**HL7 CQI Discussion on Medicare Physician Fee Schedule Proposed Rule-2014 Calendar Year**

|  |  | **Language from Proposed Rule-(Pages noted from Display version)** | **Comments** |
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| 1. 1   1. | **For PQRS Program**  **and**  **Direct data submission from EHR to CMS for EHR Incentive Program**  Comments sought on proposals to require EPs to use the most recent, updated version of an electronically specified clinical quality measure to report for PQRS and to use a direct EHR product or EHR data submission vendor that has been tested and certified to the most recent, updated version of the clinical quality measure’s electronic specifications for PQRS purposes. | (Page 323 – PQRS Program)  We [CMS] propose[s] that for purposes of PQRS, however, that the eligible professional’s direct EHR product or EHR data submission vendor must be tested and certified to the most recent, updated version of an electronically specified clinical quality measure.  For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the reporting of clinical quality measures from direct EHR products or EHR data submission vendors that have been tested and certified to versions of the electronic specifications that were updated and posted on June 2013. **We seek comment on our proposals to require eligible professionals to both use the most recent, updated version of an electronically specified clinical quality measure to report for PQRS and to use a direct EHR product or EHR data submission vendor that has been tested and certified to the most recent, updated version of the clinical quality measure’s electronic specifications for PQRS purposes.**    For PQRS EHR measures also reportable under EHR Incentive Program, EPs must report the most recent, updated version of a clinical quality measure. [eg, for PQRS reporting period 2014, CMS will only accept the reporting of clinical quality measures that are electronically specified using versions of the electronic specifications that were updated and posted on June 2013 on the EHR incentive program website]  (p. 430 – EHR Incentive Program)  In the EHR Incentive Program Stage 2 final rule, we finalized the CQMs from which EPs would report beginning in CY 2014 under the EHR Incentive Program (77 FR 54069, Table 8). These CQMs are electronically specified and updated routinely to account for issues such as changes in billing and diagnosis codes and changes in medical practices.  The requirements specified in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 allow for the reporting of different versions of the CQMs.  However, it is not technically feasible for CMS to accept data that is reported according to the specifications of the older versions of the CQMs, including versions that may be allowed for reporting under the EHR Incentive Program. We stated in the EHR Incentive Program Stage 2 final rule that, consistent with section 1848(o)(2)(B)(ii) of the Act, in the event that the Secretary does not have the capacity to receive CQM data electronically, EPs may continue to report CQM data through attestation (77 FR 54076). **Therefore, we propose that EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs.**  **Language included in the Stage 2 Final Rule from Sept 2012—follow up from 7/26/13 CQI discussion:**  Beginning in 2014 and in subsequent years, EPs, eligible hospitals and CAHs that are beyond their first year of meaningful use must electronically submit CQM data unless the Secretary lacks the capacity to accept electronic submission. In the unlikely event that the Secretary does not have the capacity to accept electronic submission, then consistent with sections 1848(o)(2)(B)(ii)and 1886(n)(3)(B)(ii) of the Act, we would continue to accept attestation as a method of reporting CQMs. We would inform the public of this fact by publishing a notice in the **Federal Register** and providing instructions on how CQM data should be submitted to us. | HL7 supports the proposal to require EPs to use the most recent version of the CQM specifications, including the most recent version of the value sets published in the Value Set Authority Center (VSAC), if EPs will submit data directly to CMS. Recognizing, however, that new releases of health care standards will be published in the near future, HL7 advises that these standards must be pilot tested before being applied to CQMs in a CMS final rule. HL7 cautions CMS that the adoption of new standards without the validity and feasibility of these standards in practice, will lead to failures and data inconsistencies. For example, HQMF R1, a known standard, has yet to be successfully implemented into an EHR, despite its widespread use. Furthermore, HQMF Release 2 will soon be published as a Draft Standard for Trial Use (DSTU) and may be considered for use to represent eCQMs as part of MU Stage 3. Through the work of the HL7 Clinical Quality Information (CQI) workgroup, members are developing recommendations for addressing the readiness of such standards for widespread use. As the release of HQMF R2 approaches, it is essential to establish clearly defined criteria for successful testing of this new standard. Documented success in the implementation of any new health standard should be the basis upon which CMS chooses to adopt new standards, such as HQMF R2, for use in quality measurement and incentive programs.  Finally, vendors and providers should be given adequate time, ideally 18 months, to implement the standards so that they are prepared for a successful transition to a new platform. HL7 strongly recommends that confirmation of reliability and success should be a requirement before any standard is adopted and included in a CMS final rule.  [Need HL7 CQI and EHR Workgroup feedback on: What specific suggestions can HL7 include in the comment letter ns on how “successful testing and implementation” are defined? Reference S&I recommendations on readiness?] |
| 1. 1   2. | **Reporting from Clinical Registries on the EHR Incentive Program** | (Page 428)  As EPs are required to use CEHRT under section 1848(o)(2)(A)(iii) of the Act, **we propose that for the Medicare EHR Incentive Program, an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part of the EP’s CEHRT**.  For example, if the registry would collect patient level data from EPs, calculate the CQMs, then submit to CMS the calculated results on behalf of the EP in either an aggregate level Quality Reporting Document Architecture (QRDA) Category III file or patient level QRDA-I files, then the registry would need to be certified for the CQM criteria listed at 45 CFR 170.314(c)(2) (“import and calculate”) for each CQM that will be submitted and 45 CFR 170.314(c)(3) (“electronic submission”).  We note that EPs would still need to include a certified EHR Module as part of their CEHRT that is certified to the CQM criteria listed at 45 CFR § 170.314(c)(1) (“capture and export”) for each of the CQMs that would be submitted to CMS for the purposes of meeting the CQM requirements of the Medicare EHR Incentive Program.  If the qualified clinical data registry is performing the function of data capture for the CQMs that would be submitted to CMS, then the registry would need to be certified to the “capture and export” criteria listed at 45 CFR 170.314(c)(1).  **The certified EHR Module must be part of the EP’s CEHRT. We intend to revisit the certification criteria with ONC in the Stage 3 rulemaking for the purpose of developing a more flexible clinical data registry reporting option and certification criteria for the EHR Incentive Program when Stage 3 begins. We welcome public comment and recommendations on a more flexible clinical data registry reporting option for meeting the CQM reporting requirement for MU and on the certification criteria that ONC could incorporate for clinical data registries.** | HL7 supports the proposal to require a clinical registry to be certified for the functionality it is intended to fulfill as well as the additional requirement to include an EHR module that is certified to the CQM criteria as part of the CEHRT. Furthermore, HL7 supports the notion that the standards in use for quality reporting from an EHR be applied to the requirements for quality reporting from a clinical data registry. An important consideration is that as EHR functionality and versions evolve, over time, the registry capabilities would need to keep up with these enhancements. For example, the CQM specification used for the clinical data registry should be consistent with the specification used for reporting from an EHR (ie, HQMF), and the reporting format for the clinical data registries and EHR technology should also use the same standards (ie, QRDA Category I or QRDA Category III). [Question for EHR workgroup: Are clinical registries referenced in the EHR-FM? What are the functions and specification standards for registries in the EHR-FM? Is the proposal from CMS for clinical registries to become a CEHRT module acceptable? How should HL7 articulate that the requirement that registries being used in place of EHR technology to report CQMs must be capable of capturing and submitting this information at the same level as the CEHRT? ]  HL7 strongly recommends that if CMS allows registries to serve as alternative reporting mechanisms to CEHRT, registries must be evaluated and certified in a similar manner to the way EHRs are evaluated. The criteria for acceptance need to be established and should be explicit. |