

Note: These observations are not a comprehensive summary of the new Final Rules, but rather point out major differences from earlier stages of Meaningful Use and significant new requirements.

IIS-relevant Comments on CMS Stage 3 Final Rule

- The final rule (FR) addresses two time periods:
 - 2015-2017, where participants can continue to use 2014-certified EHRs but the program is consolidated and streamlined.
 - 2018, where participants are required to use 2015 certified EHRs and move to Stage 3.
 - Optionally, a participant can move to Stage 3 in 2017 with 2015 certified EHRs.
 - The definition of certified EHR technology was moved from the ONC Rule to this FR for simplicity.
 - The comment period is only relevant to the ultimate incorporation of the EHR Incentive Programs into MIPS in 2019 and beyond.¹
- For 2015-2017,
 - There is now one public health objective with multiple measures, including IIS data submission. EPs select 2 measures, EH/CAHs select 3 measures (not counting any exclusions). *With this in place, participants will no longer be required to submit data to an IIS if they select other measures.* Under Stage 2, data submission to an IIS was required (subject to exclusions).
 - Bi-directional interoperability is *not* included.
 - “Ongoing submission” has been recast as “active engagement.” There are three phases of active engagement (completed registration; testing and validation; production), and they map well to current IIS onboarding work flow. Participants need not register every year, and registration that pre-dates this rule need not be redone.
 - For the first time, the FR specifically mentions the role of public health agency (PHA) communications with participants to support attestation: “Providers can demonstrate meaningful use by using communications and information provided by a PHA or CDR to the provider directly.”²
 - With respect to Objective 2 (CDS), the FR links CDS to clinical quality measures (CQMs). Since immunization up-to-date status is a core quality measure, CDSi appears to be a perfectly legitimate selection for this objective.
 - With respect to Objective 5 (HIE), immunization information continues to be included as an information domain for a transition of care document.

¹ “In light of the passage of MACRA, this final rule with comment period also allows for a 60-day public comment period on certain provisions noted in the 'Supplementary Information' section above in part to support the transition to MIPS. The comments received during the comment period may be considered as we prepare for future rulemaking to implement MIPS, which in general is expected to be more broadly focused on quality and care delivery.” Pre-release Final Rule, p. 13.

² Ibid, p. 248.

- With respect to Objective 6 (Patient-specific Education), it may be worth considering whether required VIS distribution could/should be highlighted as a compliant form of patient-specific education.
- With respect to Objective 8 (Patient Electronic Access), immunization data is *not* included in the “View/Download/Transmit” data set.
- For 2018 (Stage 3), the following additional clarifications or differences are noted:
 - Within the one public health objective, EPs select 2 measures, EH/CAHs select 4 measures (not counting any exclusions). *With this in place, participants will no longer be required to submit data to an IIS if they select other measures.* Under Stage 2, data submission to an IIS was required (subject to exclusions).
 - A PHA has to declare its readiness to support a public health measure at least 6 months before the start of a reporting period (January 1 of the reporting year) in order to avoid participants being able to claim an exclusion. The PHA does not actually need to be ready six months before, just to declare its intention to be ready when the reporting period begins.
 - Bi-directional interoperability between IIS and EHRs is now required, however “...a provider's health IT system may layer additional information on the immunization history, forecast, and still successfully meet this measure.”³ This means that an EHR can receive an immunization history and forecast, incorporate some or all of the information, and produce a new forecast if desired. Though the language is sloppy, this allows an EHR to ignore a forecast from an IIS if it feels it has more complete information or a better method of producing the forecast. The EHR apparently must still demonstrate that it can receive the forecast from the IIS.⁴
 - With respect to Objective 7 (Medication Reconciliation), the reconciliation of immunization history is not included even though immunization data *is* included in the core data set. This is a key function of an interoperable EHR to support immunization functionality.
- The request for comment that is part of this FR is a limited comment period related to the ultimate incorporation of the EHR Incentive Programs into MIPS in 2019 and beyond.

³ Ibid., p. 437.

⁴ The ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria goes on to say, “While we agree with commenters that some health IT (e.g., EHR products) may sometimes have a version of the immunization history or a version of the forecast that may differ from the immunization registry, we still believe that it is important for an EHR to receive the history and forecast from the registry. Based on compliance with the Release 1.5 IG, a user would be able to see and compare the forecast from the certified health IT (e.g., EHR products) with the forecast from the immunization registry. However, we note that this criterion does not prescribe a particular workflow or reconciliation requirements. Providers and health IT developers may reconcile forecast and history information in a manner that best meets their needs for workflow and patient safety.” (Pre-release document p. 222)

Additional Comments on ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria

- Coding standards now include CVX codes for historical immunizations and NDC codes for newly-administered immunizations. The FR indicated that MVX codes were not included and referred the reader to a later discussion which did not really address the issue.
- Patient-specific Education appears to only support provision using the InfoButton standard.
- Within the Transitions of Care document,
 - There seems to be a shift away from using Maiden Name to a more generalized Previous Name, citing cultural differences in some parts of the population as well as the complexity of multiple marriages and divorces.
 - Not ready to endorse inclusion of Place of Birth.
 - Support for Time of Birth within Date of Birth.
 - Immunizations not included in Reconciliation functionality within the receiving EHR though it was noted in a comment.
 - Adopted Care Plan template, which may be useful for representing a vaccination forecast.
- Transmission to Immunization Registries relies on v1.5 of the Implementation Guide with the associated July 2015 addendum. This is true as well for participants starting Stage 3 in 2017.
- Immunization data is now included in the Common Clinical Data Set, referencing both CVX and NDC codes as discussed above.
- Common Clinical Data Set continues to include patient sex but not sexual orientation or gender identity due to the immaturity of these standards.