

MITRE Analysis of Stage 2 Meaningful Use Proposed Rules
(March 2012)

Line Item #	TT Stage 2 Meaningful Use Recommendation	Proposed Stage 2 Meaningful Use Rule	Proposed Certification Standards Rule	Questions/Potential TT Discussion Topics
Digital Certificates				
1	EPs and EHRs should be required to obtain digital certificates per previous P&S TT recommendations. EHR certification process should include testing on the use of digital certificates for appropriate transactions. (HITPC 4/18/11 p. 3)	Not addressed	Not addressed	P&S TT may consider whether to raise the issue of digital certificates for Stage 2.

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E-Prescribing Controlled Substances				
2	<p>EPs are required to comply with the DEA rule regarding e-prescribing of controlled substances. Certification testing criteria should include testing of compliance with the DEA authentication rule, which requires 2-factor authentication. (HITPC 4/18/11 p. 3)</p>	<p>Drug Enforcement Administration's (DEA) interim final rule on electronic prescriptions for controlled substances (75 FR 16236) removed the Federal prohibition to electronic prescribing of controlled substances, some challenges remain including more restrictive State law and widespread availability of products both for providers and pharmacies that include the functionalities required by the DEA's regulations. However, as Stage 2 MU would not go into effect until 2014, it is possible that significant progress in the availability of products enabling the electronic prescribing of controlled substances may occur. We encourage comments addressing the current and expected availability of these products and whether the availability would be sufficient to include controlled substances in the Stage 2 measure for e-Rx or to warrant an additional measure for EPs to choose that would include controlled substance electronic prescriptions in the denominator. (p. 54)</p>	Not addressed	<p>Rules and measures do not at present address e-prescribing of controlled substances. P&S TT may consider responding to request for comments on the availability of products to support e-prescribing of controlled substances.</p>

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Security Risk Analysis and Encryption				
3	Stage 1 MU requires EPs and EHs to conduct or review a security risk analysis. This measure should also be included in Stage 2 MU. (HITPC 4/18/11 p. 5)	Conduct or review a security risk assessment. (pp. 82-83)	We do not believe that EHR technology would be able to capture that a security risk analysis was performed by an EP, EH, or CAH except through a manual entry by the EP, EH, or CAH affirming the completion of the risk analysis. (p. 38)	None; recommendation adopted.

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4	Providers/hospitals must address encryption/security functionalities for data at rest, which includes data located in data centers and data in mobile devices. Providers and hospitals must attest that they have done this. (HITPC 4/18/11 p.6)	Conduct or review a security risk assessment, including addressing the encryption of data at rest. (pp. 82-83)	Perform transmissions which provide for encryption and integrity protection. (p. 28) <i>Either:</i> (1) If EHR technology manages EHI information on an end-user device and it is stored on that device after the use of the HER technology has stopped, EHI must be encrypted. <i>Or</i> (2) EHI managed by EHR technology is never stored on end-user devices after the use of EHR technology on these devices has stopped. This capability must be enabled (i.e., turned on) by default and only be permitted to be disabled (and re-enabled) by a limited set of identified users. (p. 174 see also pp. 80-83)	None; recommendation adopted.

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Patient Portals				
5	Patient portals should include appropriate provisions for data provenance, which is accessible to the user, both with respect to access and upon download. (HITPC 4/18/11 p. 5)	Not addressed	“...our policy goals can be accomplished through the adoption of the Consolidated CDA standard. This approach also addresses the HITSC’s recommendation for this certification criterion to include “data provenance” with any health information that is downloaded. (pp. 34-35)	Recommendation adopted? The Consolidated CDA prescribes standard formats, for example, for Author (created content), Data Enterer (transferred content to clinical document), Informant (source of content), Legal Authenticator (single person legally responsible for the document), etc. (HL7 Implementation Guide for CDA 2.1.1 – 2.1.7)

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6	<p>Patient portals should include mechanisms that ensure information in the portal can be securely downloaded to a third party authorized by the patients. (HITPC 4/18/11 p.6)</p>	<p>More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information. (Transmission can be any means of electronic transmission according to any transport standard(s). (p. 159)</p> <p>More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the EHR reporting period. (p. 159)</p>	<p>The ability to transmit a summary care record to a third party. (p. 27)</p> <p>For transport, two standards are available, consistent with the Direct Project - SMTP/SMIME and SOAP. (p. 28)</p> <p>“HITSC recommended that we require as a condition of certification other privacy and security oriented capabilities such as single factor authentication and secure download. We did not include these additional capabilities in our proposals because we believe their technical implementations are commonplace and ubiquitous. Thus, there would seem to be little value added by requiring that these capabilities be demonstrated as a condition of certification.” (p. 30)</p>	<p>TT may wish to discuss the proposal concerning “secure download.”</p>

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7	<p>EPs/EHs should deploy audit trails for a patient's portal, and at least, be able to provide these to patients upon request. (HITPC 4/18/11 p. 5)</p>	<p>Not addressed</p>	<p>EHR technology certified to this criterion include a "patient accessible log" to track the use of the view, download, and transmit capabilities included in this certification criterion (i.e., record the user identification, the user's actions, and the health information viewed, downloaded, or transmitted) and make that information available to the patient. (pp. 29 – 30; p. 176)</p>	<p>None; recommendation adopted.</p>
8	<p>Certified EHRs should include a capability to detect and block programmatic attacks or attacks from known but unauthorized persons (such as auto lock-out after a certain number of unsuccessful log-in attempts). (HITPC 4/18/11 p. 5)</p>	<p>"...implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process." (p. 83)</p>	<p>Certification criterion should provide some of the basic technical tools necessary to comply with the HIPAA Privacy Rule. (p. 26)</p>	<p>The HITSC's Privacy and Security Workgroup commented: In considering the potential implications of this policy for EHR technology, the Workgroup concluded that this objective/measure does not align well with today's security technology, such as technology that allows entities to federate user identity, (e.g., OpenID, OAuth, SAML). We recommend that the HITSC ask the HITPC to reconsider this objective/measure as a potential "guidance" or "good practice" statement rather than as policy to be implemented in HER technology.</p>

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9	<p>Providers should require at least a user name and password to authenticate patients. This single-factor authentication should be a minimum – providers may want to at least be able to offer their patients additional security (such as through additional authentication factors) or provide such additional security for particularly sensitive data. In setting authentication requirements, providers should also be mindful of guidelines for identification and not set requirements so high that patients are discouraged from participating or cannot meaningfully participate (for example, by requiring complicated passwords). ONC should work with NIST to provide guidance to providers on trusted authentication methods. (HITPC 4/18/11 p. 5)</p>	Not addressed	<p>“HITSC recommended that we require as a condition of certification other privacy and security oriented capabilities such as single factor authentication and secure download. We did not include these additional capabilities in our proposals because we believe their technical implementations are commonplace and ubiquitous. Thus, there would seem to be little value added by requiring that these capabilities be demonstrated as a condition of certification.” (p. 30)</p>	<p>P&S TT may consider whether to comment.</p>
10	<p><i>Note:</i> P&S TT provided best practices (as opposed to certification criteria) on providing guidance to patients using the view and download functionality. (HITPC 8/16/11 pp. 3-4)</p>	<p>The HIT Policy Committee recommended best practice guidance for providers, vendors, and software developments. We believe the hospital can sponsor education and awareness activities that result in patients viewing their information. (p. 147)</p>	Not addressed	<p>P&S TT may wish to underscore reference to the best practices in its comments.</p>

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(March 2012)

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Patient Matching and Demographics				
11	HITSC should identify standard formats for data fields that are commonly used for matching patients (for ex: name, DOB, zip, address, gender) (HITPC 4/18/11 p. 8)	EPs/HPs must record the following demographics as structured data: <ul style="list-style-type: none"> - Preferred Language - Gender - Race - Ethnicity - Date of birth - Date and preliminary cause of death in the event of mortality (HPs only) (p. 156) 	Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth; date and preliminary cause of death (HPs only) (p. 114) We request public comment on whether we should require, as part of the “incorporate summary care record” certification criterion, that EHR technology be able to perform some type of demographic matching or verification between the patient in the EHR technology and the summary care record about to be incorporated. This would help prevent two different patients summary care records from being combined. (p. 59 – 60)	Recommendation adopted? Although the rules do not specifically address the data fields needed for patient matching, the Consolidated CDA prescribes standard formats for name, gender, address, date of birth, (<i>shall</i> be precise to year; <i>should</i> be precise to day), telephone number, and zip code contained in the document header; these fields are required. TT may wish to discuss this further. P&S TT may also wish to consider whether to provide comments on the need for certification criteria for demographic matching between the EHR technology and the summary care record.

MITRE Analysis of Stage 2 Meaningful Use Proposed Rules
(March 2012)

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12	HITSC should specify standards that describe how missing demographic data should be represented during exchange. (HITPC 4/18/11 p. 8)	"If a patient declines to provide one or more demographic elements, this can be noted in the Certified EHR Technology..." (p. 63)	Not addressed	Recommendation adopted? The Consolidated CDA prescribes a series of "null flavors" to designate missing information, for example, NI (no information) and ASKU (asked but not known). These "null flavors" <i>may</i> be used to address required fields. TT may wish to discuss this further.
13	HITSC should consider whether USPS normalization would be beneficial to improved matching accuracy and whether it should be added to the demographic standards. (HITPC 4/18/11 p. 8)	Not addressed	Not addressed	Recommendation adopted? The Consolidated CDA prescribes standards for entering addresses and zip codes. It is our understanding, however, that addresses have not been normalized. TT may wish to discuss this further.
14	Certification criteria should include testing that (i) appropriate transactions are sent/received with correct demographic data formats and (ii) data entry sequences exist to reject incorrectly entered values. (HITPC 4/18/11 p. 9)	Not addressed	Not addressed	P&S TT may consider whether to comment.

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Amendments				
15	<p>Certified EHR technology should have the capability to support amendments, including a provider's compliance with HIPAA requirements to respond to patient requests for amendments: Make amendments to the patients health information in a matter consistent with the entity's obligations w/r/t the legal medical record (i.e., ability to view the original data and identify changes) Append information from the patient and any rebuttal from the entity regarding the data. (HITPC 7/25/11 p. 2)</p>	Not addressed	<p>Enable a user to electronically amend a patient's health record to: (A) Replace existing information in a way that preserves the original information; and (B) Append patient supplied information, in free text or scanned, directly to a patient's health record or by embedding an electronic link to the location of the content of the amendment. (ii) Enable a user to electronically append a response to patient supplied information in a patient's health record. (p. 173) We specifically request comment on whether EHR technology should be required to be capable of appending patient supplied information in both free text and scanned format or only one or these methods to be certified to this proposed certification criteria. (p. 26)</p>	<p>Recommendation adopted. TT may consider whether to provide comments on whether EHR technology should be required to be capable of appending patient supplied information in free text or scanned format, or both.</p>

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16	Certified EHR technology should have the ability by MU Stage 3 to transmit amendments, updates, or appended information to other providers to whom the data has been previously transmitted. (HITPC 7/25/11 p. 2)	Not addressed	Not addressed	None; recommendation could be addressed in Stage 3.

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EHR Modules				
17	<p>To enable the certification process to more effectively address security integration, the Workgroup recommends that the ONC and National Institute of Standards and Technology (NIST) consider modifying the certification process so that each privacy and security certification criterion is treated as “addressable.” To meet the criterion, each Complete EHR or EHR Module submitted for certification would need to either: (1) implement the required security functionality within the complete EHR or EHR module(s) submitted for certification; or (2) assign the function to a third-party security component or service, and demonstrate how the certified EHR product, integrated with its third-party components and services, meets the criterion. (HITSC 10/21/11 p. 3)</p>	Not addressed	<p>We propose not to apply the privacy and security certification requirements at §170.550(e) for the certification of EHR Modules to the 2014 Edition EHR certification criteria. Stakeholder feedback, particularly from EHR technology developers, has identified that this regulatory requirement is causing unnecessary burden (both in effort and cost). Based on our proposal that EPs, EHRs, and CAHs must have a Base EHR to meet our proposed revised definition of CEHRT that would apply beginning with FY/CY 2014, we believe that we can be responsive to stakeholder feedback with our proposal to not to apply the privacy and security certification requirements at § 170.550(e) for the certification of EHR Modules, while still requiring an equivalent or higher level of privacy and security capabilities to be part of CEHRT (p. 125)</p>	<p>P&S TT may wish to consider whether to raise the issue of revisions to EHR Module certification requirements.</p>

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(March 2012)

Sources: The Department of Health and Human Services notices of proposed rulemaking (NPRMs) related to Stage 2 Meaningful Use: Medicare and Medicaid Programs; Electronic Health Record Incentive Program available at: <https://www.federalregister.gov/articles/2012/03/07/2012-04443/electronic-health-record-incentive-program--stage-2-medicare-and-medicaid-programs> and also available at: http://www.ofr.gov/OFRUpload/OFRData/2012-04443_PI.pdf, and Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology available at: <https://www.federalregister.gov/articles/2012/03/07/2012-04430/electronic-health-record-technology-2014-edition-health-information-technology-implementation> and also available at: http://www.ofr.gov/OFRUpload/OFRData/2012-04430_PI.pdf.