The Office of the National Coordinator for Health Information Technology

ONC Policy Update: FDASIA and Meaningful Use

Health IT Standards Committee Meeting
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FDASIA

FDASIA Section 618

- Requires the posting of a ***report*** on agencies' websites
  - Within 18 months (by January 2014)
  - Report must contain:
    - a proposed strategy and recommendations on a risk-based regulatory framework pertaining to health IT, including mobile applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.
- Permits the HHS Secretary to convene a working group of external stakeholders to provide input on the strategy and recommendations included in the report.

FDASIA Workgroup Charge

Provide input on issues and concepts identified by FDA, ONC, and the FCC ***to inform the development of a report*** on an appropriate, risk-based regulatory framework.

FDASIA Workgroup Process

- 3 months of deliberation
- 1 in-person meeting
- 3 subgroups
  - taxonomy,
  - risk & innovation,
  - and regulations
- Considered much of the prior work done in this area including IOM committee recommendations
- Included input from:
  - Three agencies
  - The public
  - The HIT Policy Committee (August 7, 2013 meeting)

Workgroup Public Input

Request for Public Comment

- Federal Register Notice published on May 30, 2013 (78 FR 32390).
- Comments received by:
  - *June 30, 2013,* were forwarded to the FDASIA workgroup for consideration.
  - *Aug 31, 2013,* will be considered by the agencies.

FDASIA Workgroup Review and Consideration

- The workgroup reviewed 14 timely received submissions.
- These comments were discussed at the July 26, 2013 meeting.

Consideration of Additional Public Comment

- At the close of each FDASIA workgroup and subgroup meeting, members solicited public comments.

Workgroup Work Product

- Provided a taxonomy for considering the parameters of HIT and what HIT might be considered for a regulatory framework.
- Described current regulatory frameworks, including perceived ambiguities, deficiencies, and duplication
- Provided suggestions to promote innovation in both the short and long-term and maintain patient safety
- Provided recommendations for a new risk framework, including the stratification of HIT by risk and assessment of regulation need
- Supplemented recommendations with use cases

HIT Taxonomy

Assigned HIT to One of Two Categories:

Subject to risk-based regulatory framework	Not subject to risk-based regulatory framework

Established "Guiding Principles":

- All HIT addressed by the risk-based regulatory framework can be described by a set of defining characteristics
- Framework must be sufficiently robust to be able to meet future undefined needs
- Avoid creating an inclusive inventory for determining what is regulated
- A decision tree approach that emphasizes **functionality** as a primary scoping criterion
- Functionality will help distinguish between two similar innovations, one requiring risk-based regulation and one not

HIT Taxonomy – Eight Key Dimension of HIT

1. Intended use
2. Conditions of use
3. User type
4. Developer/ 'Manufacturer' type
5. Distribution model
6. Phase of the product lifecycle
7. Product categories
8. Other

HIT Classification Only by Product Category

Possibly subject to Risk-based Regulatory Framework

- EHRs (installed, SaaS)
- Hospital information systems-of-systems
- Decision support algorithms
- Visualization tools for anatomic, tissue images, medical imaging and waveforms
- Health information exchange software
- Electronic/robotic patient care assistants
- Templating software tools for digital image surgical planning

***Likely not subject* to the Risk-based Regulatory Framework**

- Claims processing software
- Health benefit eligibility software
- Practice management / Scheduling / Inventory management software
- General purpose communication applications (e.g., email, paging) used by health professionals
- Software using historical claims data to predict future utilization/cost of care
- Cost effectiveness analytic software
- Electronic guideline distribution
- Disease registries

FDASIA: Framework for Risk and Innovation DIMENSIONS of ASSESSING RISK of PATIENT HARM

	Lower risk	Medium Risk	Higher Risk/More Attention
Purpose of software product	Information-only; purpose is transparent and clear	Makes recommendations to user	Automated decision making (e.g., intelligent IV pump, AED)
Intended user(s)	Targeted user(s) are knowledgeable and can safely use product	Makes recommendations to knowledgeable user	Provides diagnosis or treatment advice directly to knowledgeable user
Severity of injury	Very low probability of harm	Potential for non-life threatening adverse event	Life-threatening potential
Likelihood of hazardous situation arising	Rare (<1 per 10,000 patient-years)	Unpredictable, but hazardous situation arises > 1:10K pt-yrs and < once a year	Common (arises once per -year)
Transparency of software operations, data and included content providers	Software output is easy to understand and its "calculation" (data and algorithm) transparent	Software operates transparently and output is understandable by software expert	"Black box"
Ability to mitigate harmful conditions	Human intermediary knowledgeable and empowered to intervene to prevent harm	Human intermediary may be (but not routinely) involved	Closed loop (no human intervention)
Complexity of software and its maintenance	Application of mature, widely adopted technologies with information output that is easy to understand by the user	Medium complexity. Testing procedures exist that reliably assess patient-safety risk profile of product.	Complexity of data collection and "transformation" involved in producing output is significant. Difficult to test reliably for all safety risks
Complexity of implementation and upgrades	The "build" and configuration of the software is straight-forward and does not materially affect the integrity of the output. Safety upgrades can be accomplished easily.	The "build" and configuration of the software is moderately complex, but "guard rails" significantly limit types of changes that might induce life-threatening risk.	The "build" and configuration of the software is complex and can introduce substantial changes that can induce serious risk. Limited or no "guard rails."
Complexity of training and use	The software system output is clear and easy to interpret. Minimal training needed.	Moderate complexity. Less than 2 hr of training required.	The complexity of the user interface and density of data presented can cause important errors or oversights that can lead to serious risk. Formal training necessary.
Use as part of more comprehensive software/hardware system	Used as a standalone product, or output is unambiguously used as part of larger integrated system. Certified to specific hardware. Redundancy reduces single points of failure	Software interacts with 1-3 other systems with mature, well described interfaces	Almost always used as part of a larger software system AND output is subject to interpretation or can be configured in multiple ways whose mis-interpretation may induce harm. [e.g., DDI thresholds].
Network connectivity, standards, security	Wired and wireless licensed spectrum	Wireless spectrum that is licensed by rule with interference protection and low risk of harmful interference	Wireless unlicensed spectrum, which has no protection from harmful interference

Regulations - Questions Addressed

1. Are the three regulatory systems – ONC, FCC and FDA – deficient in any way with regard to how HIT is regulated?
2. Are there ambiguities in the three regulatory systems that need to be clarified so that HIT vendors and others can proceed more easily to innovate?
3. Do any of the three regulatory systems duplicate one another, or any other legal, regulatory or industry requirement?
4. Setting aside existing approaches, is there a better way to assure that innovation is permitted to bloom, while safety is assured?

Recommendations

- Definition of what is included in HIT should be broad but have also described exclusions
- Patient-safety risk framework and examples provided should be used as building blocks to develop a more robust and transparent framework which would allow application of oversight by level of risk
- The agencies should address the identified perceived ambiguities, deficiencies, and duplication
- New framework(s) with some of the characteristics aimed at stimulating innovation as identified by the workgroup may be helpful

Recommendations

- Substantial additional regulation of HIT beyond what is currently in place is not needed and would not be helpful, except for:
  - Medical device data systems (MDDS)
  - Medical device accessories
  - Certain forms of high risk clinical decision support
  - Higher risk software use cases
    - For the regulated software, it will be important for the FDA to improve the regulatory system to accommodate the characteristics that make software development, distribution and use different from physical devices
- New risk framework(s) should support reevaluation of what is currently regulated as well as new HIT

Recommendations

As recommended by the IOM Committee:

- Vendors should be required to list products which are considered to represent at least some risk and a non-burdensome approach should be developed for this
- Better post-market surveillance of HIT is needed
  - Should include standard formatting of involved reports
  - Transparency of products and results
  - Post-implementation testing
- An approach is needed to allow for aggregation of safety issues at the national level, including federal support to enable this
  - FDA and other agencies need to take steps to strongly discourage vendors from engaging in practices that discourage or limit the free flow of safety-related information
  - How to organize the governance of this should be addressed by a cross-agency group, which should include key stakeholders
  - Approach (es) would be provisional, to be re-examined periodically

Recommendations – National Accountability

- Outcomes assessment rather than product definitions
- Use of international/national standards for quality process – measureable and transparent
- Use of international/national interoperability standards to lower the entry cost
- Encourage configuration and extension to support process and solve problems
- Transparency of product and results
- Support ability to experiment or iteratively develop
- Aggregation of safety issues at a national level

Recommendations – Local Accountability

- Design, document, and prove a local control system
  - Could be co-owned with vendor
- Accreditation of the software implementation process – e.g., through an entity such as JCAHO
- Scope
  - Local configuration of software
  - Local extensions of software
  - Ability to iteratively develop, implement, and measure changes
  - Integration with medical processes
  - Training of end users
  - Sharing of lessons learned
  - Surveillance by the organization
  - Post-implementation testing

ONC-Specific Recommendations

- Increase the flexibility of compliance
  - Define the desired features
  - Avoid specific implementations in the description
  - Increase flexibility of compliance certification
- Avoid requirements dependent on effectively a single source
- Increase predictability
  - Staging the definition of the requirements versus having a defined roadmap of features
  - Re-certification criteria

FDA-Specific Recommendations

- FDA should actively establish a policy of "Enforcement Discretion" for **lowest-risk** HIT, where enforcement of regulations is inappropriate
- FDA should assess exemption from GMP for **lower-risk** HIT
- FDA should expedite guidance on HIT software, mobile medical apps and related matters
- FDA lacks internal coordination on HIT software, and mobile medical apps policies and regulatory treatment
- FDA should utilize external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA
- There may exist a need for additional funding to appropriately staff and build FDA expertise in HIT and mobile medical apps

Next Steps

- ONC, FDA and the FCC will collaboratively review and consider the work of the FDASIA Workgroup
- The agencies will also review and consider all the public comments received through the Request for Comment mentioned earlier
  - A total of 39 submissions were received
- The agencies will issue a report that contains a proposed strategy and recommendations for a risk-based regulatory framework for HIT, including mobile medical applications.

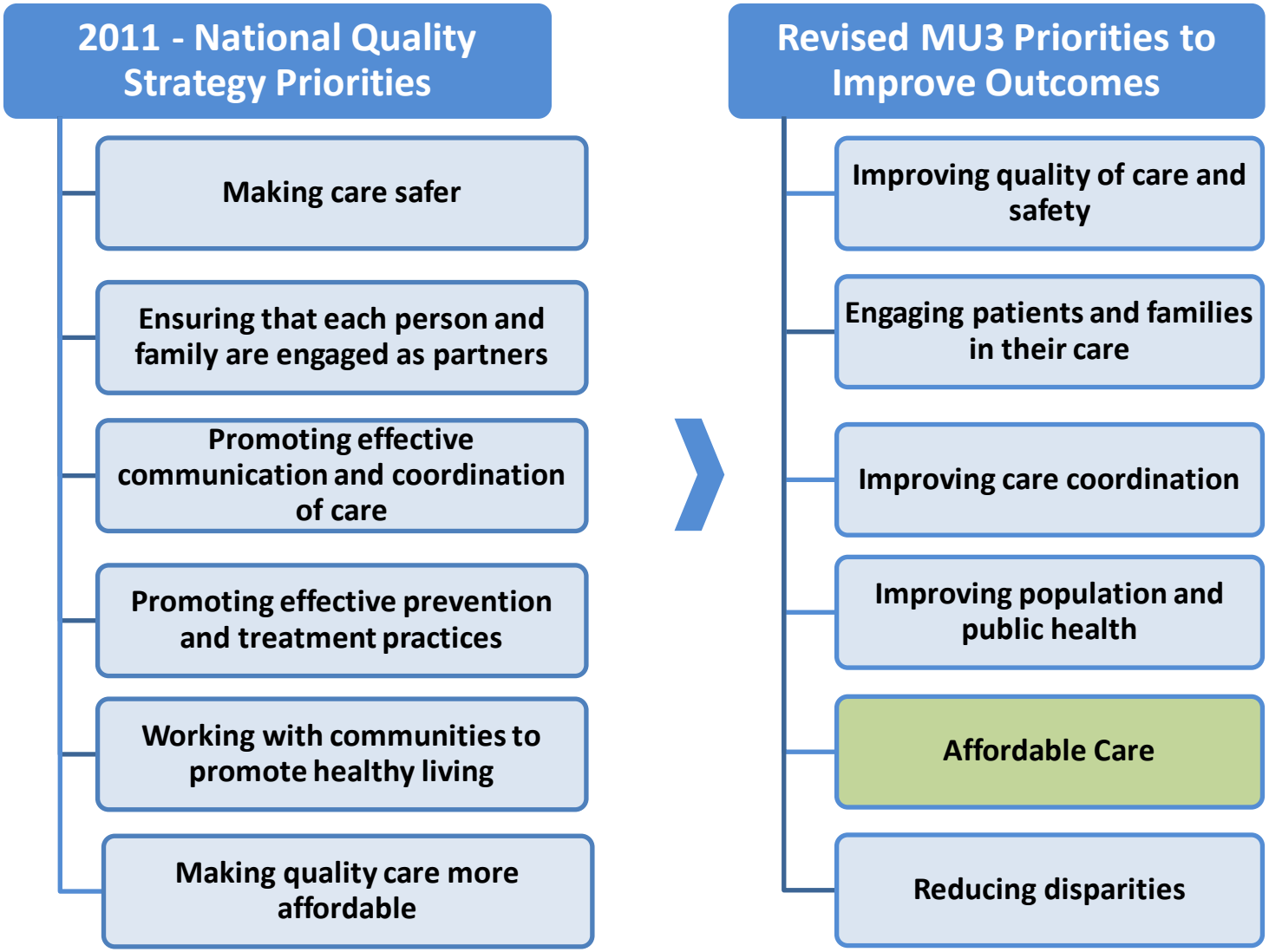
Meaningful Use Update

Meaningful Use Update

- **High Level Outcomes Framework Approved by HITPC (on Sept 4):**
  - Developed by Meaningful Use WG in response to HITPC questions on the overarching principles that should guide MU3
  - Outcomes Framework will guide further consideration of MU3 this fall

- **The Approved Outcomes in the Outcomes Framework:**
  - Improving quality of care and safety
  - Engaging patients and families in their care
  - Improving care coordination
  - Improving population and public health
  - Affordable Care
  - Reducing disparities

Outcomes Approved MU Priorities Aligned with National Quality Strategy



MUWG: Additional Work Underway in the Fall

- Detailed Recommendations expected in November 2013. Key areas:
  - **Functional Objectives:** Detailed recommendations on functional objectives; expected to build on the Outcomes Framework
  - **Deeming:** Recommendations on the potential for an optional functional deeming pathway for MU attestation
  - **eCQMs:** In October, AC/CQM Tiger Team will conduct an analysis of current and pipeline eCQM measures and concepts that would be important for Stage 3 and for a deeming pathway (MUWG will consider as it develops its recommendations for November)

HITPC Updates

HITPC Updates

- Upcoming HITPC Hearings
  - Advance directives: virtual hearing 9/23/13
  - Accounting for disclosures: virtual hearing 9/30/13

- HITPC Certification and Adoption Workgroup
  - Charged with recommending a process for prioritizing health IT capabilities for voluntary EHR certification that would improve interoperability across a greater number of care settings
  - HITSC liaisons: John Derr and Stan Huff
  - ONC Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments: published 9/9/13

Questions?