

HIMSS

transforming healthcare through IT

architects of change

HIMSS 8th Annual Policy Summit

Washington, DC
September 22-23, 2009

“Heard on the Hill”

K. Meredith Taylor, MPH
Director, HIMSS Congressional Affairs
September 22, 2009

Agenda

- US Congress
- Congressional Committees
- A Look at ARRA
- Healthcare Reform
- Questions

U.S. Congress

- House of Representatives
 - 435 Members (256 Democrats, 178 Republicans, 1 vacant seat)
 - Each member represents a district and serves a two-year term
- Senate
 - 100 Senators (57 Democrats, 47 Republicans, 2 independents, and 1 vacant seat)
 - Two Senators per state, each member serves a two year term and each serve 6 year terms

U.S. Congress

- House of Representatives
 - Speaker of the House: Nancy Pelosi (D-CA)
 - Majority Leader: Steny Hoyer (D-MD)
 - Minority Leader: John Boehner (R-OH)
- Senate
 - President of the Senate: Vice President Joe Biden
 - Majority Leader: Harry Reid (D-NV)
 - Minority Leader: Mitch McConnell (R-KY)

Congressional Committees

- Committees with jurisdiction over healthcare reform
 - Senate: Finance and Health, Education, Labor and Pensions (HELP) Committee
 - House: Education and Labor, Ways and Means, and Energy and Commerce Committees
- From the Appropriation Committees, Homeland Security, to the Veterans Affairs Committees, healthcare is a prominent issue

A Big Day...



"Because we know that spiraling healthcare costs are crushing families and businesses alike, we're taking the most meaningful step in years towards modernizing our healthcare system. It's an investment that will take the long overdue step of computerizing America's medical records, to reduce the duplication and waste that costs billions of healthcare dollars and medical errors that cost thousands of lives each year. ... We have done more in 30 days to advance the cause of healthcare reform than this country has done in an entire decade."

President Barack Obama
February 17, 2009

A Look at ARRA

- February 17, 2009, President signed into law the **American Recovery and Reinvestment Act of 2009 (ARRA) or PL 111-5**, providing over \$30 billion for health IT, referred to by many as a **“foundation for healthcare reform”**
 - \$2 billion for the Office of the National Coordinator (ONC)
 - Over \$30 billion in incentives through Medicare and Medicaid
 - Codification of the ONC
 - Establishment of 2 Federal Advisory Committees
 - Grants and Loans to Foster the Use of Health IT
 - New privacy and security provisions
 - ARRA viewed as the first step towards healthcare reform

Healthcare in the US

- 2008 total healthcare spending in the U.S. is expected to reach \$2.4 trillion, 16.6% of the GDP
- By 2016, CMS projects that healthcare spending will be over \$4.1 trillion, accounting for 19.6% of GDP
- About 45% of American suffer from one or more chronic diseases, accounting for 75% of all healthcare spending and 70% of deaths

*Kaiser Family Foundation

Healthcare Reform

- Democrats and Republicans recognize the need to transform healthcare
- 9 comprehensive healthcare reform bills introduced in 2009
- 3 leading healthcare reform bills in the House and Senate
 - Affordable Health Choices Act (Senate HELP Committee)
 - American's Healthy Future Act (Senate Finance Committee)
 - Affordable Health Choices Act, H.R. 3200 (House Tri-Committees)

Affordable Health Choices Act, Senate HELP Committee

- Senate HELP Committee's Legislation, the Affordable Health Choices Act, would:
 - Establish state-based health insurance exchanges through which individuals and small businesses could purchase coverage
 - Build upon health IT provisions included in the ARRA and leverage health IT to improve healthcare delivery and outcomes
- Provisions related to health IT surround such issues as administrative simplification, a national strategy for quality improvement, and primary care training

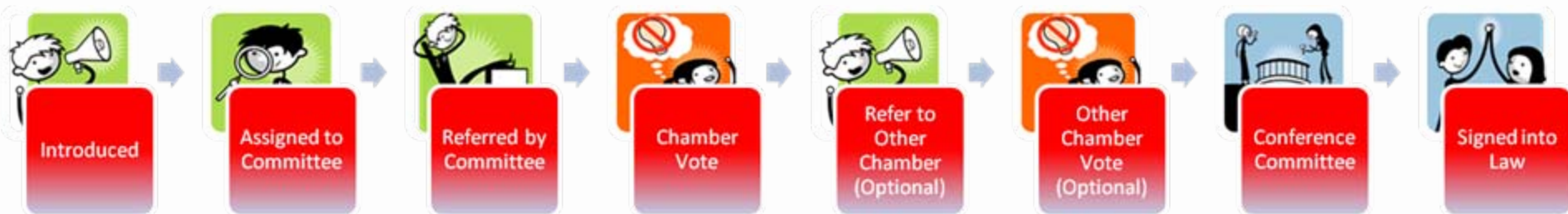
American's Healthy Future Act, Senate Finance Committee

- Senate Finance Committee's legislation would:
 - Establish non-profit co-operatives (co-ops)
 - Establish health information exchanges
 - Expand Medicaid coverage
- Provisions related to health IT surround such issues as risk assessments, incentives, national workforce strategy, and long-term care

Affordable Health Choices Act of 2009, H.R. 3200

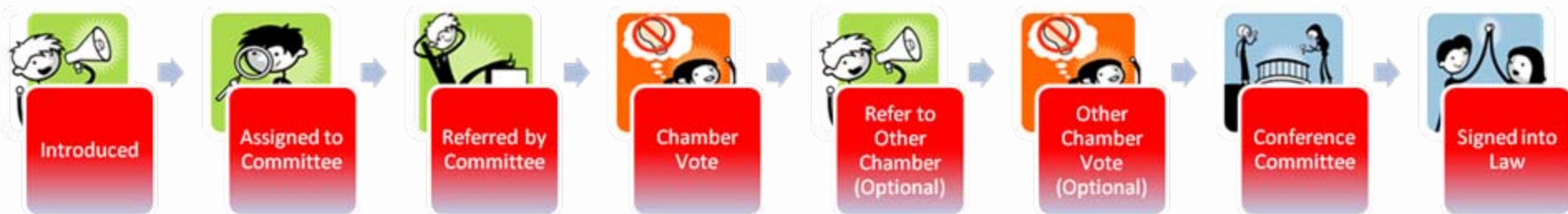
- Legislation would:
 - Establish a public health insurance option and a health insurance exchange
 - Establish many provisions that aim to leverage health IT to improve the efficiency of healthcare
- Health IT related provisions address such issues as administrative simplification, testing incentive models that reduce the growth of healthcare spending and improve health outcomes, and a new Bureau of Health Information

What's Next?



- Two Senate bills will likely be merged into one bill to compliment its counterpart in the House (H.R. 3200)
- Congressional leaders hope to vote on healthcare reform legislation this fall
- The chambers can send their perspective bills to the other chamber for a vote or they can go straight to a Conference Committee.
- Following passage by Congress, a bill would then be sent ¹⁴ to the President for his signature

What's Next?



- Members of Congress will continue to introduce legislation that pertains to health IT
- In the 111th Congress, legislation introduced that:
 - builds on the ARRA and
 - Leverages health IT to improve Veterans Healthcare

Questions/Discussion

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Transforming Healthcare Through Information Technology

HMSS Advocacy Day

September 23, 2009

Hon. Gayle Harrell

***Member of the Health Information Technology Policy Committee
Former Member of the Florida House of Representatives, District 81***

The Health Information Technology Policy Committee

- **Established under American Recovery and Reinvestment Act 2009 (ARRA 2009)**
 - **A Federal Advisor Committee**
- **13 Members appointed by GAO in designated areas**
 - **4 Members appointed by the US Congress**
 - **3 Members appointed by the Secretary of HHS**

Committee Members

Chair:

Dr. David Blumenthal , HHS/Office of the National Coordinator for Health Information Technology

Co-Chair: Dr. Paul Tang, Palo Alto Medical Foundation

Members:

- David Bates, Brigham & Women's Hospital
- Christine Bechtel, National Partnership for Women & Families
- Neil Calman, The Institute for Family Health
- Rick Chapman, Kindred Healthcare
- Adam Clark, Lance Armstrong Foundation
- Art Davidson, Denver Public Health Department
- Connie Delaney, University of Minnesota, School of Nursing
- Paul Egerman, retired CEO
- Judith Faulkner, Epic Systems Corp.
- Gayle Harrell, Former Florida State Legislator
- Charles Kennedy, WellPoint, Inc.
- Michael Klag, Johns Hopkins University, Bloomberg School of Public Health
- David Lansky, Pacific Business Group on Health
- Deven McGraw, Center for Democracy & Technology
- Marc Probst, Intermountain Healthcare
- Latanya Sweeney, Carnegie Mellon University
- Micky Tripathi, Massachusetts eHealth Collaborative
- Charlene Underwood, Siemens
- Scott White, 1199 SEIU Training & Employment Fund

Health IT and Transformed Health Care

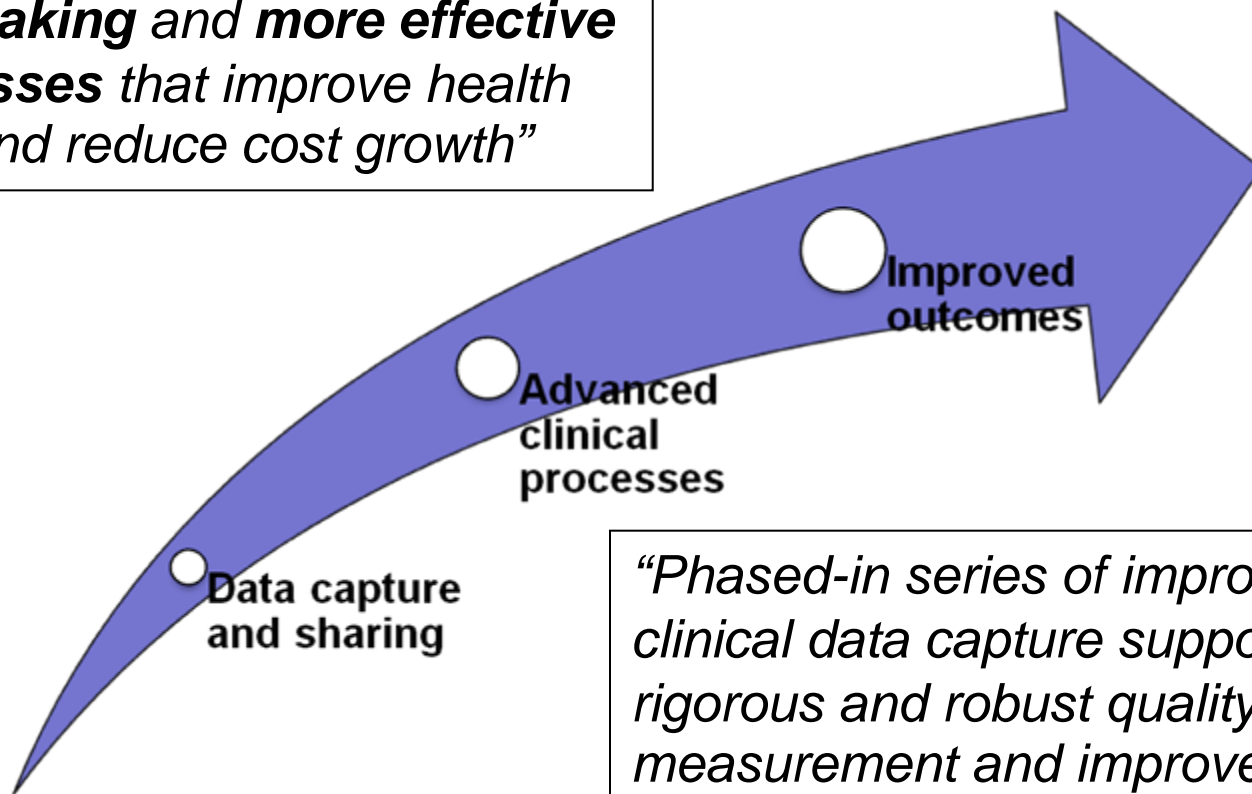
- Ultimate vision is to enable significant and measurable improvements in population health through a transformed health care delivery system.
- Key goals*:
 - Improve quality, safety, & efficiency
 - Engage patients & their families
 - Improve care coordination
 - Improve population and public health; reduce disparities
 - Ensure privacy and security protections

*Adapted from National Priorities Partnership. National Priorities and Goals: Aligning Our Efforts to Transform America's Healthcare. Washington, DC: National Quality Forum; 2008

Bending the Curve Towards Transformed Health

Achieving Meaningful Use of Health Data

*“These goals can be achieved only through **the effective use of information** to support **better decision-making** and **more effective care processes** that improve health outcomes and reduce cost growth”*



“Phased-in series of improved clinical data capture supporting more rigorous and robust quality measurement and improvement.”

Responsibilities of the Policy Committee

- **Meaningful Use:** Make recommendations to the National Coordinator regarding the process for defining and revising meaningful use and national goals, propose new meaningful use definitions and national goals and standards and policy priorities to support meaningful use and national goals.
- **Certification and readiness:** Make recommendations to the National Coordinator on issues related to the adoption of certified electronic health records that support meaningful use, including issues related to certification, health information extension centers and workforce training.
- **HIE:** Make recommendations to the National Coordinator on policies, guidance governance, sustainability, and architectural, and implementation approaches to enable the exchange of health information and increase capacity for health information exchange over time.

Workgroup on Meaningful Use

Specific Charge

- Make recommendations to the HIT Policy Committee on the definition of meaningful use for 2011 and 2013 within one (1) month of the initial meeting of the workgroup and refine within two (2) months.
- Make recommendations to the HIT Policy Committee on the definition of meaningful use for 2015 within three (3) month of the initial meeting of the workgroup and refine within six (6) months.

Workgroup on Certification

- **Specific Charges for the Certification Workgroup:**
- review the existing certification and standards setting processes and make recommendations to the HIT Policy Committee, within four (4) months of the initial meeting of the workgroup, about how these processes should be structured in the future.
- Make recommendations for the development of Regional Extension Centers and workforce training.

Workgroup on Health Information Exchange

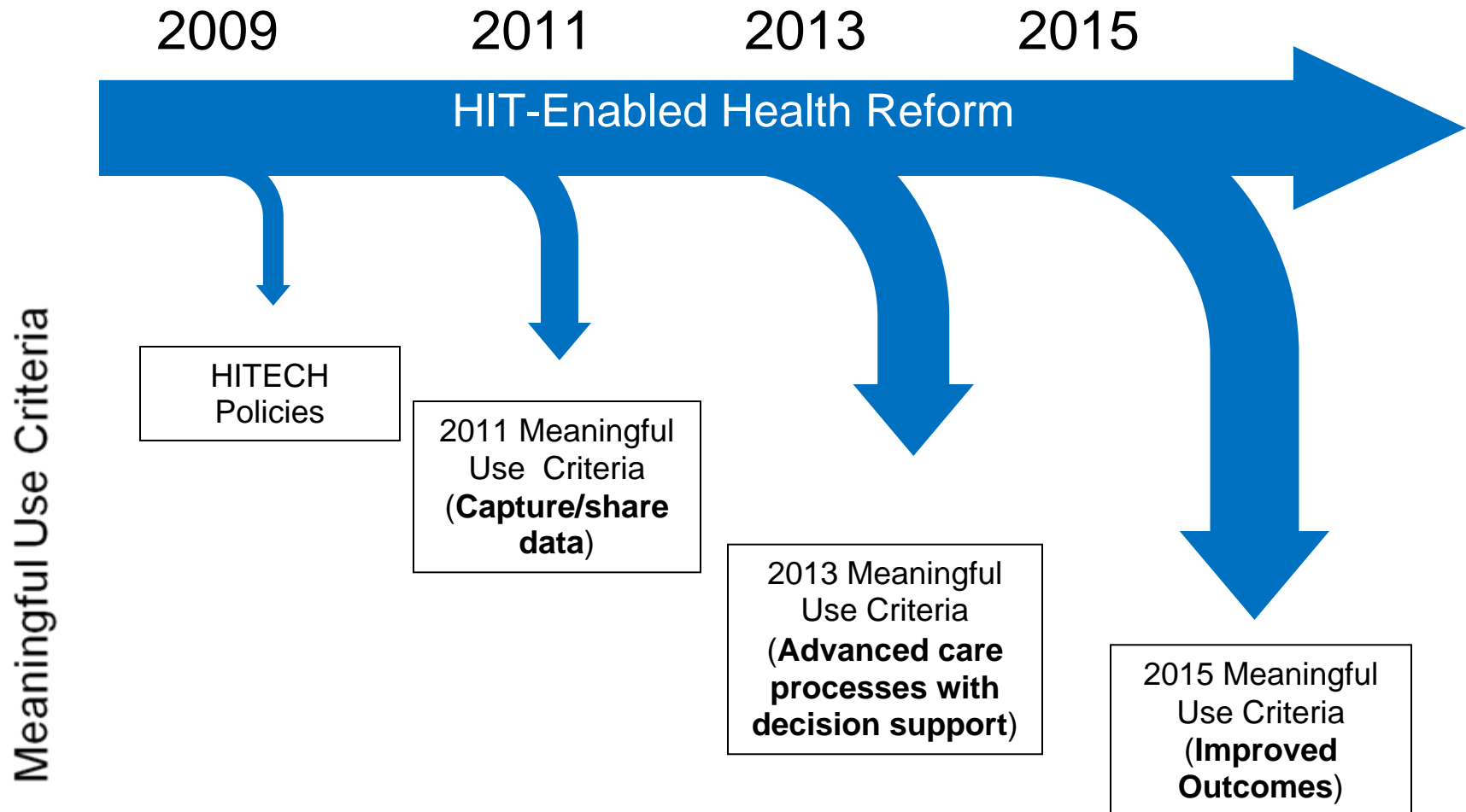
- **Specific Charges for the Information Exchange Workgroup:**
 - Make recommendations to the HIT Policy Committee within six (6) months regarding priority policy areas and other issues that are necessary in the short term to advance the exchange of health information through implementation of HITECH.
 - Make recommendations to the HIT Policy Committee to inform and provide guidance on the implementation of the Nationwide Health Information Network (NHIN)



ACHIEVING MEANINGFUL USE

HIT-Enabled Health Reform

Achieving Meaningful Use



Meaningful Use Recommendations - Matrix

Health Outcomes Policy Priorities	Care Goals	2011 Objectives <i>Goal is to electronically capture in coded format and to report health information and to use that information to track key clinical conditions</i>	2011 Measures	2013 Objectives <i>Goal is to guide and support care processes and care coordination</i>	2013 Measures	2015 Objectives <i>Goal is to achieve and improve performance and support care processes and on key health system outcomes</i>	2015 Measures
Improve quality, safety, efficiency, and reduce health disparities	<ul style="list-style-type: none"> • Provide access to comprehensive patient health data for patient's health care team • Use evidence-based order sets and CPOE • Apply clinical decision support at the point of care • Generate lists of patients who need care and use them to reach out to patients (e.g., reminders, care instructions, etc) • Report to patient registries for quality improvement, public reporting, etc 	<ul style="list-style-type: none"> • Use CPOE for all order types including medications [OP, IP] • Implement drug-drug, drug-allergy, drug-for-multry checks [OP, IP] • Maintain an up-to-date problem list [OP, IP] • Generate and transmit permissible prescriptions electronically (eRx) [OP] • Maintain active medication list [OP, IP] • Maintain active medication allergy list [OP, IP] • Record primary language, insurance type, gender, race, ethnicity [OP, IP] • Record vital signs including height, weight, blood pressure [OP, IP] • Incorporate lab-test results into EHR [OP, IP] • Generate lists of patients by specific condition to use for quality improvement, reduction of disparities, and outreach [OP] • Send reminders to patients per patient preference for preventive /follow up care [OP, IP] 	<ul style="list-style-type: none"> • Report quality measures, including: <ul style="list-style-type: none"> - % diabetics with A1c under control [OP] - % hypertensive patients with BP under control [OP] - % of patients with LDL under control [OP] - % of smokers offered smoking cessation counseling [OP, IP] • % of patients with recorded BMI [OP] • % eligible surgical patients who received VTE prophylaxis [IP] • % of orders entered directly by physicians through CPOE • Use of high-risk medications in the elderly [OP, IP] • % of patients over 50 with annual colorectal cancer screenings [OP] 	<ul style="list-style-type: none"> • Use evidence-based order sets [OP, IP] • Record clinical documentation in EHR [IP] • Generate and transmit permissible prescriptions electronically [IP] • Manage chronic conditions using patient lists and decision support [OP, IP] • Provide clinical decision support at the point of care (e.g., reminders, alerts) [OP, IP] • Report to external disease (e.g., cancer) or device registries [OP (esp. specialists)] [IP] • Conduct medication administration using bar coding [IP] 	<ul style="list-style-type: none"> • Additional quality reports using HIT-enabled NQF-endorsed quality measures [OP, IP] • % of all orders entered by physicians through CPOE [OP, IP] • Potentially preventable Emergency Department Visits and Hospitalizations [IP] • Inappropriate use of imaging (e.g. MRI for acute low back pain) [OP, IP] • Other efficiency measure (TBD) [OP, IP] 	<ul style="list-style-type: none"> • Achieve minimal levels of performance on quality, safety, and efficiency measures • Implement clinical decision support for national high priority conditions [OP, IP] • Medical device interoperability [OP, IP] • Multimedia support (e.g. x-rays) [OP, IP] 	<ul style="list-style-type: none"> • Clinical outcome measures (TBD) [OP, IP] • Efficiency measures (TBD) [OP, IP] • Safety measures (TBD) [OP, IP]

Meaningful Use Recommendations

- Goals
- Objectives
- Measures
 - Improve Quality, Safety, Efficiency
 - Engage Patients and Families
 - Improve Care Coordination
 - Improve Population and Public Health
 - Ensure Privacy and Security Protections

Improve Quality, Safety, Efficiency

2011 Objectives

- Capture data in coded format
 - Maintain current problem list
 - Maintain active medication list
 - Maintain active medication allergy list
 - Record vital signs (height, weight, blood pressure)
 - Incorporate lab/test results into EHR
 - Document key patient characteristics (race, ethnicity, gender, insurance type, primary language)
- Document progress note for each encounter (outpatient only)
- Use CPOE for all order types (IP) (10% OP)
 - Use electronic prescribing for permissible Rx
 - Implement drug-drug, drug-allergy, drug-formulary checks
- Manage populations
 - Generate list of patients by specific conditions (outpatient only)
 - Send patient reminders per patient preference

Improve Quality, Safety, Efficiency

2011 Measures

- % Labs incorporated into EHR in coded format
- % CPOE orders entered directly by physician
- Report quality measures using HIT-enabled quality measures (HIT-QM)
 - % Diabetics with A1c under control
 - % Hypertensives with BP under control
 - % LDL under control
 - % Smokers offered smoking cessation counseling
 - % Patients with recorded BMI
 - % Colorectal screening for 50+
 - % Mammograms for women 50+
 - % Current pneumovax status
 - % Annual flu vaccination
 - % Aspirin prophylaxis for patients at risk for cardiac event
 - % Surgical patients receiving VTE prophylaxis
 - Avoidance of high risk medications in elderly
- Quality reports stratified by race, ethnicity, gender, insurance type

Engage Patients and Families

2011 Objectives

- Provide patients with electronic copy of- or electronic access to- clinical information per patient preference
 - Includes labs, problem list, medication list, allergies
- Provide access to patient-specific educational resources
- Provide clinical summaries for patients for each encounter

Engage Patients and Families

2011 Measures

- % Patients with electronic access to personal health information
- % Patients with access to patient-specific educational resources
- % Encounters where clinical summary provided

Improve Care Coordination

2011 Objectives

- Exchange key clinical information among providers of care
- Perform medication reconciliation at relevant encounters

Improve Care Coordination

2011 Measures

- Report 30 day readmission rate
- % Encounters where medication reconciliation performed
- Implemented ability to exchange health information with external clinical entities
 - Problems, labs, medication lists, care summaries
- % Transitions in care where summary care record is shared (in 2011, could use any modality)

Improve Population and Public Health

2011 Objectives

- Submit electronic data to immunization registries where required and can be accepted
- Submit electronic reportable lab results to public health agencies
- Submit electronic syndrome surveillance data to public health agencies according to applicable law and practice

Improve Population and Public Health

2011 Measures

- Report up-to-date status of childhood immunizations
- % Reportable lab results submitted electronically

Ensure Privacy and Security Protections

2011 Objectives

- Compliance with HIPAA Rules and state laws
- Compliance with fair data sharing practices set forth in the National Privacy and Security Framework

Ensure Privacy and Security Protections

2011 Measures

- Full compliance with HIPAA
 - Entity under investigation for HIPAA violation cannot achieve meaningful use until entity is cleared
- Conduct or update a security risk assessment and implement security updates as necessary

Looking Forward: 2013

Objectives

- Improve quality, safety, efficiency
 - Evidence based order sets
 - Clinical documentation recorded (inpatient)
 - Clinical decision support at point of care
 - Manage chronic conditions using patient lists and decision support
 - Report to external disease registry
- Engage patients and families
 - Offer secure patient-provider messaging
 - Access to patient-specific educational resources
 - Record patient preferences
 - Documentation of family medical history
 - Upload data from home monitoring devices
- Coordinate care
 - Medication reconciliation at each transition of care
 - Produce electronic summary of care at each transition
 - Retrieve and act on electronic prescription fill data

Looking Forward: 2013 (continued)

Objectives

- Improve population and public health
 - Receive immunization histories from registries
 - Receive public health alerts
 - Electronic syndromic surveillance data sent to public health agencies
- Ensure privacy and security protection
 - Use summary or de-identified data when reporting data for population health purposes

Looking Forward: 2015

Objectives

- **Improve quality, safety, and efficiency**
 - Achieve minimal levels of performance on quality, safety, and efficiency measures
 - Implement clinical decision support for national high priority conditions
 - Achieve medical device interoperability
 - Provide multimedia support (e.g., x-rays)
- **Engage patients and families**
 - Provide access for all patients to PHR populated in real time with data from EHR
 - Provide patients with access to self-management tools
 - Capture electronic reporting on experience of care
- **Coordinate care**
 - Access comprehensive patient data from all available sources

Looking Forward: 2015 (continued)

Objectives

- Improve population and public health
 - Use epidemiologic data derived from EHRs
 - Automate real-time surveillance
 - Provide clinical dashboards
 - Generate dynamic and ad hoc quality reports
- Ensure privacy and security protection
 - Provide patients with accounting of treatment, payment, and health care operations disclosures
 - Protect sensitive health information

Certification

Certification Work Group:
How should products be
certified and who should do
it?

Certification: Questions Considered

Certification Process

- What should be the governance of the certification process?
- Who should conduct certification?
- Should there be more than 1 certifying body?
- How should the accreditation Body be established?
- What role, if any, should ONC play in the certification process?
- Should the certification be only for whole systems or for modules/components?
- What should be the frequency of certification?
- Should the product be certified for all requirements or only gaps?
- **How should non-vendor systems be certified?**
 - **Self developed systems**
 - **Open source**
 - Integrated solutions
- What roles should CCHIT play?

Purpose of Certification

Clarifying HHS Certification

	<u>Validation</u>	<u>Certification</u>	<u>Assurance</u>
Why	Prove that the EHR systems/components in use by an organization perform per the requirements of Meaningful Use.	Ensure that the EHR systems/components are <i>capable</i> (if installed appropriately) to perform per the requirements of Meaningful Use.	A “seal of approval” which suggests that an EHR system/components/vendor includes functionality which meets or exceeds the requirements of Meaningful Use.
Who	All organizations that receive ARRA incentive funds through HITECH	By Law, all organizations that <i>desire to</i> receive ARRA incentives funds through HITECH	Whomever feels that this “seal of approval” is important to them.
How	Self Attestation/reporting/audit Government Third Party	Government defined criteria Third Party assessment	Commercial User Group
What	All <i>software</i> components required to achieve Meaningful Use.	All EHR components required to achieve Meaningful Use.	To be determined by market.
	Scope of ARRA	Work Group area of Focus	

Purpose of Certification

Proposed Definition of HHS Certification

HHS Certification means that a system is able to achieve government requirements for security, privacy, and interoperability, and that the system would enable the Meaningful Use results that the government expects.

HHS Certification is not intended to be viewed as a “seal of approval” or an indication of the benefits of one system over another.

Recommendations

1. Focus Certification on Meaningful Use
2. Leverage Certification process to improve progress on Security, Privacy, and Interoperability
3. Improve objectivity and transparency of the certification process
4. Expand Certification to include a range of software sources: Open source, self-developed, etc.
5. Develop a Short-Term Transition plan

Recommendation 1 – Focus on Meaningful Use

- Implement a New Certification Process: Focus on Meaningful Use Objectives at a high level, less specificity
- Increase Specificity on Interoperability
- Comprehends that Optional Certifications may exist - Marketplace Advisory Services

Recommendation 2 – Progress on Security, Privacy, and Interoperability

- Address all privacy and security policies described in ARRA and HIPAA, including audit trails and consent.
- Aggressively establish new, very specific requirements for Interoperability and data exchange.
- Create “test harnesses” that will enable purchasers easily self-test their software.

Recommendation 3 – Objective and Transparent Process

- Separate Criteria definition from certification testing
- Allow Multiple Certification organizations
- With the National Institute of Standards and Technology (NIST), establish accreditation organization and process

Recommendation 4 – Flexible Software Sources

- Ensure that all EHR systems are certified against identical criteria, regardless of source
- Provide flexible processes for non-vendor software
- Provide for certification of components so EHRs can be purchased from multiple sources

Recommendation 5 – Short Term Transition

- Leverage existing Certification work, whenever possible
- Establish Preliminary Certification Process so work can commence prior to completion of regulatory process
- For products that completed 2008 certification, permit an incremental certification process against “Gap Criteria,” which includes privacy review

Health Information Exchange (HIE)

Achieving True Interoperability

The state of health information exchange today

- Health reform goals of higher-quality, more affordable care will not be met without broader and deeper information exchange across the entire health delivery system
- **The current state of health information exchange today is spotty and piecemeal**
 - The vast majority occurs in a narrow set of transaction silos, such as labs and medication prescriptions, and even here, penetration is very low (4% of eligible prescriptions and 12% of office-based prescribers, for example)
 - Direct exchange of data between EHRs and exchange through organized state/regional health information exchange entities also occurs, but penetration is extremely low and highly variable across implementations
 - Electronic reporting for public and population health measurement and improvement is almost non-existent in the market today

Health information exchange occurs in the market today, but penetration is very low and non-uniform

Barriers that prevent the market from moving forward

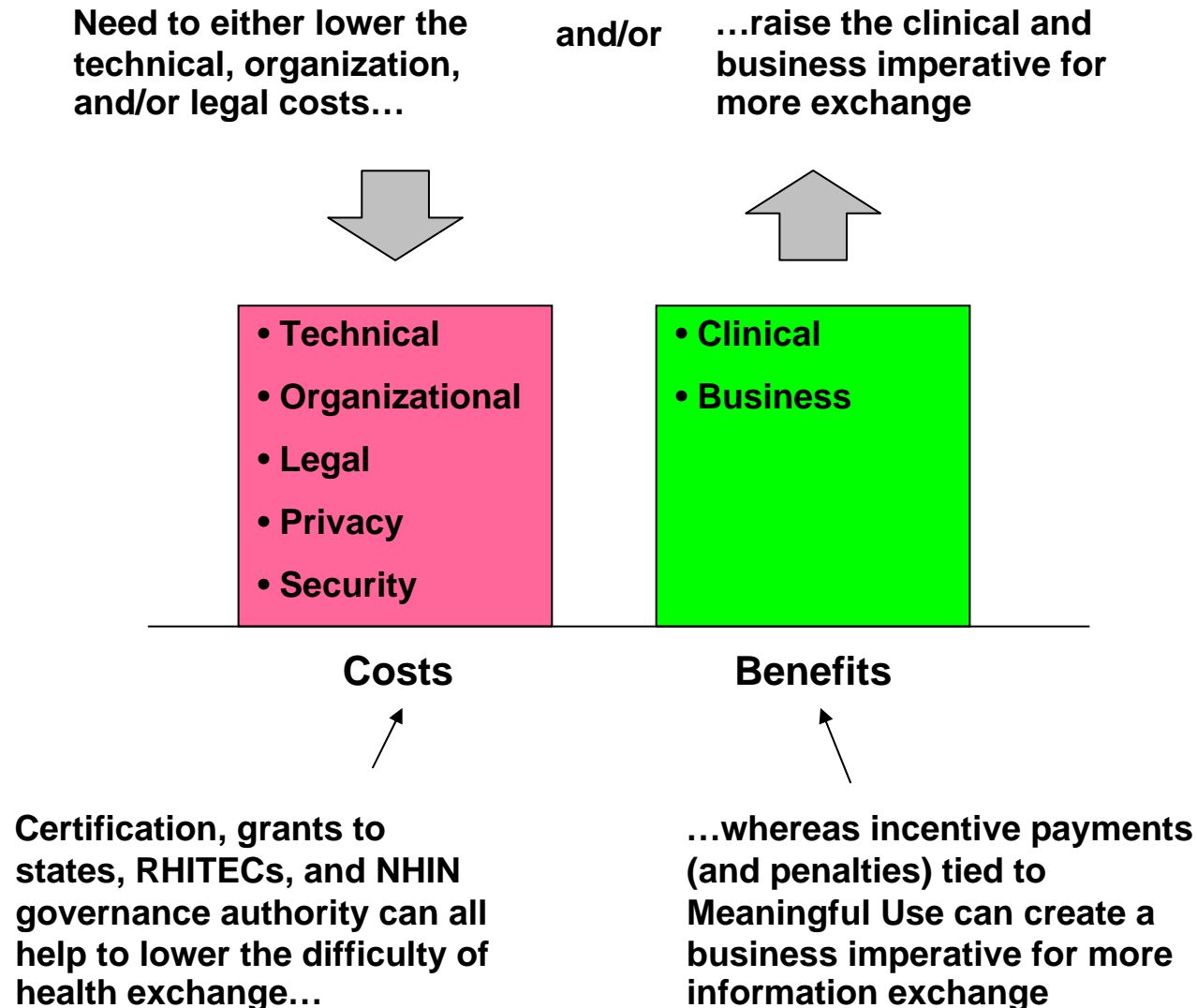
- **Silos:** A lot of health information exchange happens today, yet vast majority occurs in small number of transaction silos, such as labs and eRX
- **Barriers** to adoption are high because of technical and transaction costs
 - **Technical costs**
 - Standards harmonization progressing rapidly, however, market and/or regulatory enforcement mechanisms are still lacking
 - This, combined with disparate, heterogeneous legacy systems, makes it difficult to lower the hard and soft costs of implementation
 - **Transaction costs** are high because our health care delivery system is highly fragmented, and there is a lot of variation in state policies related to ehealth
- **Lack of cohesive and integrated network of HIO's:** While there are a significant number of organized state/regional health information exchange entities in various stages of maturity, each of them varies significantly.
- **Low penetration:** Though health information exchange occurs today, penetration is still low and non-uniform

Barriers that prevent the market from moving forward

- The main barriers to health information exchange today are:
 - Too much uncertainty about legal issues
 - Too little business and clinical imperative to exchange more information
 - Too much technical and organizational difficulty of setting up and maintaining business- and clinically-relevant electronic exchange
- Getting over these barriers will require:
 - Incentives and/or penalties to help increase business demand for exchange and encourage a plurality of exchange architectures that are cost-effective and sustainable
 - Actionable standards
 - Monitoring and enforcement mechanisms to ensure adherence to standards

There are many barriers to health information exchange today, and there is thus no single solution to getting more exchange

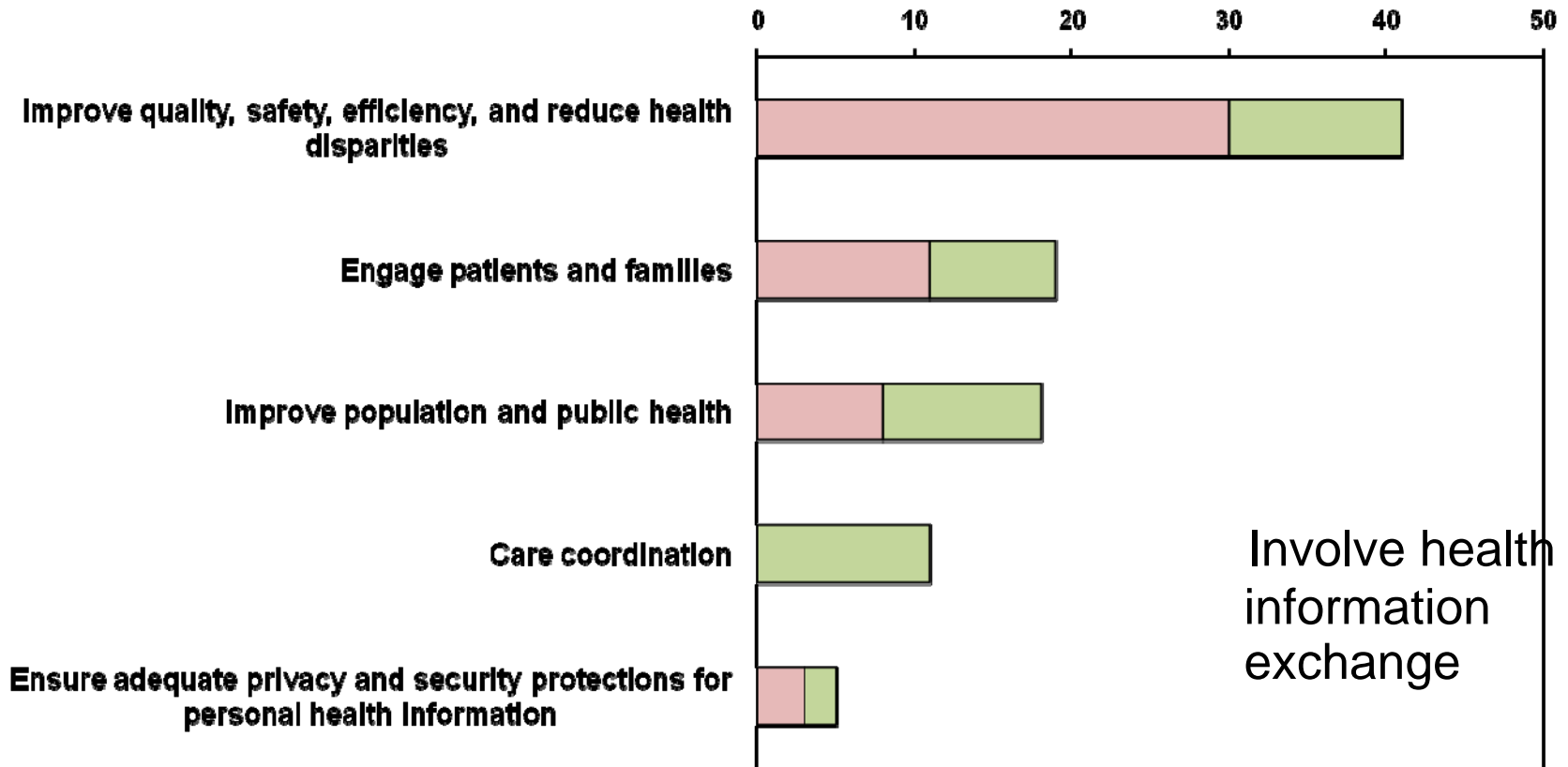
If implemented judiciously, ARRA funding can help create a value proposition for health exchange



Of all of the tools provided by ARRA, MU incentives are the most powerful lever of change

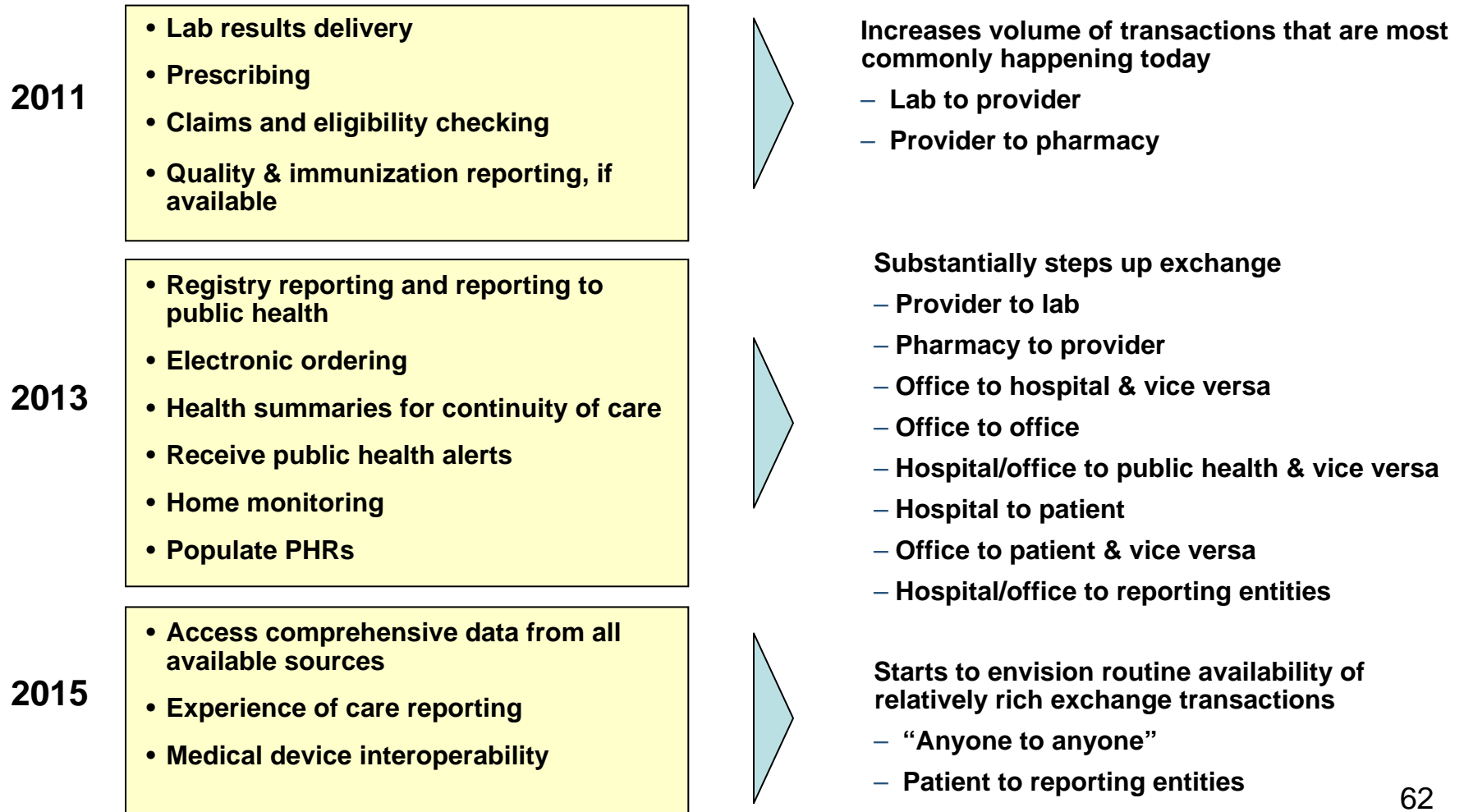
- **Of the various levers available to the government, Meaningful Use criteria are by far the most influential**
 - ~\$45B in incentives vs ~2B in discretionary ONC programs
 - Directly affects the value proposition at the point of purchase
- **While ONC doesn't have the ultimate decision on incentive criteria, it can create enablers for robust incentive criteria that would inform and allow robust incentive rules requiring health exchange**
 - **Meaningful use criteria (objectives and measures) that require standards-based exchange**
 - **Definition of core requirements for exchange to meet recommended meaningful use criteria**
 - **Certification of interoperability components that adhere to such requirements**

Of 94 MU objectives specified in the original MU definition, 42 of them seem to involve health information exchange



Strength of health exchange objectives in current version of MU rises substantially by 2013

Meaningful Use objectives requiring health exchange



Recommendations

Information exchange requirements

- There should be core information exchange requirements that are **technology- and architecture-neutral** and would apply to all participants seeking to demonstrate meaningful use to CMS

Core Requirements

- Consistent with the recommendations of the Certification Workgroup, these core requirements should be focused on the capability to achieve meaningful use and include **interoperability, privacy, and security**

Certification of interoperability components

- Federal government should **certify EHR and health information exchange components** on these core requirements to ease burden on eligible professionals and hospitals for meeting and demonstrating adherence with meaningful use requirements

Aligning federal and state efforts and bringing existing efforts into alignment

- Federal and state-government approaches should be complementary, **and grants to states should require alignment with federal meaningful use objectives and measures**

Additional Points

- Setting criteria that all systems and components must meet allows eligible professionals and hospitals to **have a choice among models of exchange while still qualifying for meaningful use incentives** (for example, direct or through vendor-specific or transaction-specific hubs, or through national or subnational networks (HIOs)). For example:
 - Certified EHRs with robust interoperability standards
 - Certified components that have to meet same interoperability standards in order to allow space for market innovation and address transition from non-certified legacy systems
- Systems not seeking or required to be certified would have market incentives to adopt in order to be able to exchange data with certified systems or through certified components
- Consistent with Certification Workgroup recommendations, should be tied to **capability to exchange to meet meaningful use criteria in 2011, with a clear pathway to more robust exchange in 2013 and 2015**

Additional Points

- Core requirements should be focused on exchange required to meet meaningful use and should include interoperability, privacy, and security
- (1) Interoperability – a basic level of the transport/communication, package and content standards that are necessary to ensure exchange can occur
 - Top priority: transport/communication standards plus container/envelope standards for key clinical payloads so all can at least send and receive human readable data
 - Top priority: measure definitions and semantic standards for clinical data required for 2011 CMS and public health reporting
- (2) Privacy and (3) Security
 - Meet requirements of current law & those enacted in ARRA that will need to be implemented over the next 1-3 years
- Policy Committee has a role to play in shaping these requirements and should provide clear guidance to the Standards Committee

Additional Points – Federal/State Interplay

- **States may impose state-level requirements on information exchange to satisfy state-level meaningful use definitions.** Such requirements should be complementary to federal efforts
- To qualify for meaningful use, information exchange in a state must meet federal requirements to qualify for Medicare meaningful use payments, and may also be required by a state to meet state-level requirements for receipt of Medicaid meaningful use payments
- The federal definitions and requirements of meaningful use should be a “floor” for state-level Medicaid meaningful use requirements

Clarification: Certification and HIOs

- We are not recommending a separate certification pathway for HIOS, with separate HIO standards
- We are recommending that health information exchange **components be certified**
- One role that HIOs have played in the past and may continue to play in the future -- along with other technologies such as those supplied by EHR vendors and new technologies still to come -- is providing the components that enable heterogeneous providers and systems to more easily exchange data

Achieving Real Privacy And Security

Health IT Privacy and Security

- Success of health information technology and exchange rests on consumer and provider confidence in privacy and security protections
- Privacy and security are fundamental building blocks for Meaningful Use
- Leverage technology to improve protections

ARRA Privacy and Security Related Provisions

- Business Associates (OCR)
 - Certain HIPAA Privacy & Security Rule requirements apply to business associates (BAs)
 - Entity that provides data transmission of personal health information (PHI) to a covered entity (CE) or BA, and requires routine access, and vendor that provides PHR as part of an EHR, must have a BA agreement
- New breach notification requirements
 - For covered entities and business associates (OCR)
 - For vendors of PHRs and other non-covered entities (FTC)
 - Guidance on technologies/methodologies for rendering PHI unusable, unreadable, or indecipherable (ONC/OCR)

ARRA Privacy and Security Related Provisions

- Provides individual right to restrict disclosures to a health plan for payment or health operations or for items and services paid “out of pocket”
- Requires CE to limit use, disclosure and requests for PHI to limited data sets, as possible, or minimum necessary
 - Guidance on minimum necessary
- CEs and BAs to provide accounting of disclosures through EHRs for for treatment, payment, operations
- CE must provide copy of PHI in electronic format to individual or other designees if CE has an EHR

ARRA Privacy and Security Related Provisions

- Prohibits CE/BA from remuneration for PHI without authorization (with some exceptions for exchanges)
- Limits other CE/BA communication about products or services when entity received remuneration
- Regulations to require clear opt-out for CE fundraising communication with individual
- Study and recommendations to Congress for privacy and security (P&S) requirements for non-CE PHR vendors (ONC/FTC)

ARRA Privacy and Security Related Provisions

- Enforcement:
 - Extends HIPAA civil and criminal penalties to BAs
 - Changes civil penalty structure
 - Provides State Attorneys General (AGs) with authority to enforce HIPAA
 - Provides that employees/individuals can be criminally liable
 - Requires periodic audits to ensure compliance

HIT Standards Committee: Privacy and Security Recommendations

Product Standards – domains

1. Access control
2. Encryption and decryption
3. Accounting and audit
4. Authentication
5. Consent management
6. Consumer EHR
7. HIPAA de-identification
8. Data integrity
9. Transmission Security

Infrastructure Standards – areas

1. Consistent time
2. Document exchange
3. Service access
4. Domain name service
5. Directory access

Summary

- Journey to 21st century a transformed health system requires
 - Meaningful use of transformation-capable HIT,
 - Real exchange of data
 - Standards that provide true interoperability
 - and the confidence of the public that the system is secure and will protect their privacy
- ARRA makes a major investment in HIT
 - Over \$44 Billion of taxpayer dollars will be spent
 - One opportunity to do it “right”



QUESTIONS AND DISCUSSION

HIMSS

transforming healthcare through IT

architects of change

HIMSS 8th Annual Policy Summit

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