Health Program
Health Project

Accelerating Electronic Information Sharing to Improve Quality and Reduce Costs in Health Care

Bipartisan Policy Center Health Information Technology Initiative

October 2012

BIPARTISAN POLICY CENTER

ABOUT BPC

Founded in 2007 by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole, and George Mitchell, the Bipartisan Policy Center (BPC) is a non-profit organization that drives principled solutions through rigorous analysis, reasoned negotiation, and respectful dialogue. With projects in multiple issue areas, BPC combines politically balanced policy making with strong, proactive advocacy and outreach.

DISCLAIMER

This report is the product of the Bipartisan Policy Center's Health Project. The findings and recommendations expressed herein do not necessarily represent the views or opinions of the Bipartisan Policy Center, its founders, or its board of directors.

Introduction

Health information technology (IT) and electronic health information sharing play critical and foundational roles in addressing the cost, quality, and access challenges of the United States health care system.

One reason that costs are high and health care quality suffers is that care is typically delivered in a fragmented delivery structure—in silos. Medicare patients see, on average, seven physicians, including five specialists, split among four different physician practices.[1] Lack of care coordination results in both gaps and duplications in care and often leads to overtreatment, costing the United States between $148 and $226 billion annually.[2]

To deliver coordinated, accountable, patient-centered care, a clinician and other members of the care team must access information that resides in multiple settings where care and services are delivered. Health information about patients can reside in many disparate locations: in the offices of their primary care physicians and specialists, hospitals and clinics, laboratories and radiology centers, health plans, pharmacies, nursing homes, and even with patients themselves. As a result, the electronic exchange of information across the multiple entities that deliver care and services to patients is a central and foundational component of coordinated, accountable, patient-centered care.

The need for electronic health information sharing was highlighted in a Bipartisan Policy Center (BPC) report titled *Transforming Health Care: The Role of Health IT,* published in January 2012. According to the report, "Without robust health information exchange it will be difficult, if not impossible, to develop and spread several common attributes of high performance, including those related to care coordination, clinical decision support, shared decision-making among the patient and the care team, and measurement of outcomes to support accountability and improvement."[3]

This report explores ways to accelerate electronic health information sharing—that is, access to patient information by clinicians and all members of the care team, regardless of care setting, while safeguarding the privacy and security of health information.

To inform these findings and recommendations, BPC collaborated with Doctors Helping Doctors Transform Health Care (Doctors Helping Doctors) to conduct a survey designed to gather clinicians' perspectives on their needs and preferences regarding electronic health information sharing, specifically to support care transitions (when a patient's care is "handed off" from one clinician to another).

The survey was developed and its results analyzed by Doctors Helping Doctors and the American College of Physicians in collaboration with BPC, and fielded by several clinician-led organizations, including AmericanEHR Partners (a program founded and managed by the

American College of Physicians and Cientis Technologies with the support of 17 medical societies), the American Academy of Pediatrics, the American College of Surgeons, and the Association of Medical Directors of Information Systems.

Results of the survey, available in greater detail in a separate report titled *Clinician Perspectives on Electronic Health Information Sharing for Transitions of Care* (Clinician Survey) published jointly by BPC and Doctors Helping Doctors, provide critical insights into how clinicians themselves want electronic health information sharing to function.

The survey asked clinicians what types of information they want in various care transitions, how they would like to receive it, and how quickly. Their answers will help both public and private sectors plan, develop, and implement health information-sharing capabilities that can effectively meet the needs of clinicians and the patients they serve. Key findings of the survey are integrated into the findings and recommendations of this report.

Findings

A Business Case for Health Information Sharing is Now Emerging

New delivery system and payment models that promote higher-quality, cost-effective care are proliferating in the marketplace, spurred by investments by the federal government, private sector, and states. Through the Center for Medicare and Medicaid Innovation (CMMI), the federal government is investing hundreds of millions of dollars in new models of care, including demonstrations of accountable care organizations, advanced primary care, the patient-centered medical home, home-based care, and bundled payments. CMMI is also promoting innovations designed to reduce hospital-acquired infections and 30-day readmissions.[4]

A recent study identified 30 accountable care arrangements within 22 health plans and this number is expected to continue to grow.[5] According to a recent survey of hospitals and health systems conducted by the Advisory Board, nearly half of respondents expect to have an accountable care organization in place by 2013, and 78 percent plan to do so by 2015.[6]

The number of patient-centered model homes is also continuing to rise. Seventy-six percent of respondents to the same Advisory Board survey are working with physicians to pursue medical homes[7] and more than 56 health plans are participating in the implementation of medical homes across 41 states and the District of Columbia.[8] Research indicates that a majority of states are advancing the medical home in their Medicaid or Children's Health Insurance Program.[9] In addition to funding medical home pilots through CMMI, the federal

government is also implementing the medical home within the Department of Defense, the Department of Veterans Affairs, and the Office of Personnel Management.[10]

Research shows that health IT and the electronic sharing of information across settings in which patients receive care and services play a critical, foundational role in these new models of care.

More robust requirements for electronic health information sharing contained in Stage 2 of the Centers for Medicare and Medicaid Services (CMS) Electronic Health Record (EHR) Incentive Programs—informally referred to as "Meaningful Use"—are scheduled to go into effect in October 2013 for hospitals and January 2014 for eligible professionals. These new requirements, combined with delivery system and payment models, are increasingly creating the "business case" for clinicians, hospitals, and other providers to begin sharing data electronically across organizational boundaries.

Stage 2 standards and certification criteria for EHR technology established by the Office of the National Coordinator for Health IT (ONC) will further improve the interoperability of and ability to exchange information among disparate EHR systems to meet the demands for electronic health information sharing. A more detailed assessment of Stage 2 Meaningful Use requirements, standards, and certification criteria is provided below.

According to the Clinician Survey, a majority of clinicians believe that electronic exchange of health information will have a positive impact on health care.

Specifically, a clear majority of clinicians surveyed believe that the electronic exchange of health information across care settings will have a positive impact on the quality of patient care (80 percent), the ability to coordinate care (80 percent), and the ability to not only meet the demands of new care models—such as the patient-centered medical home and accountable care (78 percent)—but also to participate in third-party reporting and incentive programs (72 percent). More than half of clinicians surveyed believe that the electronic exchange of information will have a positive impact on improving efficiencies in their practice setting (69 percent) and reducing health care costs (57 percent).

Lack of Interoperability and Information Exchange Infrastructure and Associated Costs are the Most Common Barriers to Information Sharing among Clinicians

According to the Clinician Survey, far more than any other issues, clinicians cite lack of interoperability between systems, the lack of an information-exchange infrastructure, and the cost of setting up and maintaining interfaces and exchanges, as major barriers to electronically sharing information to support clinical care.

As noted in Figure 1, more than 70 percent of clinicians surveyed identified these issues as major barriers, followed by 25 percent of clinicians who cited concerns about liability and privacy and security as major barriers.

Figure 1: Barriers to Clinicians Exchanging Clinical Information Electronically

Barrier	Major Barrier	Minor Barrier	Major or Minor	Not a Barrier
Inability for my EHR to communicate electronically with other systems (lack of interoperability)	71%	17%	88%	12%
Lack of information exchange infrastructure	71%	17%	88%	12%
Cost of setting up and maintaining interfaces and exchanges	69%	17%	86%	14%
Concerns about the liability associated with not acting on the clinical data made available	25%	42%	67%	33%
Concerns about privacy and security	25%	39%	64%	36%
Concerns specifically about HIPAA	22%	36%	58%	42%
No business case to justify exchanging information (e.g. no financial incentive)	22%	30%	52%	48%
Lack of ability to use the information given limitation of time	19%	35%	54%	46%
Tradition (we just haven't done it in the past)	16%	32%	48%	52%
State policies which limit the exchange of health information	14%	35%	49%	51%
Concern that I can't trust the data	8%	31%	39%	61%
Concerns about physician self-referral and anti-kickback laws	7%	25%	32%	68%

Clinicians were asked, "If you are not exchanging clinical information electronically with other clinicians, hospitals, laboratories, or other settings at any significant level today, what issues or barriers are preventing you from doing so?" Response options included "major barrier," "minor barrier," and "not a barrier."

Source: Bipartisan Policy Center and Doctors Helping Doctors Transform Health Care (2012) Clinician Perspectives On Electronic Health Information Sharing For Transitions Of Care.

These survey findings align with the results of a survey of physicians conducted by the Optum Institute in 2012. According to the survey, 55 percent of physicians who participate in health information exchange and make purchasing decisions identify the fact that "technology does not interface" as a technical barrier to accessing information outside their health system. Also, 51 percent of physicians cite "lack of access to other systems" as a technical barrier. [11]

Stage 2 of Meaningful Use Lays the Foundation for Increased Interoperability and Electronic Health Information Sharing

Stage 2 of Meaningful Use, along with the 2014 Edition of Standards, Implementation Specifications, and Certification Criteria, contains more robust requirements for interoperability and exchange, particularly as it relates to transitions of care.

While Stage 1 made the provision of summary of care record for 50 percent of care transitions and referrals optional, Stage 2 now requires it. Stage 2 also adds requirements associated with the *electronic* transmission of a summary of care record 10 percent of the time and requires at least one test of successful exchange with a recipient that uses a system designed by a different EHR vendor (with the goal of advancing interoperability across vendor systems). Finally, Stage 2 standards and certification criteria are more robust, requiring certified EHR technology to receive, display, and transmit considerably more types of data—using standards. Notably, for the first time, the Stage 2 standards specify requirements for data transport. The lack of such standards in Stage 1 has been identified by many as a barrier to more widespread exchange.

An analysis of the differences in electronic health information-sharing requirements between Stage 1 and Stage 2 of Meaningful Use and related standards and certification criteria is provided in Figure 2 below.

Figure 2: Transmission of a Summary of Care Record for Transitions of Care and Referrals: An Analysis of Stage 1 vs. Stage 2 Meaningful Use Requirements

STAGE 1 REQUIREMENTS	STAGE 2 REQUIREMENTS
MEANINGFUL USE REQUIREMENTS[12,13]	
Hospitals and eligible professionals (EPs) are required to provide a summary of care record for more than 50 percent of transitions of care or referrals (which need not be transmitted electronically)	Hospitals and EPs are required to provide a summary of care record for more than 50 percent of transitions of care or referrals (which need not be transmitted electronically)
	Hospitals and EPs are required to electronically transmit a summary of care record for more than 10 percent of transitions of care and referrals.
	Hospitals and EPs must also send at least one summary of care record electronically to a recipient that uses a different EHR vendor or a CMS-designated test EHR
Summary of care document has no required elements	Summary of care document must include the following: Current problem list Current medication list Current medication allergy list
STANDARDS AND CERTIFICATION REQUIREMENTS[14,15]	
Certified EHR technology must be able to electronically receive, display, create, and transmit a summary record that includes the following: • Diagnostic test results	Certified EHR technology must be able to receive, display, create, and transmit a summary of care record that includes the following: • Care plan fields • Care team members • Cognitive status (create and transmit only)

(laboratory test results must use standards*) • Medication allergies • Medications* • Problems* • Procedures* *Must use standards	• Date of birth • Discharge instructions (create and transmit only, inpatient setting only) • Encounter diagnoses* (create and transmit only) • Ethnicity* • Functional status (create and transmit only) • Immunizations* (create and transmit only) • Laboratory tests* • Laboratory test values/results • Medication allergies* (must also be able to incorporate in EHR) • Medications* (must also be able to incorporate in EHR) • Patient name • Preferred Language* • Problems* (must also be able to incorporate in EHR) • Procedures* • Race* • Reason for referral (create and transmit only, ambulatory only) • Referring or transitioning provider's name and contact information (create and transmit, ambulatory only) • Sex • Smoking status* • Vital signs *Must use standards

Stage 2 Meaningful Use requirements also offer another option that facilitates information sharing to support care transitions and coordination of care. Both eligible professionals and hospitals are required to have at least 5 percent of patients with the ability to "view online, download, and transmit to a third party" their health information from the certified EHR after their visit or upon discharge from the hospital.

Information that must be made available for online viewing, downloading, or transmission to a third party—summarized below—largely aligns with the information that must be transferred from provider to provider for a transition of care or referral, including specified standards.

- Admit and discharge date and location (hospital only)
- Care plan field(s) including goals and instructions
- Care team
- Current and past problem list
- Demographics (sex, race, ethnicity, date of birth, preferred language)
- Discharge instructions (hospital only)
- Laboratory test results
- Medication allergy list and history
- Medication list and history
- Patient name
- Problem lists

- Procedures performed
- Provider's name and office contact information (EP only)
- Reason for hospitalization (hospital only)
- Smoking status
- Summary of care record for transitions of care or referrals
- Vital signs

As a result, many patients who receive care from either a hospital or a health care professional that implements the "view, download, and transmit to a third party" functions required by Stage 2 Meaningful Use, will be able to either (1) download their health information described above and take it with them to their next visit or (2) have their provider "transmit" the same information from the certified EHR to the provider they are seeing on their next visit, using the same standards that are required for provider to provider exchange.

Clinicians Have Common Health Information-Sharing Needs and Requirements

Health IT plays a critical role in supporting high-quality, patient-centered, cost-effective care, especially when it facilitates the effective and efficient sharing of health information across the multiple clinicians and other providers that deliver, coordinate, and support care for any individual patient. This exchange of information is especially important during transitions of care, when responsibility for a patient's care is handed off from one clinician to another.

Clinicians on average, coordinate with hundreds of other clinicians in any given year. A typical primary physician coordinates with an average of 229 other physicians located in 117 different practices just for Medicare patients.[16] Breakdowns in transitions of care result in gaps and duplications in care, causing unnecessary costs and uneven quality.

The Clinician Survey asked clinicians from a range of specialties—including primary care, medical specialties, surgical specialties, and pediatrics—to think about their health information needs and preferences in three scenarios: (1) when a patient in their care is discharged from the hospital, (2) when they are caring for a patient referred to them by another physician, and (3) when they refer a patient of theirs to another physician.

Survey results reveal clinician needs and preferences regarding electronic health information: what type of information they want in these various care transitions, how they would like to receive or access it, and how quickly. Key findings from the Clinician Survey are summarized below.

ACCESS TO MEDICATION LISTS AND RELEVANT LABORATORY AND IMAGING TEST RESULTS ARE COMMONLY RECOGNIZED AS HIGH PRIORITIES FOR TRANSITIONS OF CARE

The Clinician Survey asked clinicians to rate the relative importance of different types of information related to the three types of transitions of care outlined above.

Across all three scenarios, more than 80 percent of clinicians surveyed rate medication lists, relevant laboratory test results, and relevant imaging test results as very important or essential types of patient health information to receive during transitions of care.

Not surprisingly, an overwhelming majority of clinicians surveyed also rate the following as very important or essential:

- A discharge summary (defined as a summary of care provided and changes to the treatment plan) upon a patient's discharge from the hospital.
- A reason for referral when a patient is referred to a consulting clinician.
- A summary of care provided by and treatment plan changes recommended by a consulting clinician for review by the referring clinician.

While more research is needed, these survey results indicate a level of convergence around a priority set of data types that should be shared electronically across care settings to support transitions of care. In general, these data types are well supported by Stage 2 requirements.

An analysis of priority information needs identified by the survey, compared with Stage 2 Meaningful Use requirements and related standards and certification criteria, is provided below.

Figure 3: Treatment of Information Identified as Highest Priority by Clinician Survey within Stage 2 Meaningful Use

PRIORITIZED INFORMATION NEEDS	REQUIRED FIELD IN THE SUMMARY OF CARE RECORD FOR CERTIFIED EHR TECHNOLOGY[17]
Discharge summary (summary of care provided and treatment-plan changes)	X
Medication list	X*
Reason for referral (synopsis)	X
Relevant radiology or imaging test results	
Relevant laboratory test results	X
Summary of care provided and treatment-plan changes	X
Care plan (e.g., including problem, goal, and instructions)	X
Discharge instructions	X

Follow-up appointments, procedures, tests, and referrals	X
Medication allergy list	X*
Other providers involved in care	X
Problem list	X*

**Also required to be included in the summary of care record transmitted for Meaningful Use.*

As noted above, certified EHR technology under Stage 2 supports the creation, transmission, and receipt of health information identified on average as important, very important, or essential by respondents to the Clinician Survey in almost all cases.

Relevant radiology and imaging test results (or a link to such results) are not required to be in the summary of care record, however a certain percentage (10 percent for hospitals and 20 percent for eligible professionals) of such results must be available through certified EHR technology as a menu option (i.e., optional requirement) in Stage 2 and HHS is considering adding image exchange requirements for Stage 3.[18]

MORE THAN HALF OF CLINICIANS SURVEYED PREFER THAT INFORMATION THEY VIEW AS "ESSENTIAL" GET "PUSHED" TO THEM, WITH THE ABILITY TO ACCESS THE REST OF THE INFORMATION THROUGH A QUERY

According to the Clinician Survey, clinician preferences vary regarding how they would like to access information that is provided to them from other care settings.

When asked how they would like to receive or access information from other care settings to support clinical decision making, more than half of clinicians surveyed indicate they would like only the information they characterize as "essential" to be "pushed" to them (i.e., somewhat like secure email), with the ability to access the rest of the information through a query (i.e., a look-up function). About 20 percent said they would like all of the information to be "pushed" to them and about 10 percent said that they would like to receive an alert that the information is available, with the ability to query any of the information needed.

The Stage 2 Meaningful Use requirement for electronic transmission of a summary of care record for 10 percent of transitions of care allows eligible professionals and hospitals to either electronically transmit the summary of care record to a recipient using certified EHR technology or enable a recipient to receive the record via exchange facilitated by an organization that is a Nationwide Health Information Network (NwHIN) Exchange participant or is validated through an ONC-established governance mechanism.[19]

The 2014 Standards, Implementation Specifications, and Certification Criteria only require certified EHR support for data-transport methods and standards that support "push" models, while data-transport standards that support "query" models are optional.[20]

CLINICIANS WANT TIMELY ACCESS TO INFORMATION: A MAJORITY SAY "WITHIN 24 HOURS" IS A REASONABLE TIME FRAME FOR A PATIENT WHO REQUIRES FOLLOW-UP CARE OR IS BEING TREATED FOR AN URGENT PROBLEM

More than 80 percent of clinicians surveyed consider "immediately" or "within 24 hours" to be reasonable timeframes for the exchange of information when a patient requires follow-up care or is being treated for an urgent problem. More than 70 percent feel that "within 24 hours" or "within three business days" is a reasonable timeframe if the problem is non-urgent and/or no follow-up care is necessary.

WHEN UPDATING THE EHR WITH INFORMATION RECEIVED FROM AN EXTERNAL SOURCE, CLINICIANS PREFER TO SELECTIVELY "PICK AND CHOOSE" THE INFORMATION THEY WANT INTEGRATED

When asked how they want to update their EHRs with information received from an external source, 57 percent of clinicians surveyed said they prefer to selectively "pick and choose" the external information they want to integrate into their own EHR, compared with 16 percent who prefer to import all the information. Stage 2 EHR certification requirements for clinical information reconciliation (including that which is focused on problems, medications, and medication allergies) are consistent with the ability to evaluate and reconcile any data that is received before it is imported into the EHR. Stage 2 EHR certification requirements that allow for received patient summaries to be displayed on a section-by-section basis without incorporation into the record, are also consistent with this need.

Recommendations

Accelerating Interoperability and Electronic Information Sharing

PLANNING AND GOVERNANCE FOR STANDARDS AND INTEROPERABILITY

Broad agreement on and adoption of well-specified standards that can be consistently implemented are necessary to facilitate the electronic sharing of information to support high-quality, cost-effective health care. Significant progress has been made related to standards in such areas as data content, vocabularies and transport standards in the last several years, due to work by standards development organizations and related groups such as HL7, LOINC, DICOM, SNOMED-CT, and IHE. Adoption of these standards is being accelerated by the federal government's adoption and alignment of such standards with the requirements of the CMS Medicare and Medicaid EHR Incentive Programs.

As noted previously, several additional standards were included in the 2014 Edition of Standards, Implementation Specifications, and Certification Criteria for EHR Technology,

expanding the foundation for interoperability and health information exchange. All certified EHR technology—required to be used in order to qualify for Meaningful Use incentives—must follow the standards, specifications, and certification criteria contained in the final rule.

The Health Information Technology and Economic and Clinical Health (HITECH) Act of 2009 established a structure and a set of processes for the federal government's adoption of standards for interoperability. The Health IT Standards Committee—a federal advisory committee authorized under HITECH—is required to recommend to the National Coordinator for Health IT (National Coordinator), a set of standards, implementation specifications, and certification criteria that align with the priorities set by the Health IT Policy Committee (another federal advisory committee) as well as the strategic plan developed by the National Coordinator.[21] To date, the Health IT Standards Committee's work has necessarily focused primarily on the standards required for Meaningful Use.

There are also electronic health information-sharing and standards needs that fall outside of Meaningful Use, many of which relate to the use of data for improvements in population health. As noted in BPC's report *Transforming Health Care: The Role of Health IT*, a longer-term standards and interoperability strategy and plan is needed to support the data needs for improving care, improving the health of populations, and engaging consumers.[22]

The development of a national strategy and long-term plan for standards and interoperability, with deep engagement by all health care stakeholders and strong linkage to federal government actions, will be critically important going forward. Such a strategy will help create certainty and enable long-term planning for capital investments by both providers and vendors, provide guidance to standards-development organizations that must build future standards needs into their planning processes early, help align and eliminate any redundancy among the multitude of important and valuable standards-related efforts, and enable participating health care organizations to devote constrained resources to the initiatives that will have the most impact.

Careful evaluation and testing of any standard before its widespread adoption—with significant input from those who will need to implement the standard in practice—is also needed. The Health IT Standards Committee in August 2012 recommended a set of criteria for evaluating standards that addresses maturity of the specification and its underlying technology components; the level of market adoption; the ease of implementation, deployment, and operations; and intellectual property considerations.[23] Such evaluation—with significant input from providers and vendors—will help to assure the feasibility and workability of standards before they are required or encouraged by the federal government and others to be widely adopted.

Importantly, metrics associated with the development of a standard by a "voluntary consensus standards body" were included in the final standards evaluation criteria recommended by the Health IT Standards Committee. Under the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119, the federal government is required to use standards developed by voluntary consensus standards bodies in its

regulatory and procurement activities, unless use of such standards would be inconsistent with applicable law or otherwise impractical. Only under certain strict conditions should the federal government use any standard that is developed by the federal government itself.[24,25]

In order for standards that are required by the federal government to be implemented by providers and vendors in ways that are consistent and fully promote interoperability and productive health information sharing, more detailed implementation specifications and guides are needed.

A number of existing standards development organizations (SDOs) have a long history of developing such specifications and guides, and continue to do so. Spurred by demands for and gaps in the range of implementation guides and tools needed to achieve interoperability and actual health information exchange for both Meaningful Use and new models of care, a number of initiatives have recently emerged, reflecting both leadership and enterprise on the part of the health care industry. These projects are funded by a variety of sources, including the federal government, and many are making significant progress. Examples of such efforts funded by the federal government include ONC's Standards and Interoperability Framework, the 360X Initiative, and the Beacon Community collaboration with EHR vendors. Other efforts—funded by the private sector—include the Care Connectivity Consortium, the EHR-HIE Interoperability Working Group, Health-e-Way, and the Integrating the Health Care Enterprise (IHE) initiative.

As the demand for interoperability and exchange continues to grow, so do the calls for more activities and initiatives that are designed to gain agreement on and adopt standards and tools to promote interoperability and exchange. Each initiative draws upon and seeks the involvement of clinicians, hospitals, EHR vendors, government, and other health care stakeholders, and the level of awareness of each of these activities varies considerably.

The development, coordination, evaluation of, and effective communication and dissemination of implementation guides and specifications that will support the actual use of standards in practice, developed by such initiatives, is crucial. Broader communication and alignment of these efforts within a national strategy and long-term plan will promote clarity for those without detailed knowledge of standards but who have the need to adopt them and will promote the use of the valuable tools that emerge from these efforts in alignment with a national strategy and plan.

RECOMMENDATION 1:
DEVELOP A NATIONAL STRATEGY AND LONG-TERM PLAN FOR STANDARDS AND INTEROPERABILITY TO SUPPORT A BROAD SET OF HEALTH CARE PRIORITIES; ALIGN CURRENT PUBLIC- AND PRIVATE-SECTOR EFFORTS

1. Federal policy makers, with the active participation of a broad set of health care stakeholders who deliver and provide services in health care, such as clinicians, health plans, hospitals, laboratories, pharmacies, radiology centers, and the number of federal agencies involved in health care, should collaborate on the development of a national strategy and long-term plan for standards and interoperability to support electronic health information sharing for a broad set of health care priorities—extending beyond Meaningful Use.
2. Work conducted in this area should reflect the attributes of a "voluntary consensus standards body" as outlined in the National Technology and Transfer Act, demonstrating openness, balance of interest, due process, an appeals process, and consensus.
3. This body can inform the work of the Health IT Standards Committee—the federal advisory committee established under HITECH to recommend to the National Coordinator of Health IT a set of standards, implementation specifications, and certification criteria that align with the strategic plan developed by ONC.
4. Leaders of the multiple and valuable efforts currently underway to promote and support interoperability and exchange should agree to participate in and coordinate their activities with the national strategy and long-term plan for accelerating the use of standards for interoperability.
5. As the creation of such a long-term plan gets underway, those involved in standards-related activities should create or use an existing forum to share goals and progress, and develop and disseminate information to help a broad range of organizations operating in health care understand how their initiatives interrelate and support a broader strategy and roadmap toward standards adoption and interoperability.

COMMON INFORMATION-SHARING NEEDS FOR TRANSITIONS OF CARE

The medical profession has been at the forefront of creating new care delivery models that promote better coordination of care, such as the patient-centered medical home. New models of care require well-designed and well-implemented health IT and electronic health information sharing to support good communication and coordination across the care team.

The Clinician Survey offers valuable insights on the electronic health information-sharing needs associated with transitions of care, including what information is most important to clinicians, how they would like to receive or access this information, and reasonable time frames for its receipt.

The Health IT Policy Committee and Health IT Standards Committee and the various work groups that support them, have also studied some of these issues, the results of which have

made their way into recommendations to the U.S. Department of Health and Human Services (HHS) on Meaningful Use requirements.

As demands for electronic information sharing continue to grow and both policy and market decisions are made regarding the infrastructure needed to support them, it is imperative that the medical profession engage with hospitals and other providers, as well as health IT organizations, to gain agreement on common information needs and the actions needed to facilitate meeting those needs. This collaboration can build upon previous related activities such as the Stepping up to the Plate Alliance organized by the American Board of Internal Medicine Foundation[26], or the Transitions of Care Consensus Conference organized by the American College of Physicians in collaboration with numerous medical societies.[27]

Primary care physicians, medical specialty physicians, nurses and other clinicians, and hospitals and other provider organizations would benefit from dialogue and collaboration to address—at a minimum—the following questions:

- What types of information are needed; where are the greatest priorities?
- How is this information best delivered and received?
- What are reasonable timeframes for sharing this information?
- What are the work flow considerations?
- What policies are needed to facilitate information sharing?
- Are there common agreements that can be used?

Engaging EHR vendors, those providing health information exchange and other health IT services, health plans, laboratories, pharmacies, and imaging centers in the dialogue will enable leaders to identify and prioritize requirements in light of existing technology and capabilities, as well as anticipated, new, innovative approaches to addressing information-sharing needs.

Robust dialogue and collaboration in health care's private sector can also help to inform regulatory actions such as those related to Meaningful Use as well as other federal programs and initiatives designed to support higher-quality, more cost-effective care.

RECOMMENDATION 2:
PRIMARY CARE CLINICIANS, MEDICAL SPECIALTIES, AND HOSPITALS SHOULD COLLABORATE ON DEFINING COMMON INFORMATION-SHARING NEEDS TO PROMOTE COORDINATED, VALUE-BASED CARE

1. Primary care physicians, medical specialties, nurses and other clinicians, and hospitals and other provider organizations should collaborate on the development of consensus on common information needs for transitions of care and an incremental roadmap containing commitments to information sharing to support those needs. Key elements of the plan could include:

    a. Priorities for the types of information needed.

b. Preferred methods of delivery and receipt.

c. Reasonable timeframes for information sharing.

d. Common policies needed to facilitate information sharing.

2. Collaborating providers should engage the health IT industry, health plans, laboratories, pharmacies, and imaging centers in dialogue to identify and gain agreement on near-term and long-term approaches to meeting common information-sharing needs.

3. Results of such deliberations should be communicated to the federal government and states to inform regulatory approaches and government-funded programs designed to promote improvements in the quality and cost-effectiveness of care.

ADDRESSING NEAR-TERM CLINICIAN NEEDS FOR INFORMATION SHARING

As noted in the findings section of this report, clinicians share many common needs associated with electronic health information sharing. For example, more than 80 percent of clinicians surveyed believe that medication lists, relevant laboratory test results, and relevant imaging test results are very important or essential types of patient health information to receive during transitions of care.

Certified EHR technology under Stage 2 of Meaningful Use includes fields for nearly all of the information types identified as being very important or essential in the summary of care record, enabling transmission of such information for a referral or transition of care. Capabilities associated with the transmission of radiology or imaging results—or a link that enables viewing of such results—are less advanced in Stage 2. Stage 2 Meaningful Use does include a menu option that requires a certain percentage (10 percent for hospitals and 20 percent for eligible professionals) of such results to be available through certified EHR technology, although no transmission is required.[28]

Given the importance of receiving relevant radiology or imaging results for transitions of care (with clinicians rating its importance at 4.4 out of 5.0 across all transitions of care), voluntary efforts—with participation by the federal government—designed to accelerate the exchange of imaging results (or links to such results) should be accelerated, with strong consideration for inclusion in Stage 3 of Meaningful Use.

When asked how they would like to receive or access information from other care settings to support clinical decision-making for transitions of care, more than half of clinicians surveyed indicate they would like only the information they characterize as "essential" to be "pushed" to them with the ability to access the rest of the information through a query.

In addition, considerable feedback was received through write-in portions of the survey regarding "information overload." Several clinicians indicated that many current methods of electronic information sharing—including those encouraged by Stage 1 of Meaningful Use—result in the receipt of large amounts of data, which are difficult to sift through and often irrelevant to clinical decision making.

Stage 2 Meaningful Use requirements for electronic transmission of a summary of care record (for 10 percent of transitions of care) enable eligible professionals and hospitals to either (1) electronically transmit the record to a recipient using certified EHR technology or (2) enable a recipient to receive the record via exchange facilitated by an organization that is an NwHIN Exchange participant or is validated through an ONC-established governance mechanism (both "query" models of exchange).[29] However, a higher bar is set to prove compliance with the latter NwHIN Exchange-based methods. While a provider only needs to demonstrate that a "push" occurred in the first scenario, if the second scenario is employed the provider must demonstrate that the summary of care record was accessed by the receiving provider.

The 2014 Edition of Standards, Implementation Specifications, and Certification Criteria only require Certified EHR technology to use standards for data transport that support "push" models of exchange. Data transport standards that support "query" models are optional, and therefore need not be adopted by vendors for certification.[30] The ways in which the optional data transport standards and requirements associated with NwHIN Exchange are described in the regulations have created some uncertainty in their usage.

CMS and ONC can support clinician needs for such query-based services, including "credit" for participating in existing health information exchange efforts that go beyond the federal "push" transport standards, by providing sub-regulatory clarification for Stage 2 of Meaningful Use and more robust requirements associated with query-based methods of exchange in Stage 3.

When asked how they want to update their EHRs with information received from an external source, 57 percent of clinicians surveyed say they prefer to selectively "pick and choose" the external information they want to integrate into their own EHR, compared with 16 percent who prefer to import all the information. While Stage 2 of Meaningful Use and related standards and certification criteria partially address this need through clinical information reconciliation as well as the ability to store and display received summaries without bringing them into the record, collaboration among providers and vendors as outlined in Recommendation 2 above can help to address this need.

RECOMMENDATION 3:
THE FEDERAL GOVERNMENT SHOULD PROVIDE SUB-REGULATORY AND EXPLANATORY GUIDANCE TO SUPPORT BOTH "QUERY" ACCESS TO PRIORITY INFORMATION AND TRANSMISSION OF IMAGING TEST RESULTS NEEDED FOR TRANSITIONS OF CARE

1. ONC should provide sub-regulatory and explanatory guidance on how it expects the optional data transport criteria to work in practice and what actual EHR and health information exchange capabilities would be supported by these new criteria.

2. CMS should provide sub-regulatory and explanatory guidance on how the query-based methods for transmitting a summary of care record will work in practice and what elements of certified EHR technology must be used by these alternatives.

3. In addition, CMS should provide sub-regulatory and explanatory guidance stating that a provider who sends a summary of care record to an organization that both meets the NwHIN criteria and where the intended recipient is also a party to that NwHIN eligible organization will get "credit" for Meaningful Use without an additional requirement that the recipient access the summary of care record. This clarification will provide parity in the transmission methods outlined in the transitions of care requirements in Stage 2 of Meaningful Use.
4. Finally, ONC, through non-regulatory means, should provide guidance and promote the acceleration of transmission of radiology or imaging test results (or links that enable viewing of such results) to support priority information-sharing needs of clinicians for transitions of care.

Improving the Accuracy of Patient Matching

The fragmented nature of the U.S. health care system means that patients who receive care from more than one provider often have medical records in multiple locations such as hospitals, physician practices, laboratories, pharmacies and other settings.

As the need for electronic health information sharing grows, so does the imperative to accurately identify patients and match their information electronically across the health care settings where they receive care. Such matching can occur electronically or through manual human intervention. Regardless of approach, failure to accurately match patient data can compromise patient safety and medical efficacy, and result in medical errors and increased costs.

CHALLENGES ASSOCIATED WITH EXISTING METHODS FOR MATCHING PATIENT DATA

Organizations involved in both the delivery of care and the development of systems to support care delivery have identified multiple problems associated with the matching of patient data across the settings in which care and services are delivered, including:

- **Significant error rates.** Published analyses of patient matching efforts report error rates of about 8 percent, trending higher in high-volume patient databases.[31] Nearly half of CIOs responding to a survey conducted by the College of Health Information Management Executives (CHIME) in May 2012 experienced false-negative (records that should be linked but are not) error rates ranging from 8 to 20 percent.[32] Nearly 40 percent experienced false-positive (incorrectly linked records) error rates ranging from 8 to 20 percent.[33] Moreover, 19 percent of respondents indicated that their hospital had experienced an adverse event during the past year due to a patient information mismatch.[34]
- **Disparate methodologies.** Methodologies for identifying patients vary widely across organizations, but generally fall into two broad categories: (1) algorithms that establish identity using multiple patient attributes; and (2) unique patient identifiers,

including local identifiers assigned by a health system; biometric identifiers, such as fingerprint, voice, retinal, or vein scans; or voluntary patient identifiers.[35] The use of varied matching methods could compromise the accuracy of results.

- **Lack of agreement on or availability of data fields needed for matching**. Algorithmic approaches are highly dependent on discriminating identifiers such as name, date of birth, mother's maiden name, etc. Not all systems capture the same attributes and currently there is no widespread agreement on the set of attributes that should be used for patient matching.
- **Variable quality of data.** A successful match requires accurate data. Data fields often hold inaccurate or outdated information as a result of unreported status changes, recording errors, and sharing of identifiers.[36] In addition, the data included in these fields must be recorded in standardized ways in order for accurate patient matching to occur.
- **High resource intensity.** Matching patient data is currently a labor- and resource-intensive activity. Respondents to the CHIME survey indicated that anywhere from 0.5 to 20 full-time equivalents (more than three on average) are needed in their organizations to reconcile records and merge disparate or duplicative information.[37] Average annual costs associated with patient matching can range from $500,000 to well over $1 million on human resources alone.[38]

HHS asked the two federal advisory committees established under HITECH to study the issue of improving the accuracy of patient matching. In February 2011, the Health IT Policy Committee recommended that HHS consider the following: (1) standardized formats for demographic data fields; (2) internally evaluating matching accuracy; (3) establishing accountability; (4) developing, promoting, and disseminating best practices; and (5) supporting the role of the individual/patient in identifying errors in fields used for matching.[39]

In August 2011, the Health IT Standards Committee made detailed recommendations regarding (1) patient attributes that should be used for patient matching (the final set of which would rely upon the level of accuracy established); (2) provider and health IT developer actions designed to enable patients to verify their information and providers to identify missing attributes; (3) implementation guides for patient query patterns; and (4) policies for responses to patient queries.[40]

RECOMMENDATION 4:
DEVELOP AND IMPLEMENT A NATIONAL STRATEGY FOR IMPROVING ACCURACY OF PATIENT MATCHING

1. Federal policy makers, working with industry and consumer stakeholders, should ensure the prompt development and implementation of a national strategy for improving rates of accuracy in matching patients to their health information, which includes—at a minimum—the following:

a. Standardizing some of the methods that are currently used to match patients, including data fields, definitions, and validation methods designed to improve the accuracy and the quality of the information gathered from patients.

b. Standardizing policies that support better patient matching, including those related to the establishment of acceptable rates of error in matching.

c. Developing guidance on policies to support the use of additional data fields (such as cell phone number, driver's license number, or place of birth) voluntarily provided by patients to their providers to improve rates of accuracy.

2. This strategy should be informed by research conducted by an independent, neutral organization that:

    a. Assesses current methods.

    b. Evaluates the impact of alternative approaches for improving accuracy, including maintenance of the status quo, improvement of algorithmic methods, and national deployment of a set of unique identifiers (whether voluntary or mandatory).

    c. Assesses consumer opinions and attitudes regarding alternative approaches.

THE NEED TO EXPLORE COMMON APPROACHES

Discussions about developing a unique patient identifier (UPI) have been ongoing for years. Although the Health Insurance Portability and Accountability Act of 1996 (HIPAA) called for the creation of a UPI, concerns about privacy and security led Congress to pass a law in 1999 prohibiting HHS from using any of its funds to develop a UPI without the express approval of Congress. That restriction remains in place today.[41]

Under growing pressure to exchange information electronically, a number of our nation's providers are increasingly calling for a set of commonly accepted identifiers, whether voluntary or mandatory, to improve accuracy in patient matching.

At the same time, even UPI advocates agree that a UPI alone cannot entirely solve the various patient matching problems that currently exist. Experts point out that additional patient matching information would be required when a UPI is not known or accessible, when there are duplicate UPIs, when the information contained in the UPI is inaccurate, or to accommodate historical data not tagged with the UPI.[42]

There are mixed views on the public's acceptance of a mandatory unique identifier. As a result, numerous proposals are now emerging that would enable consumers to voluntarily sign up for a unique, common identifier that their providers could use to match their health records, with knowledge of how that identifier would be used. Such an approach could be linked with consumer-mediated methods of health information exchange (e.g., efficient, effective methods for consumers to be able to download their health records from multiple

providers to support the creation of a comprehensive health record), which are expected to become more prevalent given inclusion of requirements for a patient to be able to access, download, and transmit to a third party their health information, with Stage 2 of Meaningful Use.[43]

National dialogue informed by research is needed, with significant input from consumers, clinicians, health plans, hospitals and health systems, and technology companies—ideally with leadership by the federal government—to explore principles, policies, standards, and strategies for improving the accuracy of patient matching through consumer-facilitated approaches.

RECOMMENDATION 5:
EXPLORE PRINCIPLES, POLICIES, STANDARDS, AND STRATEGIES FOR IMPROVING THE ACCURACY OF MATCHING USING CONSUMER-FACILITATED APPROACHES

1. A nationwide effort, involving federal policy makers, consumers, health care stakeholders, and experts, should be advanced to explore and develop recommendations on principles, policies, standards, and strategies for enabling voluntary, consumer-facilitated approaches for improving the accuracy of matching.

2. Such approaches can include new methods of credentialing and identity management, such as those being developed by the National Institute of Standards and Technology's National Strategy for Trusted Identities in Cyberspace (NSTIC) Initiative, the use of additional existing identifiers (such as a driver's license number, cell phone number, etc.) on a voluntary basis, or new methods that emerge from consumers' ability to access their own health records, such as those that align with new Stage 2 Meaningful Use requirements that enable consumers to view, download, and transmit their health information from any certified EHR.[44]

SHARING LESSONS LEARNED AND BEST PRACTICES

Because of concerns about possible negative reactions, software and service vendors, as well as providers and health information exchange efforts, rarely share their patient matching accuracy rates, which can vary on a site-by-site basis. Because of the proprietary nature of the industry, there is very little sharing of methods or processes associated with matching among vendors and providers. This lack of information sharing reduces considerably the opportunities for improvements in matching methodology and practice. A national forum that facilitates the sharing of best practices and lessons learned will improve methods and approaches for improving accuracy in patient matching.

RECOMMENDATION 6:
DEVELOP AND IMPLEMENT A NATIONAL FORUM FOR SHARING LESSONS LEARNED AND BEST PRACTICES.

1. Approaches for sharing methods and results across organizations should be developed and implemented. Best practices and lessons learned regarding technology, human resources, workflow, and policy will facilitate improvement across

the industry. More transparency in disclosing accuracy rates will facilitate assessment of methods and also promote improvement.

2. A forum for sharing this information should be developed and launched by a collaborative effort involving a broad set of stakeholders in health care, with participation by federal and state government.

SHARED SERVICES CAN PROMOTE STANDARDIZATION AND REDUCE BURDEN

Common principles, policies, standards, and methods for matching patient data will facilitate the sharing of services for matching across multiple organizations, promoting standardization, improving results, and producing economies of scale. Current initiatives under development by both private-sector consortia and states to create shared services for patient matching should be assessed and leveraged for more widespread deployment.

Examples include the NSTIC in Cyberspace Initiative, referenced above, which is implementing a cybersecurity-focused identity-management vision and strategy. Guiding principles for its implementation include a process that is privacy-enhancing, voluntary, secure, resilient, interoperable, cost-effective, and easy to use. This initiative is intended to be led by the private sector with federal government support.[45]

Another example is the Care Connectivity Consortium, in which five leading health systems—Geisinger Health System, Kaiser Permanente, Mayo Clinic, Intermountain Healthcare, and Group Health Cooperative—have joined together to facilitate the effective connectivity of electronic patient information in an approach that protects patient confidentiality.[46] One of the services that the Consortium plans on making available is related to identity-management services, with the goal of lowering the barriers associated with correlating patient data across organizations.[47]

Some have suggested that the infrastructure being developed to facilitate matching of records used for the development and deployment of health insurance exchanges can be leveraged to support matching of patient data.

RECOMMENDATION 7:
SHARED SERVICES SHOULD BE EXPLORED TO IMPROVE THE EFFICIENCY AND EFFECTIVENESS OF METHODS DESIGNED TO IMPROVE ACCURACY IN PATIENT MATCHING

1. Health care stakeholders should explore the adoption of shared services for methods designed to improve accuracy in patient matching, looking to the federal government, the states, and the private sector for alternatives.

Updating Current Laws to Advance Information Sharing

The Anti-Kickback Statute and Stark Laws prohibit any remuneration in exchange for the referral or ordering of items or services paid for by a federal health care program. The Anti-Kickback Statute and Stark Laws, along with the 2006 final rules that grant safe harbors and exceptions are explored here in the context of accelerating interoperability and health information exchange.

ENABLING PAYMENT FOR CERTAIN TYPES OF ELECTRONIC HEALTH INFORMATION SHARING

The Anti-Kickback Statute and Stark Laws were intended to prevent inappropriate influence over a physician's referring and ordering decisions. However, these laws were written before the value of electronic transmission of orders for items and services and the related electronic patient data could be separated from the federally reimbursable items or services being ordered.

Stimulated in part by the CMS Medicare and Medicaid EHR Incentive Programs, referrals and other orders can increasingly be sent electronically. There is a lack of clarity regarding whether a receiver of a referral or health care order can pay for an electronic transaction for such a referral or order, on a per transaction basis, without violating the Anti-Kickback Statute or Stark Laws. OIG Advisory Opinion 11-18 opened the door for some models of per transaction payment for exchange, but it only applies to the recipient of the opinion, and it does not address Stark issues. Subscription or licensing models, as well as public or private funding, do not have the same compliance concerns.

As a result of this lack of clarity, clinicians who receive electronic messages containing referrals or orders are reluctant to pay for those services on a transaction basis, for fear of violation of the Anti-Kickback Statute or Stark Laws, which can result in substantial penalties. This fear and reluctance stifles the creation of new, innovative business models that have the potential to accelerate the rate at which health information is exchanged.

RECOMMENDATION 8: HHS SHOULD ESTABLISH AN ANTI-KICKBACK SAFE HARBOR AND STARK EXCEPTION FOR PAYMENTS ASSOCIATED WITH THE ELECTRONIC TRANSMISSION OF DATA THAT ACCOMPANIES A REFERRAL OR ORDER

1. To improve clarity and reduce perceived risk of violation of the Anti-Kickback Statute and Stark Laws for payment of electronic transmission of data and health information exchange services, HHS should establish an Anti-Kickback safe harbor and Stark exception that clearly outline the circumstances under which commercially reasonable payment for electronic transmissions or exchange associated with referrals and other orders by the providers receiving such referrals or orders will not be considered violations.

STARK EXCEPTIONS AND ANTI-KICKBACK SAFE HARBORS FOR DONATION OF HEALTH IT

In 2006, CMS and the Office of the Inspector General (OIG) within HHS issued final rules that created two new exceptions to the Stark Law and two new safe harbors to the Anti-Kickback Statute that permit, under certain circumstances, the donation of health IT and related services for the purposes of improving electronic prescribing and electronic health record capabilities.[48] These exceptions and safe harbors have stimulated the adoption of EHRs by addressing barriers created by the upfront costs associated with the purchase of EHRs, particularly for small, independent, unaffiliated physician practices. They are also playing a critical role in new accountable care arrangements that are being launched across the country to improve cost and quality outcomes. The Anti-Kickback safe harbors and Stark exceptions are scheduled to expire at the end of 2013.

Concerns about the development of closed networks in response to donated health IT facilitated by Stark exceptions or Anti-Kickback Statute safe harbors led CMS and the OIG to include provisions about the interoperability of donated health IT. In order for the exceptions and safe harbors to apply to donated software, it must be interoperable at the time that it is provided to the recipient. Software is deemed interoperable if a certifying body that has been recognized by the HHS Secretary has certified the software no more than 12 months prior to the date it is provided to the recipient. Further, the donor may not take any action to limit or restrict the use, compatibility, or interoperability of donated items or services with other electronic prescribing or EHR systems. Donors may not attempt to create closed or limited EHR systems by offering technology that effectively locks in business for the donor.[49] While these provisions require that donated health IT be interoperable, there is no requirement that actual exchange with other systems occurs.

Concerns about the lack of effective exchange were also expressed in both the proposed and final rules associated with Stage 2 Meaningful Use. In its proposed rule for Stage 2 Meaningful Use, CMS called for the summary of care records for 5 percent of transitions of care and referrals to be transmitted electronically to a recipient with no organizational affiliation that uses a different certified EHR vendor.[50] As noted in the proposed rule, this provision was designed to promote interoperability across EHR systems and health care organizations. In the final rule for Stage 2 Meaningful Use, the requirement was scaled back considerably, calling for one or more successful electronic exchanges of a summary of care record with a recipient using technology that was designed by a different EHR developer or a CMS-designated test EHR, given, as noted by CMS, perceived difficulties in the measurement of the requirements included in the proposed rule.[51] As noted previously, more than 70 percent of clinicians surveyed in 2012 cite the lack of interoperability of EHR systems as a major barrier to electronic health information sharing for transitions of care.

The Anti-Kickback Statute safe harbors and Stark exceptions for the donation of health IT and related services can play a key role in supporting adoption and Meaningful Use of interoperable EHRs and may have renewed importance as EHR incentives diminish and as new models of care that promote care coordination and accountability increase. At the same

time, given concerns about the need for interoperability among different provider organizations and their EHR systems, care should be taken to assure that requirements for interoperability of donated systems are robust. Stage 2 certification, which goes into effect in October 2013 for hospitals and January 2014 for eligible professionals, contains more robust requirements for—and testing of—interoperability within certified EHR technology. In addition, the current certification requirements associated with these provisions (which pre-date the current ONC certification process associated with Meaningful Use) should be revised so that respective timetables for certification align.

RECOMMENDATION 9:
EXTEND STARK EXCEPTIONS AND ANTI-KICKBACK SAFE HARBORS FOR HEALTH IT DONATIONS AND ASSURE ROBUST INTEROPERABILITY PROVISIONS

1. The rules issued by CMS and OIG in 2006 should be extended beyond their current expiration date of the end of 2013. These rules created two exceptions to the Stark Law and two safe harbors to the Anti-Kickback Statute that permit, under certain circumstances, the donation of health IT and related services for the purposes of improving electronic prescribing and EHR capabilities.
2. With their extension, interoperability provisions contained in the rules associated with safe harbors and exceptions for health IT donations should be revised to reflect the current certification processes and timetables, enabling alignment with the more robust interoperability requirements contained in the 2014 Edition of the Standards, Implementation Specification, and Certification Criteria.

Privacy and Security

CLARIFYING RULES ASSOCIATED WITH PRIVACY

Concerns about privacy among consumers and clinicians continue to affect willingness to share information across the settings in which care and services are delivered. According to the Clinician Survey, 25 percent of clinicians recently surveyed believe that concerns about privacy and security are major barriers to electronic information sharing, while 39 percent believe they are a minor barrier.

Since most applicable federal and state privacy laws cover identifiable health information when it is stored, used, or shared in any form (paper or electronic), most health care providers already have sufficient legal authority to electronically store, use, and share health information for treatment, payment, and routine administrative tasks ("health care operations"). Some more sensitive health data (such as mental health records, or HIV or genetic test results) may be subject to heightened privacy requirements under federal or state law.

Under HIPAA, protected health information (PHI) may be exchanged by covered entities or their business associates for certain permitted purposes, such as treatment, payment, and health care operations. Some exchanges of PHI (other than for treatment, payment, and

operations) require patient authorization. For a business associate to exchange PHI on behalf of a covered entity, a business associate agreement must set forth the permitted and required uses of PHI and satisfactory assurances that the business associate will comply with HIPAA.

In addition, HITECH introduced several changes to HIPAA including the following:[52]

- Extends applicability of certain Privacy and Security Rules to business associates and makes business associates civilly and criminally liable under such rules for violating terms of a business associate agreement.
- Extends the definition of "business associate" to organizations that transmit PHI, such as health information exchanges, regional health information organizations, and some personal health record vendors.
- Requires covered entities and business associates to provide notification of breaches of unsecured PHI.
- Prohibits sale of PHI.
- Expands individuals' rights to access and receive accounting of disclosures and sets forth circumstances in which covered entities must comply with an individual's request for restriction on disclosure of PHI.

HHS has yet to issue the final rule regarding modifications to the HIPAA Privacy, Security, and Enforcement Rules under the HITECH Act. Uncertainty about how to comply with existing and new health data privacy and security laws and regulations, coupled with concerns about liability, may make entities reluctant to share health information electronically.

There is lack of clarity regarding which uses and disclosures of PHI are permissible when exchanging health information under HIPAA. Common questions include the following:

- How should special sets of data (e.g., psychotherapy notes and information related to sexually transmitted diseases) be treated when being exchanged between covered entities through a health information exchange arrangement?
- Can the PHI of one patient be disclosed for the purpose of treating a different patient, such as a family member with a similar medical condition?
- What are the best practices and what is required under HIPAA to safeguard the privacy and security of PHI when various patient matching mechanisms are used?

Health care stakeholders—particularly those with little access to policy and legal experts, such as patients and practitioners—need easy-to-understand guidance to understand how privacy rules apply.

RECOMMENDATION 10:
HHS SHOULD ISSUE COMPREHENSIVE AND CLEAR GUIDANCE ON COMPLIANCE WITH FEDERAL PRIVACY AND SECURITY LAWS

1. HHS should consistently issue comprehensive and clear guidance on compliance with federal privacy and security laws covering personal health information, and its use in health IT generally--including EHRs, health information exchange, and data analytics--with reasonable and achievable implementation timelines. Such guidance should address access, use, and disclosure of health information for treatment and public and population health purposes and should be consistent in approach across multiple agencies.

2. Such guidance should be understandable to health care stakeholders that do not have significant legal expertise, including patients and practitioners working in small practices.

DIFFERENCES IN STATE LAWS

Health care stakeholders continue to express concerns about the lack of clarity regarding how various state privacy laws can be reconciled when PHI is exchanged among entities that operate in different states. Differences in state laws are often cited as barriers to electronic health information sharing—particularly among those that operate at a national level.

RECOMMENDATION 11:
DIFFERENCES IN STATE LAWS SHOULD BE STUDIED AND INFORM OPERATIONAL GUIDANCE AS WELL AS FEDERAL AND STATE POLICY

1. The differences in state laws regarding privacy should be studied, as well as the extent to which interpretation of such differences inhibit the effective and efficient exchange of health information across state lines.

2. Easy-to-understand guidance should be developed to support health care organizations in addressing such differences when health information is exchanged across state lines.

3. The analysis of such differences should inform individual state policies and other efforts to address the handling of such differences.

4. Should the differences in state laws be found to significantly inhibit effective and efficient electronic sharing of health information, Congress should take appropriate action to address these issues.

PATIENT CONSENT MODELS FOR USE OF PROTECTED HEALTH INFORMATION

Though not required by HIPAA, organizations that facilitate health information exchange can and do implement patient consent models with respect to the PHI they store. In cases where a patient consent model is in place, an exchange of PHI may be permissible under HIPAA for purposes related to treatment, payment, and health care operations, but the

patient's preferences would in effect "trump" HIPAA. While there are numerous types of consent models, many fall into the following categories:[53]

- No consent. Patient health information is automatically included with no option to opt-out.
- Opt-out. Default is for patient health information to be included automatically, but the patient can opt out completely.
- Opt-out with exceptions. Default is for patient health information to be included, but the patient can opt out completely or allow only select data to be included.
- Opt-in. Default is that no patient health information is included; patients must actively express consent to be included, but if they do so then their information must be all in or all out.
- Opt-in with restrictions. Default is that no patient health information is made available, but the patient may allow a subset of select data to be included.

There is some lack of clarity about how patient consent models should be implemented and applied across various settings. For example, some health care organizations believe that it can be difficult for one entity to "send" patient consent model preferences to another entity when exchanging PHI. Additionally, when PHI is exchanged between two entities that both maintain patient-consent model preferences, the preferences for one patient may not be recorded consistently between the two entities, leading to confusion among some health care organizations on how to reconcile the inconsistencies.

RECOMMENDATION 12:
HHS SHOULD WORK WITH THE PRIVATE SECTOR TO DEVELOP TECHNICAL STANDARDS AND GUIDANCE THAT SUPPORT DIFFERENT MODELS OF PATIENT CONSENT

1. An assessment of the various consent models should be performed to identify those that are most commonly used.
2. Technical standards for addressing the functionality required for the most prevalent models within EHRs should be developed and widely disseminated to support effective and efficient implementation of such models across health care settings.
3. HHS should clarify how to handle situations in which a patient has conflicting consent models on record in different care settings to support health care organizations' understanding of the current law.

About the Bipartisan Policy Center's Health IT Initiative

As one of the only Washington, D.C.-based think tank that actively promotes bipartisanship, the Bipartisan Policy Center (BPC) works to address the key challenges facing the nation, including those related to democracy, economic policy, energy, housing, national security, and health care. Established in 2007 by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole, and George Mitchell, BPC combines politically balanced policy making with strong, proactive advocacy and outreach. See www.bipartisanpolicy.org.

As part of the BPC's Health Project, which is led by Health Project co-leaders and former Senate Majority Leaders Tom Daschle (D-SD) and Bill Frist (R-TN), the BPC Health IT Initiative identifies real-world examples and best practices that facilitate coordinated, accountable, patient-centered care, and makes recommendations for ensuring that health IT efforts support delivery system and payment reforms shown to improve quality and reduce costs in health care.

One of the most recent deliverables of the BPC Health IT Initiative was the 2012 release of the report, Transforming Health Care: The Role of Health IT, which was grounded in interviews with 40 high-performing organizations and developed under the guidance of the BPC's Task Force on Delivery System Reform and Health IT (Task Force), led by former Senate Majority Leaders Tom Daschle (D-SD) and Bill Frist (R-TN) and comprised of nationally respected experts and leaders across every sector of health care.

Key areas of focus in 2012 include engagement of stakeholders across health care in a collaborative effort focused on accelerating the adoption of several of the Task Force's recommendations, including those that accelerate: (1) alignment of incentives with health IT-enabled, high-quality, cost-effective care; (2) electronic exchange of health information to support coordinated, accountable, patient-centered models of care; and (3) expanded engagement of consumers using electronic tools to support improvements in health and health care.

Acknowledgements

BPC would like to thank Janet Marchibroda, BPC Health IT Initiative chair; Ann Gordon, writer and editor; and Katie Golden, BPC policy analyst for their contributions to this report. BPC would also like to thank the following organizations that shared their experiences and insights to inform our research and development of the report.

Allscripts

America's Health Insurance Plans

American Academy of Family Physicians

American Academy of Pediatrics

American College of Cardiology

American College of Physicians

American Hospital Association

American Osteopathic Association

American Society of Clinical Oncology

Ascension Health

Association of Medical Directors of Information Systems

Athenahealth

Blue Cross Blue Shield Association

Brookings Institution

Care Connectivity Consortium

CaleConnect

Center for Democracy and Technology

CentraStateHealth System

Cerner Corporation

CHIME

Dell

Doctors Helping Doctors Transform Health Care

Dossia

e-MDs, Inc.

GE Healthcare

Geisinger Health System

Greenway Medical

Health Level Seven

HIMSS

Intel Corporation

Intermountain Healthcare

Mayo Clinic

McKesson Corporation

Medical Group Management Association

MedStar Health

Memorial Sloan-Kettering Cancer Center

National Association of Public Hospitals and Health Systems

National Governors Association

National Partnership for Women and Families

National Quality Forum

NextGen Healthcare

Oregon Office of Health Information Technology

Poudre Valley Medical Group and Poudre Valley Health System

Regenstrief Institute and Indiana University School of Medicine

Sharp HealthCare

Siemens Healthcare

St. Claire Regional Medical Center

Tennessee Office of eHealth Initiatives

Texas Office of eHealth Coordination

United Health Group

Vermont Office of Health Care Reform

WellPoint

It is important to note that the organizations identified above were not asked to formally endorse the recommendations in the report.

Endnotes

[1] Pham H.H.,Schrag D., O'Malley A.S., Wu B., and Bach P.B. (2007) Care Patterns In Medicare And Their Implications For Pay For Performance. *New England Journal of Medicine*. 356(11):1130-1139.

[2] Berwick D. and Hackbarth A. (2012) Eliminating Waste In U.S. Health Care. *Journal of the American Medical Association*. 307(14).

[3] Bipartisan Policy Center (2012) *Transforming Health Care: The Role Of Health IT.* Washington, D.C.: Bipartisan Policy Center.

[4] Center for Medicare and Medicaid Services (2012) Center For Medicare And Medicaid Innovation's One Year Of Innovation: Taking Action To Improve Care And Reduce Costs. Available at: http://innovations.cms.gov/Files/reports/Innovation-Center-Year-One-Summary-document.pdf Accessed September 27, 2012.

[5] Higgins A., Stewart K., Dawson K., et al. (2011) Early Lessons From Accountable Care Models In The Private Sector. *Health Affairs.* 30(9): 1718-1727.

[6] Gray J. and Gabriel S. (2011) Financial Leadership Council Survey Of Hospital Executives By The Advisory Board Company Regarding Key Priorities Related To Anticipated Delivery And Payment System Changes In Coming Years. Washington, D.C.: The Advisory Board. Available at: http://www.advisory.com/Research/Financial-Leadership-Council/White-Papers/2012/Accountable-Payment-Survey Accessed September 27, 2012.

[7] Ibid.

[8] America's Health Insurance Plans. (2012). Washington, DC: AHIP.

[9] Kaye N., Buxmaum J., and Takach M. (2011) Building Medical Homes: Lessons From Eight States With Emerging Programs. National Academy for State Health Policy. Washington, D.C.: The Commonwealth Fund.

[10] Nielsen M., Langner B., Zema C. et al. Patient-Centered Primary Care Collaborative (2012) Benefits Of Implementing The Primary Care Patient-Centered Medical Home. Washington, D.C.: Patient-Centered Primary Care Collaborative.

11 Optum Institute (2012) *Accelerating Health Information Exchange: A Review Of Physician And Consumer Survey Data From The Optum Institute*. Presentation during May 16 meeting of Bipartisan Policy Center Collaborative on Health IT and Delivery System Reform. Washington, D.C.

[12] Department of Health and Human Services (2010) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program Final Rule*.

[13] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule*.

[14] Department of Health and Human Services (2010) Office of the Secretary 45 CFR Part 170, *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule*.

[15] Department of Health and Human Services (2012) Office of the Secretary 45 CFR Part 170, *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology*.

[16] Pham H.H., O'Malley A.S., Bach P.B., et al. (2009) Primary Care Physicians' Links To Other Physicans Through Medicare Patients: The Scope Of Care Coordination. *Annals of Internal Medicine*. 150(4):236-242.

[17] Department of Health and Human Services (2012) Office of the Secretary 45 CFR Part 170, *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology*.

[18] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule*.

[19] Ibid.

[20] Department of Health and Human Services (2012) Office of the Secretary 45 CFR Part 170, *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology*.

[21] The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5), was enacted on February 17, 2009.

[22] Bipartisan Policy Center (2012) *Transforming Health Care: The Role Of Health IT.* Washington, D.C.: Bipartisan Policy Center.

[23] Office of the National Coordinator for Health Information Technology (2012) HIT Standards Committee Website. *HIT Standards Committee NwHIN Power Team final recommendations for standards evaluation criteria*. Available at: http://www.healthit.gov/sites/default/files/2012aug15_hitsc_nwhinp_baker.pdf. Accessed September 20, 2012.

[24] National Technology Transfer and Advancement Act of 1995.

[25] OMB Circular No. A-119.

[26] American Board of Internal Medicine Foundation. (2007). Stepping Up to the Plate Alliance. Principles and standards for managing transitions in Care.

[27] Snow, V., Beck, D., Budnitz, T. et. al. (2009). Transitions of care consensus policy statement American College of Physicians-Society of General Internal Medicine-Society of Hospital Medicine-American Geriatrics Society-American College of Emergency Physicians-Society of Academic Emergency Medicine. *J Gen Intern Med*. April 2009.DOI: 10.1007/s11606-009-0969-x.

[28] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule*.

[29] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule*.

[30] Department of Health and Human Services (2012) Office of the Secretary 45 CFR Part 170, *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology*.

[31] RAND Corporation (2008) *Identity Crisis: An Examination Of The Costs And Benefits Of A Unique Patient Identifier For The U.S. Health Care System*.

[32] College of Healthcare Information Management Executives (2012) *Summary Of CHIME Survey On Patient Data-Matching.* Presentation during May 16 meeting of Bipartisan Policy Center Collaborative on Health IT and Delivery System Reform. Washington, D.C.

[33] College of Healthcare Information Management Executives (2012) *Summary Of CHIME Survey On Patient Data-Matching*. Presentation during May 16 meeting of Bipartisan Policy Center Collaborative on Health IT and Delivery System Reform. Washington, D.C.

[34] Ibid.

[35] Grannis, S. (2012) *An Overview Of Patient Matching*. Presentation during May 16 meeting of Bipartisan Policy Center Collaborative on Health IT and Delivery System Reform. Washington, D.C.

[36] Ibid.

[37] College of Healthcare Information Management Executives (2012) *Summary Of CHIME Survey On Patient Data-Matching*. Presentation during May 16 meeting of Bipartisan Policy Center Collaborative on Health IT and Delivery System Reform. Washington, D.C.

[38] Bipartisan Policy Center (2012) *Challenges And Strategies For Accurately Matching Patients To Their Health Data*. Washington, D.C.: Bipartisan Policy Center.

39 U.S. Department of Health and Human Services (2011) Health IT Policy Committee letter to Department of Health and Human Services. February 8. Available at: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__policy_recommendations/1815.

40 U.S. Department of Health and Human Services (2011) Health IT Standards Committee letter to Department of Health and Human Services. August 17. Available at: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_recommendations/1818.

[41] Grannis S., Banger A., and Harris D. (2009) P*rivacy And Security Solutions For Interoperable Health Information Exchange. Perspectives On Patient Matching: Approaches, Findings, And Challenges*. Prepared for Office of National Coordinator for Health Information Technology and Agency for Healthcare Research and Quality by RTI International. Retrieved from materials of December 9, 2010, meeting. Available at: http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=2833&PageID=19477

[42] Ibid.

[43] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule*.

[44] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule*.

45 Office of the National Coordinator for Health Information Technology (2012) HIT Policy Committee website. Identity In Cyberspace: Improving Trust For Health Information Exchange. Presented by Jeremy Grant during September 6 HIT Policy Committee meeting. Available at: http://www.healthit.gov/sites/default/files/nstic_jgrant_hitpc09612.pdf.

[46]Press Release. *Five leading health systems create new Care Connectivity Consortium* (2011) Available at: http://www.prnewswire.com/news-releases/five-leading-health-systems-create-new-care-connectivity-consortium-119301529.html

[47] Kravitz J.M. (2012) *Care Connectivity Consortium*. Presentation during May 16 meeting of Bipartisan Policy Center Collaborative on Health IT and Delivery System Reform. Washington, D.C.

[48] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Part 441, *Medicare Program; physician referrals to health care entities with which they have had financial relationships; exceptions for certain electronic prescribing and electronic health records arrangements.*

[49] Ibid.

[50] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Proposed Rule*.

[51] Department of Health and Human Services (2012) Centers for Medicare and Medicaid Services 42 CFR Parts 412, 413, 422, and 495, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule*.

[52] The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5), was enacted on February 17, 2009.

[53] Goldstein M. and Rein A. (2012) *Consumer Consent Options For Electronic Health Information Exchange: Policy Considerations And Analysis*. Prepared for Office of the National Coordinator for Health IT. March 2010.

BIPARTISAN POLICY CENTER

1225 Eye Street NW, Suite 1000
Washington, DC 20005
(202) 204-2400

WWW.BIPARTISANPOLICY.ORG