Patient Safety: Response to the ONC Report and Legislative Options
January 2, 2013

healthITnow.org

Agenda

1. Introductions

2. Legislative Outlook: Drew Kent, Deputy Chief of Staff, Congressman Tom Marino

3. ONC Patient Safety Action & Surveillance Plan

4. HITN Recommendations on Patient Safety

5. Legislative Options
    1. Energy and Commerce and HELP Committee Working Draft
    2. H.R. 3239 (Marino)
    3. H.R. 6043 (Murphy)

6. Q&A and Discussion

About HITN

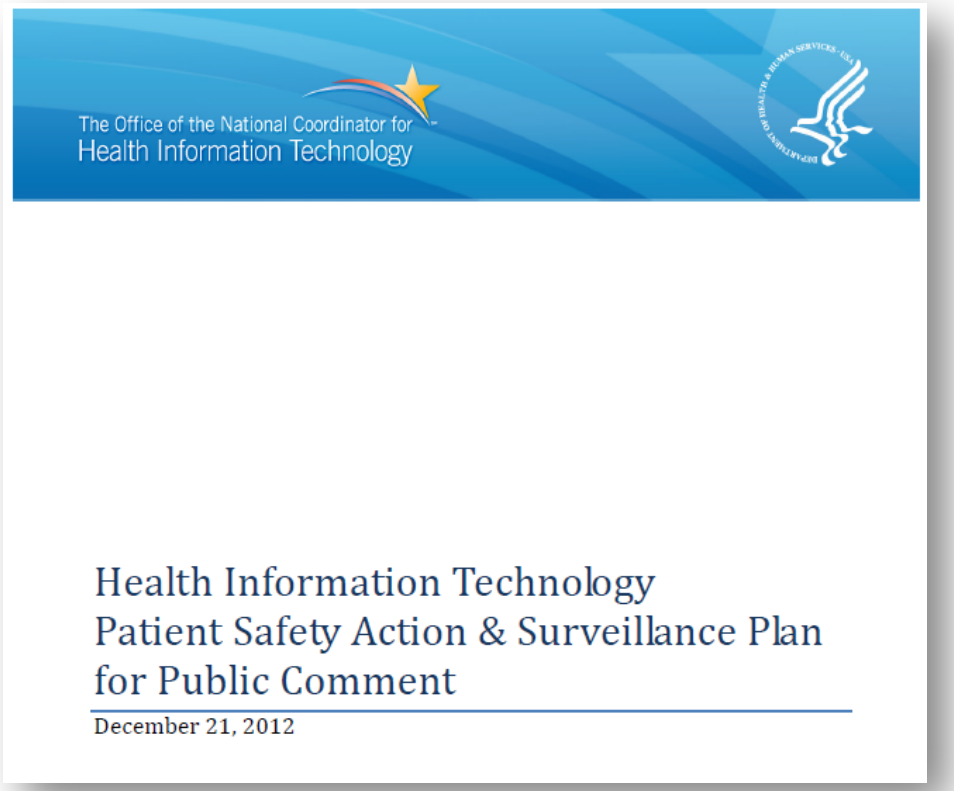
- Not-for-profit founded in 2007
- Central goal is advancing the adoption and use of health information technology to:
  - Lower costs
  - Improve quality
  - Better Outcomes
  - Promote Safety
- 65 Diverse organizations representing patients, providers, employers and payers

2013 Priorities

- **Expand incentives to adopt and use HIT**
  - Protections for reporting adverse events
  - Financial incentives, such as SBA loans, MU expansion, tax credits
- **Improve the utility of HIT**
  - End data silos
  - Promote standards that improve clinical workflows
  - Expand Stark exception to require interoperability
  - Better standards aligned with payment and delivery reforms
- **Expand Telemedicine in Medicare, Medicaid and Private Markets**
- **Create a Regulatory Framework for Patient Safety and Innovation**
  - Establish a regulatory environment that promotes innovation and patient safety
- **Leverage Health IT to prevent or reduce waste, fraud an abuse**
- **Use HIT to expand research opportunities and lower their cost**

ONC Plan

- Response to 2011 IOM Report
- Comments open until February 4
- HITN has requested a meeting with Dr. Mostashari
- Outlines Goals, Objectives, Strategies and Actions

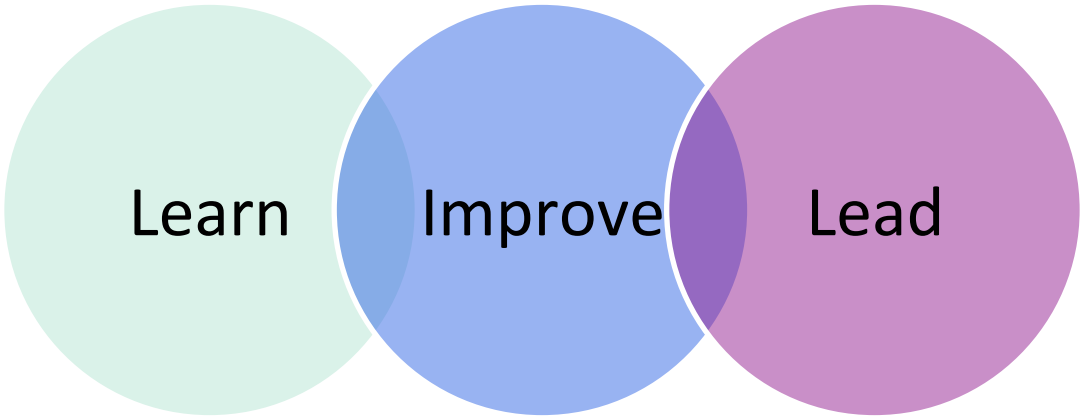


ONC Plan

- **Patient Safety Goal:** patients and providers have confidence in the safety of the health care system, including its HIT infrastructure, based on evidence of safety.

- **Objectives:**
  1. Use HIT to make care safer
  2. Continuously improve safety of HIT

- **Strategies:**



- Assumes expanded use of HIT creates opportunities to improve patient safety.
  - Requires interoperable systems.
  - Requires shared responsibility (clinicians, patients, developers, etc.)

ONC Plan

Learn

1. Make it easier for clinicians to report patient safety events using EHR technology. Utilize AHRQ Common Formats.

2. Encourage developer reporting of adverse events and risks to PSOs. Develop industry code of conduct.

3. Support use of PSOs to identify, aggregate and analyze safety events.

4. Use ONC-ACBs for post-market safety and functionality surveillance.

5. Align CMS surveys and COPs to ensure safety.

6. Collect data on HIT safety through the CMS Quality & Safety Review System.

7. Monitor HIT adverse event reports to FDA's MAUDE database.

ONC Plan

Improve

1. Leverage MU of EHR to improve safety (i.e. Stage 3 recommendations).

2. Incorporate safety into certification criteria for HIT products (user centered design, for example).

3. Support R&D, testing and best practices for HIT safety and its safe use (various tools and patient matching).

4. Incorporate HIT safety into medical education and training of providers.

5. Investigate and take corrective action when problems are identified.

ONC Plan

Lead

1. Develop HIT safety priority areas, measures and targets.

2. Fulfill FDASIA requirement: report on strategy and recommendations for an appropriate risk-based regulatory framework for HIT (ONC, FDA, FCC).

3. Establish an ONC safety program to coordinate implementation of the Plan (ONC, AHRQ, CMS, FDA, OCR).
   - Analyze data from the data streams.
   - Submit policy recommendations to government agencies and Congress.
   - Eliminate or reduce inefficiencies across programs.

4. Encourage State governments to incorporate HIT into safety oversight.

5. Encourage private sector leadership and shared responsibility for patient safety.

Pros and Cons: ONC Plan

CON

- Requires statutory changes to increase impact (PSOs, liability)
- Requires Changes to MU standards unlikely to be made until 2016
- Does not replace FDA approach

- Builds on Private Contractors to Assess Safety
- Leverages PSOs
- Recognizes Data Silos Create Safety Issues
- Uses CMS "Big Stick"
- Shared Responsibility

PRO

HITN Response

HITN Principles

- Expanded use of Health IT can reduce adverse events.
- A Regulatory framework should:
  - Be Risk-based;
  - Be Expert-based;
  - Promote innovation and flexibility;
  - Reduce duplication;
  - Lower costs;
  - Stimulate product development/time to market through streamlined approval.
- Reporting adverse events should build off existing structures and encourage a culture of learning and improvement, not punishment.
- Standards should be harmonized across markets.

HITN Response to ONC Plan

1. **Legal**

- Fulfill the FDASIA requirement as soon as possible.

2. **Process**

- Funnel reporting to PSOs and ONC-ACBs. The FDA MAUDE database is not appropriate for non-medical devices.
  - Recommend that a similar database be made available on the ONC website
- Better Define "User-Centered Design" into something that can be standardized and tested, ideally through NIST.
- Failures of EHR systems to function *as-certified* should be considered a patient safety event.
- Data silos should be defined as a patient safety problem.

3. **Learn from the Process**

- Require reports to PSOs to be forwarded to the ONC-ACB that certified the product.
- Report "corrective action" to ONC so we may better understand the effectiveness of the action.
- ONC-ACBs that with more than the average number of PSO reports should be subject to annual re-evaluation by their ONC-AA.

Legislative Options

H.R. 3239 – SAFE Medicare Patient Act (Marino), H.R. 6043 (Murphy)

- Creating a system for reporting errors that occur when using EHRs or HIEs.

–The process would provide an incentive to identify problems, report them to existing certification bodies, and receive feedback on what went wrong and how to fix it.

–Information in the reports would be privileged and confidential, similar to bipartisan protections enacted by Congress in 2006 to report medical error.

–This creates an incentive to address problems, rather than covering them up.

- Limiting e-discovery to ensure EHRs aren't used as an easy source of lawsuits.

–A 2009 Study by the FTC showed evidence that hospitals are 33% less likely to adopt electronic medical records if there are state laws that facilitate the use of electronic records in court.

–De-risking technology use by establishing process protections that ensure parties responsible for errors are held accountable.

Legislative Changes

1. Include developers as reporters and subject to same protections
2. Create alternative risk based regulatory framework
3. Eliminate data silos as unsafe practice

Next Steps

- Comment letter on ONC Plan (February 4)
- Comment letter on HITPC MU3 Recommendations (January 14)
- Meeting with Dr. Mostashari
- Hill meetings to pursue legislation
- Other?

HITN Risk Based Framework

- Develop an alternative regulatory process for health technologies and software that function exclusively as information management systems.
  - Systems that exclusively manage health information would not be required to go through the existing 510(k) or Pre-Market Approval (PMA) processes but rather would be evaluated based on risk.
  - Focus on how to make the data that these technologies manage as consistent and as safe as possible.
  - Focus safety certification process on a systems ability to function *as-certified* and adherence to required program standards.

- Categorize technology by risk based on the potential for variability in the health information system's function. The level of risk determines the proper regulator and regulatory process .

  1. **Category 1 - No Perceived Risk**
  2. **Category 2**
     1. *A – Low Risk*
     2. *B – Moderate Risk*
  3. **Category 3 – High Risk**

- The Low to Moderate risk category has two subgroups based on a manufacturer's adherence to standards. Once a technology is categorized by risk, the appropriate regulator acts.

HITN Risk Based Framework

Identifying Regulators

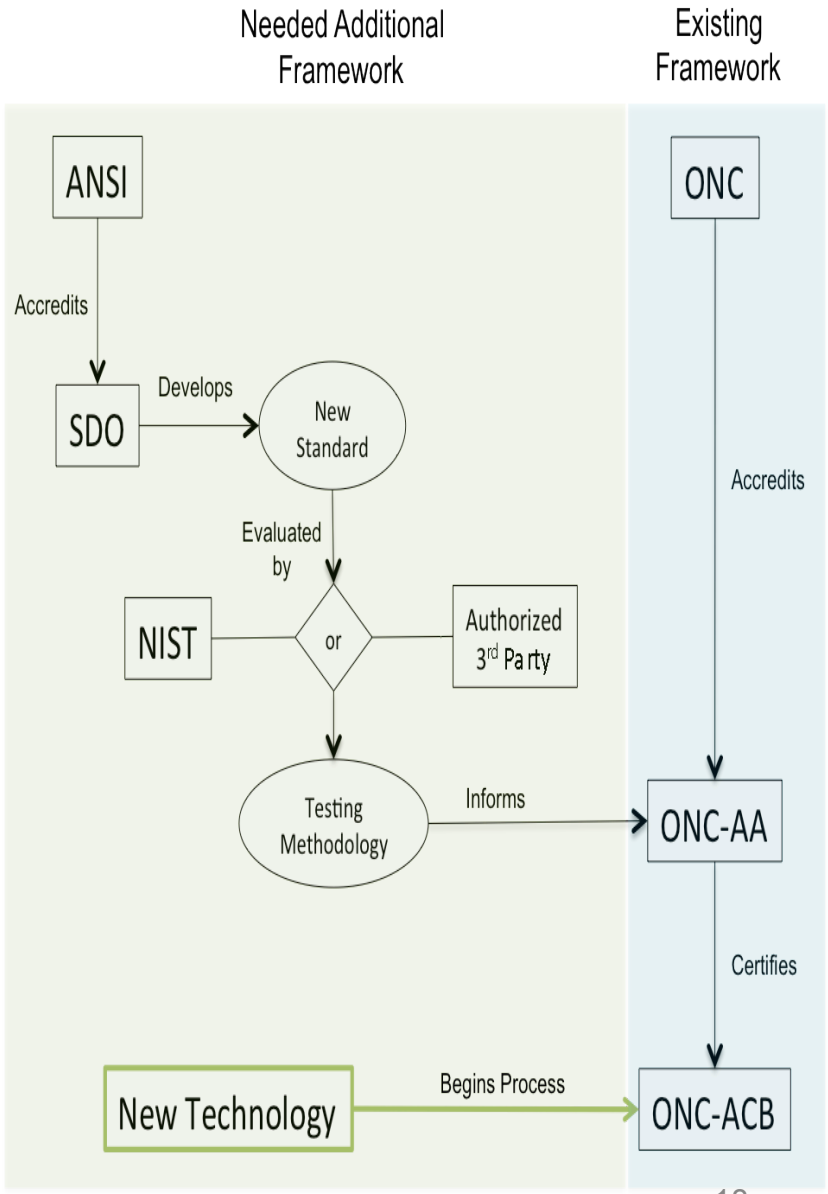
•Develop a standards based approach to stratify risk that addresses challenges related to expertise, burden and backlog.

•Use a process similar to the ONC's approach in certifying EHRs and EHR modules for use in MU through accredited industry certifiers.

•Implement a public-private certification process for health information systems and software—overseen jointly by ONC and NIST—that focuses exclusively on the developer or manufacturer's adherence to sound engineering practices and standards that have been evaluated by SDOs.

HITN Recommendations

- **ANSI will accredit SDOs**
- **SDOs develop new standards**
- **NIST will:**
  - Define a testing methodology for standards created by SDOs.
  - Define a process to identify SDOs and private industry to develop testing methodology for new standards as they are developed.
- **ONC will:**
  - Maintain a registry of industry accreditors and certifiers.
  - Work with NIST, develop a permanent certification process for SDOs and private industry certify technologies as well as accredit other organizations to certify technology.
  - Identify entities (ONC-AAs) to accredit certify technology (ONC-ACBs) as it does in the Meaningful use program.
- **ONC-AAs will use the methodology developed by NIST or its 3rd party proxy to identify ONC-ACBs that will be able to test to that standard.**
- **ONC-ACBs will evaluate new technologies**



New Framework by Category

No Perceived Risk

Adhere to Current Good Manufacturing Processes (CGMP) [(61 FR 52602)] or implement a Quality Management System (QMS) [§170.314(g)(4)]

Register the product with NIST, or a NIST approved accreditor.

Low (in addition to requirements for no risk)

Demonstrate compliance with certification through the necessary number of standards test-beds

Products must be recertified through a test-bed if the technology is changed in a way that it requires the use of standards outside of its original certification.

Moderate (in addition to low risk)

Enter into a business agreement with a relevant Patient Safety Organization (PSO)

Publically report de-identified adverse events – quarterly- for one year through a relevant PSO

High

To address legitimate patient safety concerns, the FDA 510(k) and PMA process are likely the most appropriate regulatory frameworks that are currently available.

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