



The Office of the National Coordinator for
Health Information Technology



ONC 2015 Edition EHR Certification Criteria Notice of Proposed Rulemaking

HIT Standards Committee

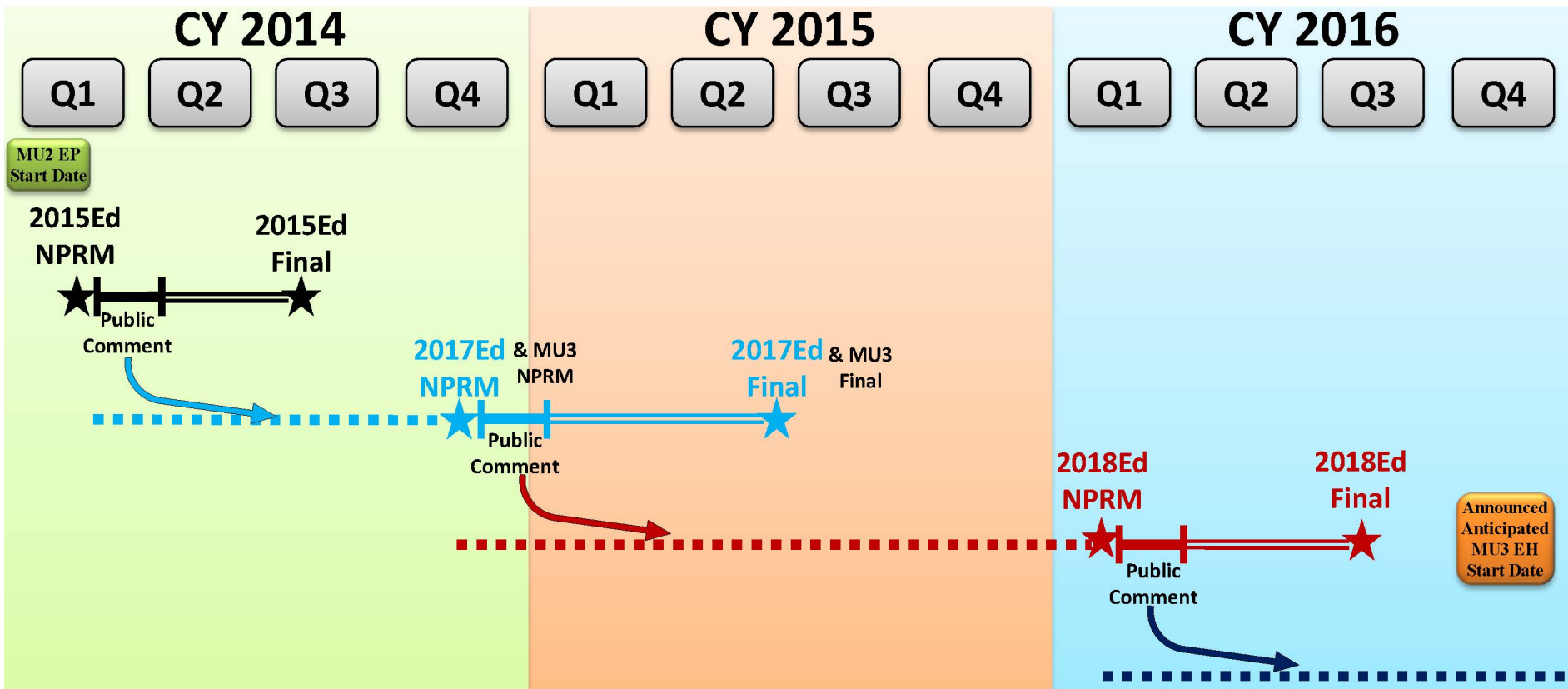
Steve Posnack



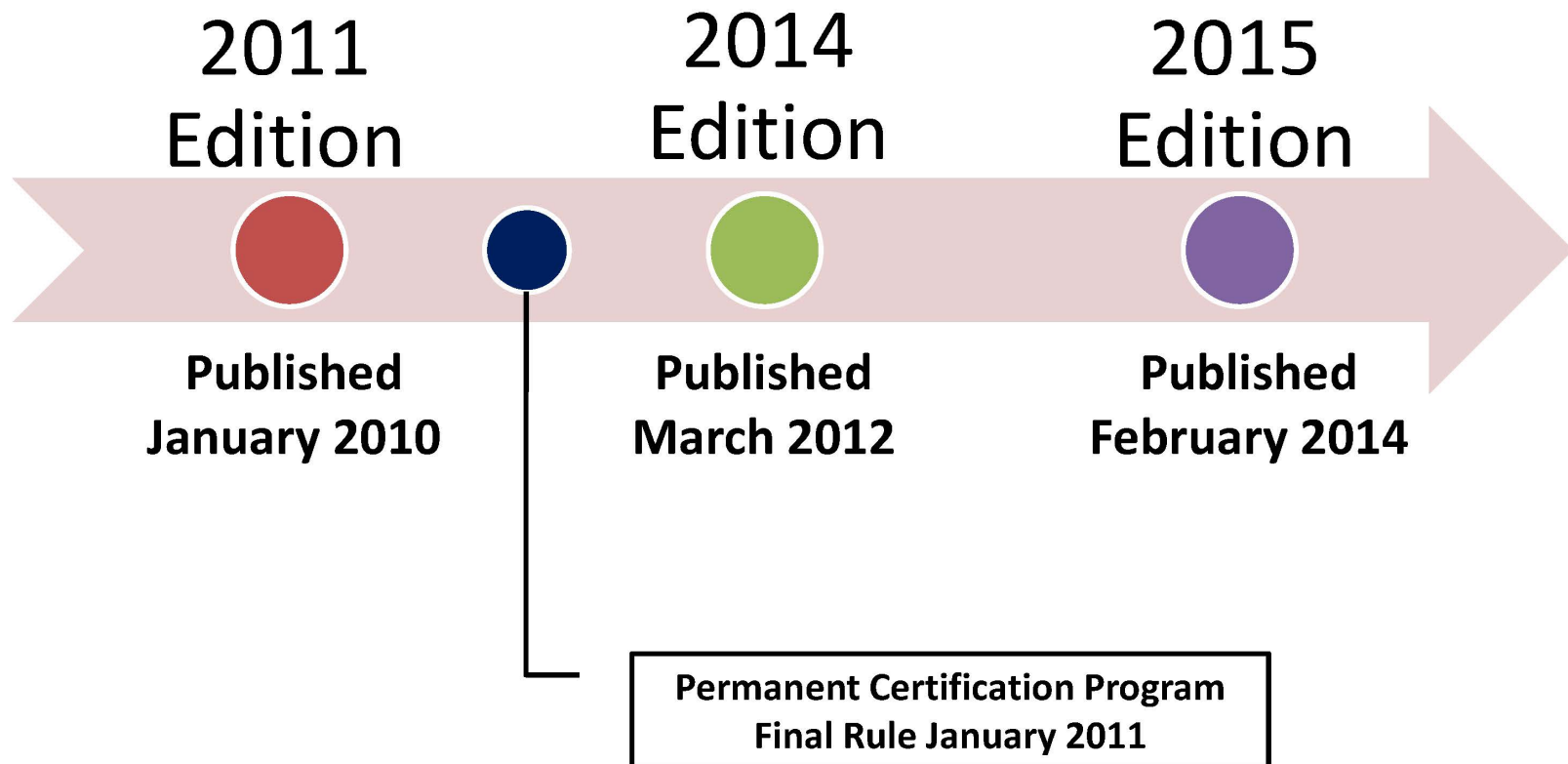
- Why a 2015 Edition?
 - 30,000ft and 10ft
- Certification Policy Perspective
 - Past
 - Present
 - Future
- Highlights:
 - 2015 Edition Proposals
 - 2017 Edition topics under consideration

- Why certification?
 - For meaningful use incentives it's required by law (HITECH)
 - In general, certification provides assurance and accountability
 - Creates a “gold baseline” in a sense
- ONC's role as a coordinator, convener, & enabler
 - Certification program policy as a service to others
 - “Policy API” for convergence – a method through which industry and other Federal policy and program needs can be met with mutually beneficial outcomes.
 - Means to reduce overall regulatory burden (“compliance fast-track”)

The future: 3-year ONC Rulemaking Roadmap (milestones reflect best guestimates)



Major Certification Rulemakings Timeline by Proposed Rule/IFR Release



What does more incremental rulemaking accomplish?

- Makes rulemaking more nimble, better able to keep up with industry updates.
- Less change between editions of certification criteria.
 - Gap certification between the 2014 Edition and 2015 Edition and then between the 2014/2015 Editions and 2017 Edition could significantly expedite certifications and reduce regulatory burden.
- Provides ample opportunity for public comment and earlier visibility into potential policy directions.

- Included the concept of “gap certification”
- *Gap certification* means the certification of a previously certified Complete EHR or EHR Module(s) to:
 1. All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and
 2. All other applicable certification criteria adopted by the Secretary at subpart C of this part **based on the test results used to previously certify the Complete EHR or EHR Module(s).**

Chronological Composition (New/Revised/Unchanged) of Certification Criteria Editions by Year

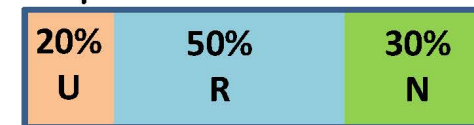
Ambulatory

2011 Edition



n = 33

2014 Edition



n = 9 22 13

2015 Edition

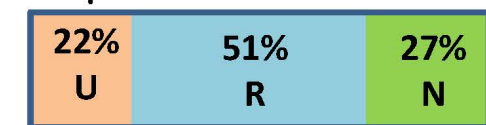


n = 34 15 4

Inpatient



n = 32



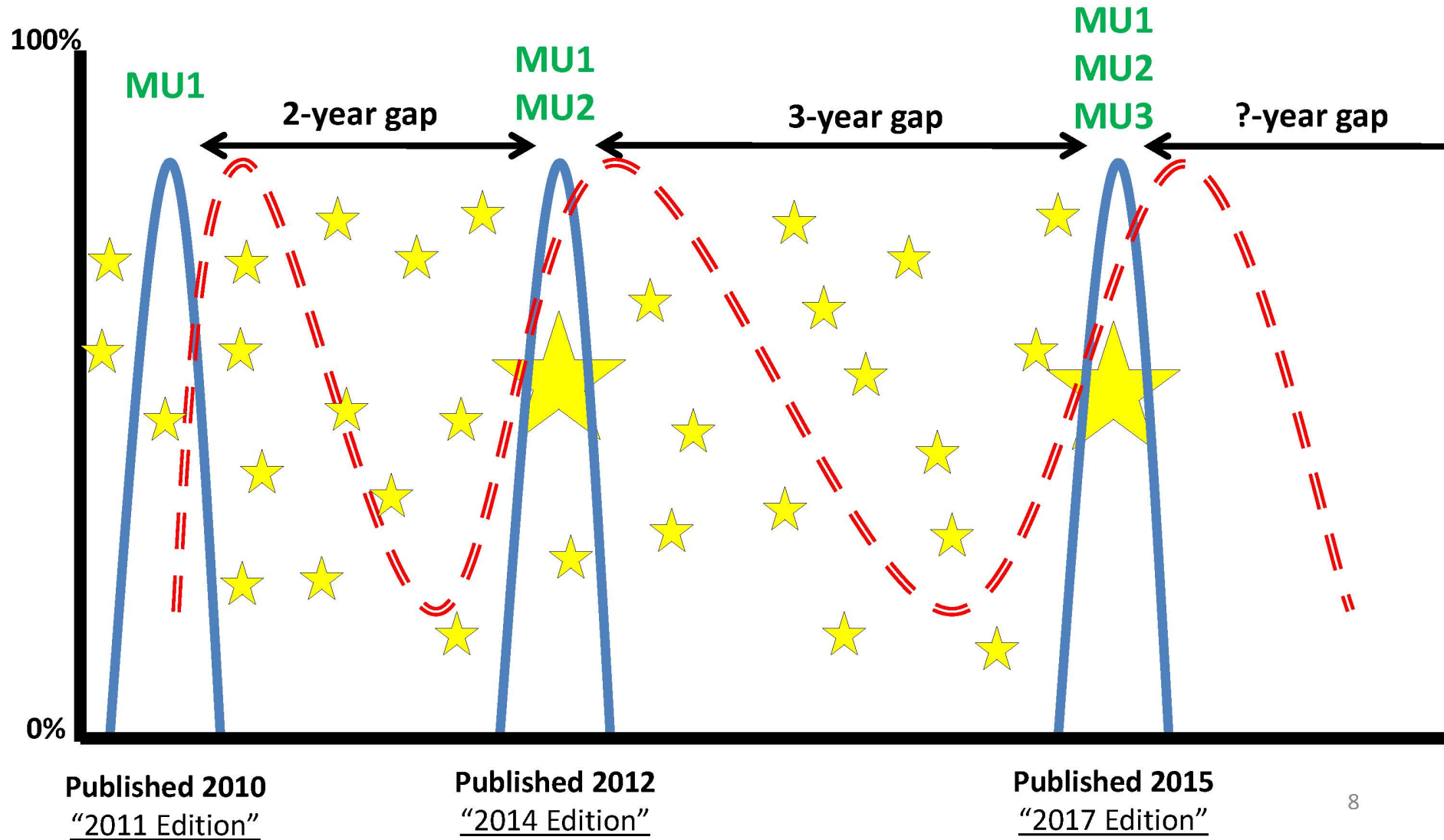
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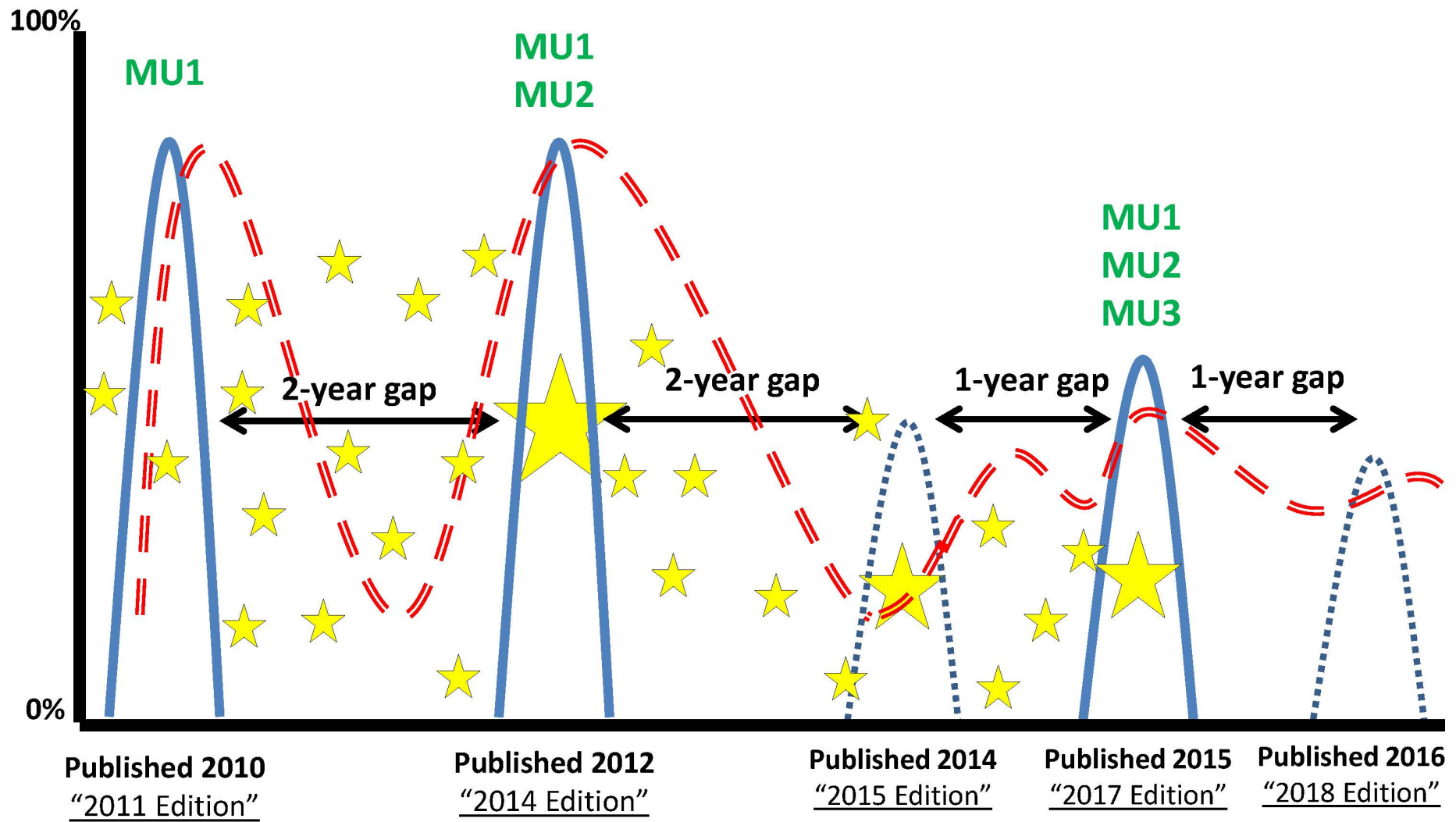
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- Over 60% of the 2015 Edition certification criteria are eligible for gap certification
- Possible for an HIT developer to get a 2015 Edition certification without retesting

Resource Allocation Comparison: Rulemaking vs HIT Developer (no incremental rules)



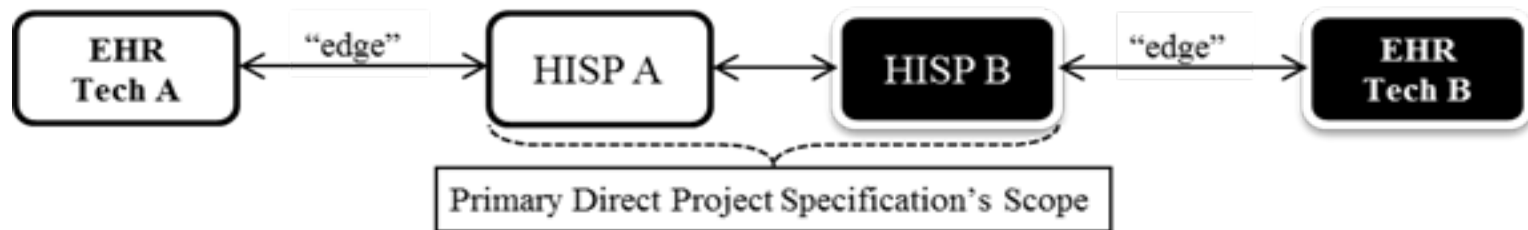
Resource Allocation Comparison: Rulemaking vs HIT Developer (with incremental rules)



- Lab orders & CLIA compliance
 - Computerized Provider Order Entry (CPOE) for lab order IG
 - Incorporate lab test results updated IG
- Clinical Decision Support (CDS)
 - Propose the adoption of the Health eDecisions work.
 - Requirements for computable CDS as well as interface requirements needed to request CDS guidance from a CDS supplier.
- Implantable device list
 - Record and display the unique device identifiers (UDIs) associated with a patient's implanted devices

- Transitions of Care

- Propose to separately test and certify:
 - “Content” capabilities (i.e., Consolidate CDA); and
 - “Transport” capabilities (i.e., Direct Project specification).
- Propose to require testing to an “edge protocol” implementation guide



- Propose a new “performance standard” that would require EHR technology to successfully receive Consolidated CDA’s no less than 95% of the time.
- Data quality constraints to improve patient matching¹¹

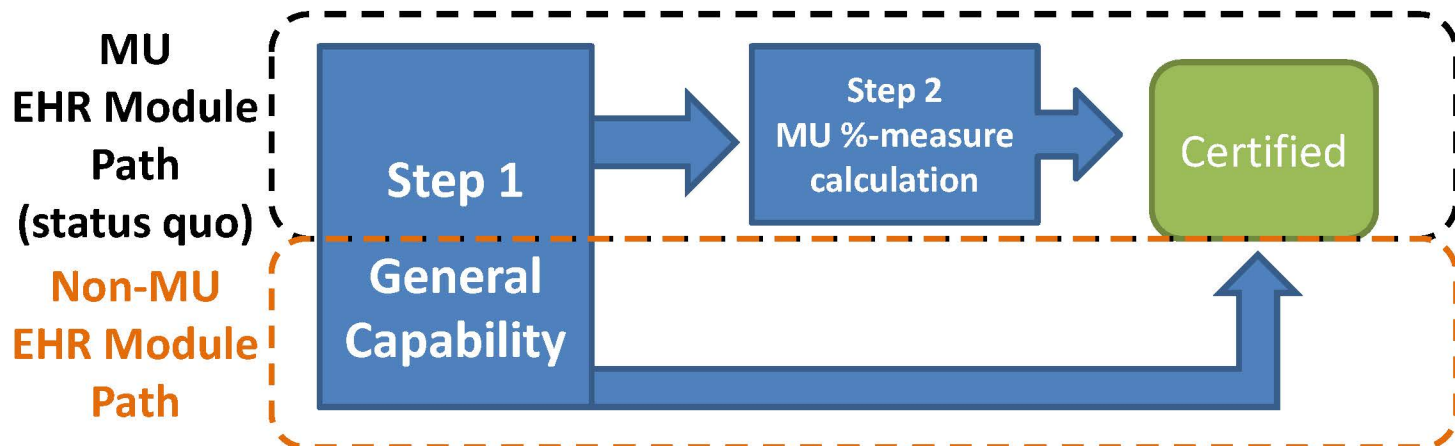
- Patient Population Filtering for CQMs
 - Ability to create different patient population groupings by, for example:
 - practice site
 - primary and secondary insurance
- Syndromic Surveillance
 - Propose to revise the 2014 Edition version as well as adopt a 2015 Edition that mirrors those revisions
 - Add certification alternatives for CDA and QRDA III standards

- Non-Percentage-Based Measures
 - Re-proposed in response to OIG recommendation
- Transmission
 - Four separate certification criteria for transmission
 - Newest includes Direct + Delivery Notification

- “Complete EHR” certification
 - Propose to discontinue
 - Outlived original intent
 - Misnomer
 - Only applies to scope of all certification criteria not entire product
 - Exceeds the flexibility now provided in the Certified EHR Technology definition
 - Not necessarily “complete”
 - No guarantee that it will included all CQM capabilities
 - May not include capabilities designated as “optional” certification criteria

• Non-MU EHR Technology Certification






- Propose to remove existing regulatory burden that would require EHR technology designed for non-MU purposes to include MU measure calculation capabilities in order to get certified.
- Propose to permit “MU EHR Modules” and “non-MU EHR Modules” to be certified. The latter would not need to include the MU-specific measure calculation capabilities to get certified.



1. Additional Patient Data Collection
 - Disability information
 - US Military Service
 - Work Information Industry/Occupation
2. Medication Allergy Coding
3. Certification Policy for EHR Modules and Privacy and Security
4. Provider Directories
5. Oral Liquid Medication Dosing
6. Medication History
7. Blue Button +
8. 2D Barcoding
9. Duplicate Patient Records
10. Disaster Preparedness
11. Certification of Other Types of HIT and for Specific Types of Health Care Settings
 - Best way to distinguish beyond “EHR technology”
 - Specific types of health care settings

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