers that focuses on interoperability functionality.

**Standards and Electronic Exchange**

Commenters expressed support for current initiatives such as the Direct Project and Stage 2 objectives for the EHR Incentive Programs and associated certification criteria. Commenters requested a clear definition of what information must be exchanged from provider to provider and a standard to support the electronic exchange of the information (e.g., a longitudinal care
summary record). Commenters recommended that HHS address standardization of data elements, including the alignment of clinical quality measures and reporting requirements. Several commenters recommended extending standards and technology solutions to LTPAC patient information structures, such as the Outcome and Assessment Information Set (OASIS) for home health and the Minimum Data Set (MDS) for nursing homes. Commenters recommended that CMS and ONC encourage more bi-directional information exchange and eliminate the need for multiple interfaces that impact interoperability. Multiple commenters also recommended that the federal government foster open source software development.

**Provider Directories**

Commenters overwhelmingly agreed on the need for provider directories. Commenters identified the National Plan and Provider Enumeration System (NPPES)\(^{15}\) as the preferred backbone for data collection. Commenters also supported existing solutions such as the Universal Provider Datasource\(^{16}\) and the NwHIN\(^{17}\) and suggested that they could be used in conjunction with NPPES. A commenter suggested that HHS apply open data principles to provider databases such as NPPES, EHR Incentive Programs attestation, and the national provider identifier to make data available to the market for the creation of provider directories.

**Patient Engagement**

Commenters expressed support for patient access to their health information. Commenters suggested a variety of methods for how patients should access and use their health information in the management of their care. Some examples include: adding questions in the Consumer Assessment of Health Care Providers and Systems (CAHPS) surveys to measure patient and family engagement and its impact on care; requiring Blue Button Plus\(^{18}\) as part of Medicaid; enabling patient access to immunization information contained in registries; and credentialing patients to support validation needs for HIE activities.

**Laboratory Tests/Results Exchange**

Commenters raised concern about barriers to using standardized electronic laboratory results including the cost of interfaces and the current trend towards creating preferred laboratories.

\(^{15}\) [https://nppes.cms.hhs.gov/NPPES/Welcome.do](https://nppes.cms.hhs.gov/NPPES/Welcome.do)


Commenters suggested finalizing the Proposed Rule entitled “Clinical Laboratory Improvement Amendments (CLIA) Program and HIPAA Privacy Rule; Patients’ Access to Test Reports”\(^{19}\) to expand patients’ rights to access health records directly from laboratories. Commenters also advocated for further integration of Logical Observation Identifiers Names and Codes (LOINC\(^{20}\)) into every possible program as the best method to increase interoperability and the electronic exchange of laboratory test results. To make progress in this area, commenters identified mapping other standards to LOINC\(^{20}\) as a critical step in facilitating the adoption of LOINC\(^{20}\) and suggested that HHS could provide such mapping as it has done in other areas. A few commenters recommended that CLIA regulations be revised to require laboratories to send results using LOINC\(^{20}\). Commenters also suggested that ONC ensure that laboratory-related certification criteria under the ONC HIT Certification Program (e.g., 45 CFR § 170.314(b)(5) and (6)), including the Laboratory Results Interface (LRI) specification, are consistent with 42 CFR 493.1291 and CLIA guidance. Once these certification criteria are consistent, some commenters suggested that HHS consider offering a “safe harbor” or allow anyone who appropriately uses a laboratory system certified to the laboratory-related certification criteria to be deemed in compliance with CLIA regulations.

Privacy and Security Issues and Potential Solutions
While the RFI did not request information specifically related to privacy and security, a large number of respondents submitted comments on these topics. Many commenters expressed concerns about being able to follow state and federal privacy laws in an electronic environment, particularly those that require express patient authorization (often called authorization or consent depending on the law) to disclose health information (e.g., the confidentiality of alcohol and drug abuse treatment patient records under 42 CFR Part 2, and various state laws that require express permission to share mental health-related information or human immunodeficiency virus (HIV) status). They recommended HHS undertake additional work on developing standards and technology to facilitate electronically obtaining patient consent to disclose their health information and communicating that consent along with the related health information. Commenters expressed reluctance to exchange health information due to concern about the potential breach of electronic protected health information (ePHI), potential liability, and the assignment of responsibility. They expressed the continued need for provider education and outreach. Commenters also cited developing advances in data provenance (identifying the original source of the information) and data verification/accuracy as potential means of

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\(^{20}\) LOINC\(^{20}\) is a database of universal standards for identifying medical laboratory observations.
facilitating exchange. Commenters stated that there is an opportunity for HHS to reduce the potential risks of engaging in exchange by focusing more resources on consent policies, patient data-matching, and associated technologies.

III. Principles for Accelerating HIE

HHS believes all patients, their families, and providers should expect to have consistent and timely access to standardized health information that can be securely shared between primary care providers, specialists, hospitals, mental health and substance abuse services, LTPAC, home and community-based services, other support and enabling services providers, care and case managers and coordinators, and other authorized individuals and institutions.

It will take time to build a fully electronic interoperable system of coordinated care and communication across health care providers. HHS will seek out opportunities to accelerate and promote the development of this capacity across the health care system through incentives and by reducing barriers. HHS is fully committed to ensuring ubiquitous, standards-based electronic exchange of health information across all care settings through a multi-year approach that is consistent, incremental, yet comprehensive.

As the overall HIT ecosystem evolves and matures, its components are becoming more modular and distributed. Increasingly, EHRs themselves are modular and can include data services from multiple sources. There is a clear need to ensure standardization of data structure and format and interfaces through HIE standards and policies that are understood by vendors, providers, HHS programs, public and private payers, and other users. This will enable the use of a diverse and distributed set of interoperable technology solutions.

Based on the responses to the RFI, HHS has identified the need for a set of principles to guide a comprehensive effort across HHS agencies to accelerate HIE. These principles will guide and inform HHS in making future decisions about health care programs and policies. They will also provide a framework against which to judge the formulation and implementation of programs and policies that build upon and move beyond the foundation of the EHR Incentive Programs and the ONC HIT Certification Program.

The principles are organized into three categories: Accelerating HIE; Advancing Standards and Interoperability; and Consumer/Patient Engagement.
A. **Accelerating HIE**

1. HHS will seek to ensure that all new regulations and guidance on existing programs enable a patient’s health information to follow them wherever they access care to support patient-centered care delivery.
2. HHS will implement policies that encourage HIE incrementally and could evolve from incentive and reward structures to ultimately considering HIE a standard business practice for providers.
3. HHS will enable HIE where possible in support of state-led delivery and payment reform through federal and state partnerships.
4. HHS will encourage interoperability across states’ electronic information infrastructures, including Medicaid and State Survey Agencies and other HHS-funded enterprise systems.
5. HHS agencies will collaborate with other Departments in the federal government to facilitate the adoption and use of HHS HIT standards and interoperability requirements by those Departments and their constituents.
6. HHS will educate consumers from diverse cultural and socioeconomic backgrounds on HIE and what it means for them.
7. HHS will support the privacy, security, and integrity of patient health information across all of its HIE acceleration activities.

B. **Advancing Standards and Interoperability**

1. HHS will advance multi-stakeholder development of standards through the Standards and Interoperability Framework and coordination with standards development organizations such as HL7 and WEDI.
2. HHS will accelerate interoperability through adoption of HIT standards through a variety of policies and programs, informed by advice from the HIT Policy Committee, HIT Standards Committee, and the NCVHS.
3. HHS will, when appropriate, align HIT standards for quality measurement and improvement across Medicare and Medicaid programs.
4. HHS will accelerate alignment and implementation of electronic clinical quality measures, electronic decision support interventions and electronic reporting mechanisms.
5. HHS will develop standards and policies to enable electronic management of consent and HIE among providers treating patients with sensitive health data such as those with behavioral health conditions or HIV.

6. HHS will strengthen data provenance to enhance providers’ confidence in the original source of the data they receive.

C. **Consumer/Patient Engagement**

1. HHS policies and programs will support appropriate patient access to their health information.

2. HHS will support appropriate access to a patient’s health information by family care givers.

3. HHS will make HHS standardized data available to patients wherever possible.

**IV. Strategy for Accelerating HIE**

HHS is committed to an incremental, yet comprehensive and strategic approach to accelerating different types of HIE in support of care coordination, quality improvement and value-based payment. Where feasible, we plan to leverage available authorities to go beyond HITECH implementation to accelerate interoperability and electronic exchange of health information across the health care system. Incremental steps to accelerate HIE will stem from Affordable Care Act delivery reform programs, and Medicare and Medicaid payment. The program-specific changes to accelerate HIE would be intended to result in expanded patient access to their health information, as well as routine sharing of health information between multiple stakeholders, such as: hospitals and physicians; primary care physicians and specialists; and hospitals and nursing homes, home health providers, and other post-acute care and community-based providers. While many of our program and policy levers are specific to a setting of care they will be used to collectively achieve system-wide HIE to ensure health information always follows a patient regardless of where and when they receive health care services. A critical part of enabling the secure flow of information across the system is advancing the adoption of HIT standards through voluntary certification of HIT and HIE products and services. CMS will consider various ways in which the voluntary certification of HIT and HIE products and services under the ONC HIT Certification Program could be aligned with Medicare and Medicaid payment policy, to the extent feasible and within the scope of applicable law.
HHS’ approach to accelerating HIE among health care providers is expected generally to follow a natural lifecycle of incentives followed by payment adjustments and finally through conditions of participation in Medicare and Medicaid programs as HIE becomes an established enabler of patient-centered care delivery. This lifecycle can be illustrated through the potential implementation of the following policies over the next several years that could advance HIE-enabled transitions of care from one setting to another. Meeting the standards for meaningful use of EHRs has been identified in the CY 2014 Medicare Physician Fee Schedule proposed rule as a potential requirement for practices to furnish a new billable service for complex care management of chronically ill beneficiaries. Stage 3 of the EHR Incentive Programs could continue to require the sharing of e-summary of care records to support transitions in care for eligible professionals and hospitals to avoid payment adjustments. Eventually, as the market for HIE services matures and providers’ HIT capacity evolves, sharing of e-summary care records across hospitals and SNFs and nursing facilities will become a routine part of care delivery and a common business practice. As we monitor this progress we can compare existing Conditions of Participation/Conditions for Coverage/Requirements for Medicare (often also applicable to Medicaid) related to admissions, discharges and transfers with HHS-adopted standards for e-summary of care record exchange to ensure consistent standards that promote both patient health and safety and efficient information exchange.

For HIT and HIE functions that are critical to evolving a fragmented provider-centric health care system to a patient-centered system—such as sharing e-summary of care records for each care transition and team based e-care planning—CMS is evaluating strategies that begin with incentives or rewards through value-based payment programs and end with defining well-established types of HIE as a part of quality standards related to reimbursement under Medicare and Medicaid. This could in turn inform a pathway and timeline for standards development, HHS standards adoption, and incorporation into HIT product certification. HHS agencies will collaborate to ensure that an interoperability and certification road map will serve as a transparent planning tool to guide standards development, adoption, and HIT certification. CMS is also leveraging its e-health strategic planning to align health care administrative and clinical standards across HHS in support of interoperability. For example, CMS is coordinating ICD-10 implementation across the Department’s operating divisions such as HRSA, the Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS) and the National
Institutes of Health (NIH).  Altogether HHS will facilitate the types of HIE across health care providers needed to support patient-centered and value-based care delivery and the successful participation in new Medicare and Medicaid care delivery and payment programs, such as ACOs and bundled payment demonstrations.

HHS will continue to support HIE by: developing additional guidance materials that clarify federal policies for the privacy and security of electronic health information; developing and maturing the necessary HIT standards for interoperability; enabling patient access to electronic laboratory test results and focusing on the development of standards and policies that facilitate the exchange of laboratory test results; and facilitating the development of provider directories. HHS will also continue to evaluate short and long-term steps to accelerate HIE—including those suggested by commenters via the RFI—in relation to the Department’s health care delivery and payment transformation priorities; current authorities; available funding; and cost-benefit and risk analyses.

HHS has taken steps this year to accelerate HIE as part of the larger strategy to transform health care delivery and payment. Some of these recent actions include:

1. The CMS release of guidance to states on planning and implementing super-utilizer programs through Medicaid including allowable funds for HIE to enable improvements in quality and reductions in cost.
2. The CMS State Innovation Model awards via its Innovation Center that incorporate incentives and funding for HIE and EHR adoption among long-term care providers, behavioral health providers, and federally qualified health centers (FQHCs) and other safety net providers to enable multi-payer service delivery and payment models.
3. The CMS and the Office of the Inspector General proposed to extend the expiration date for and otherwise modify the physician self-referral exception (Stark Law) and anti-kickback safe harbor, respectively, for certain donations of interoperable EHR software, information technology, and training services.
4. The CMS Health Care Innovation Awards will fund up to one billion dollars of new awards (Round 2) to test new models of value-based payment and service delivery, such

21 ICD-10 integration across HHS is managed by CMS under the auspices of the Department’s Domain IT Steering Committee, which provides a formal approval body for making IT policy, strategy, and investment decisions across HHS staff and operating divisions.
as models that allow for advancement of HIE to support care coordination, quality improvement, and lower costs.

5. The CY 2014 Medicare Physician Fee Schedule Notice of Proposed Rulemaking that proposes reimbursement of complex chronic care management services furnished by physicians (and other qualified non-physician practitioners) beginning in 2015. This includes a proposal to develop standards for the practices that furnish these services which could include the use of EHRs that meet the most recent HHS regulatory standard for the EHR Incentive Programs.

6. HHS’ continued support of beneficiaries’ access to their own health information, including:
   a. A CMS Medicare Advantage call letter asking for participating plans to advance beneficiary access to health information through Blue Button.
   b. The ONC Blue Button Plus Implementation Guide that was released to provide data holders with a toolkit to meet and go beyond Stage 2 requirements of the EHR Incentive Programs for enabling patients the ability to view, download, and transmit their health information.

7. Medicaid’s use of existing authorities to engage with states to promote HIE and quality data reporting through FFS and Managed Care Organization state models.

8. The CMS’ organization and planned roll-out of “e-health University” to provide targeted outreach, education and technical assistance to promote e-health (e.g., prioritizing small and rural providers), optimally leveraging existing resources across HHS and industry.

9. ONC, through the HHS Entrepreneurs Program, is developing targeted, open source toolkits (“Health Information Service Provider (HISP)-in-a-box and Admission, Discharge, and Transfer (ADT)-Alerts-in-a-box”) that can be rapidly and cost-effectively deployed by a wide range of health care entities including those that are not eligible for the EHR Incentive Programs (e.g., SNFs, surgery centers, and home health agencies).

10. ONC funded two HIE governance entities to develop and adopt policies, interoperability requirements and business practices that align with national priorities; reduce implementation costs; and assure the privacy and security of health information. ONC also launched a Governance Framework for Trusted Health Information Exchange which includes guiding principles and outcomes for HIE governance.

11. HHS issued consumer engagement materials to empower knowledge and awareness on the rights under the HIPAA Privacy Rule for an individual to access and share their health information with a third party in an electronic format.
HHS looks forward to continued collaboration with stakeholders as strategic actions are taken across a variety of programs and policies over the next several years to accelerate HIE among health care providers and patients. We all share the goal to realize an electronically connected health care system that is truly patient-centered and value-driven.