

July 14, 2014

**VIA ELECTRONIC SUBMISSION**

*Title: Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition*

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**Attention:** Karen DeSalvo, MD, MPH, MSc, National Coordinator for Health Information Technology  
Marilyn Tavenner, Acting Administrator, Centers for Medicare & Medicaid Services  
Sylvia Burwell, Secretary, Department of Health and Human Services

Dr. Karen DeSalvo and Ms. Tavenner,

On behalf of the Governor's Office of Electronic Health Information (GOEHI) in the Cabinet for Health and Family Services (CHFS) for the Commonwealth of Kentucky, we would like to respectfully submit to your office for consideration the attached comments, questions, concerns, and recommendations relating to the aforementioned Proposed Rule for the Medicare and Medicaid EHR Incentive Programs for 2014; and Health Information Technology revisions to the certified EHR technology definition.

The attached is a group effort aggregated from key stakeholders and Meaningful Use subject matter experts in Kentucky who have collaborated on this notice of proposed rulemaking, in the interest of facilitating the strategic initiative towards a fully interoperable and patient-centered electronic health information environment. These stakeholders include the following organizations:

- Kentucky Division of Medicaid Services (EHR Incentive Program)
- Kentucky Health Information Exchange / Cabinet for Health and Family Services
- Kentucky Regional Extension Center
- Health-Bridge and the Tri-State Regional Extension Center
- Northeast Kentucky Regional Health Information Organization

Please evaluate these collective comments with respect to your office's strategic vision of Meaningful Use and incorporate their influence in the revisions to the EHR Incentive Program. Thank you.

Sincerely,

Polly Mullins-Bentley

Kentucky Health I.T. Coordinator, Kentucky Health Information Exchange



## General Comments on 2014 Stage One and Two Meaningful Use Requirements

### Topic: Transitions of Care

Comments: The Transitions of Care objective requires the use of a health information service provider (HISP). To meet these requirements under the program rules for 2014, the certified EHR technology (CEHRT) must integrate with the HISP if not natively available via the EHR. KY recommends that the CMS temporarily suspends Measure 1-3 of transitions of care for Meaningful Use Stage 2.

Requirements around electronically sending a patient's records from one provider directly to another provider are flawed because it:

- a) Circumvents and undermines the HIE, by its usage by providers and patients, as well by the data aggregation for the benefits of public health.
- b) The receiving provider will focus more on the record received from the sending provider and NOT the comprehensive HIE record. The HIE record should have the same information from the sending provider as well as a wealth of information from other providers creating a more complete picture of the patient's medical history.

Despite the ability for eligible providers and hospitals to connect to various Direct Trust Accredited HISPs, the technical capabilities of the healthcare community at large are variable and complicate a potentially interoperable network. Because EPs and EHs are on different timelines for MU, providers are unable to send and receive messages because their community of care may not align with their technical and MU capabilities, thus proving to be a major gap in the objective.

Additionally, the newness of this technology requires more robust testing among distinct EHR vendors and distinct HISPs to ensure testing is successful and messages are received to the appropriate recipient. Several EHR vendors currently cannot receive CCDAs electronically inbound. Allowing different levels of certification and varying Meaningful Use Stages would reduce a providers' ability to send electronic messages to their community of care—thus adding an additional layer of complexity to the objective. In working with providers and CEHRT vendors across the state, we have recognized several issues with counting for measure 2. There are gaps in the certification standards across vendors as it relates to the requirements for the objective, thus creating problems with accurately counting an electronic transition of care for measure 2. This issue highlights the need for standardized certification among distinct vendors and clear and concise guidance on counting/reporting for meaningful use.

We feel that a good faith effort to connect with a HISP would allow providers to meet the measure, without a specific threshold tied to the electronic submission of CCDAs. KHIE recommends that the ONC develop a national provider directory with common standards for providers to obtain Direct addresses. Kentucky also recommends either an exclusion from this objective due to technical difficulties and moving it from a Core to a Menu objective, or suspending the objective including all of its measures.

### Topic: Patient Electronic Access and View, Download and Transmit

Comments: The HISP and vendor technology to support VDT continues to be in its early phases of development and testing. Because the technology is new and there are significant issues tied to the HISP and the EHR connection, KY recommends suspending VDT. If suspension is not possible, then allowing exclusion for VDT is the second option.

Requiring providers to adopt a patient portal for electronic access to information is not feasible for all providers and provider types. Patient portals are costly and require a large amount of resources to maintain. Often times providers purchase untethered or stand-alone personal health records that do not automatically connect to their EHR systems, which create difficulties with reporting meaningful use objectives and interfacing with their current systems. Kentucky feels the technology is growing and developing and thus the measures do not reflect the struggles that providers face with implementation and the integration of systems.

There is strong concern and opposition about holding a provider accountable for the actions of the patient outside of their control. This specifically refers to a patient accessing their record electronically. Providers have no way of controlling this, unless they compel the patient to view their record online. There are no guidelines or suggested education practices for patients accessing these records from a public computer (such as a public library computer). Patients should be made aware of safety and privacy issues surrounding the access of their health records and given general guidelines and instructions on where to save these documents and how to securely view these records in a public setting.

Kentucky also recognizes the difficulties that rural providers and patients face in accessing their health information electronically. Several patients, although may not fall under the VDT access exclusion, continue to face challenges with accessing their health information electronically. The geographical landscape of Kentucky, coupled with the disparate population lends itself to poor internet access faulty connections, thus creating barriers for the neediest patients to retrieve their health information.

Requiring providers to meet this objective has been made more challenging with the concurrent federal initiatives. We feel strongly that successfully implementing patient-engagement initiatives requires well-thought out workflows, processes and plans. Unfortunately, binding providers' success of Meaningful Use to patient engagement objectives does not allow providers enough time to integrate the patient's perspective well into their healthcare facility.

Kentucky recommends a suspension of VDT or broader and robust options for exclusions from the objective. Kentucky also recommends providing alternatives for expanded options to meet the requirement. Currently, political ramifications may be tied to applying for a hardship exemption. To offset this, Kentucky recommends that CMS offers alternative opportunities to meet this requirement outside of the VDT standard requirements.

#### Topic: Payment Adjustments

Comments: Any circumstances that are beyond the control of the provider, and where the provider has demonstrated an attempt to meet the MU requirements, should make the provider eligible for an exemption from any penalties or delays. We recommend that penalties/payment adjustments are delayed for an additional year until October 2015. A good faith effort at implementing a HISP for ToC and VDT, and providing patients electronic access to their health information should exempt a provider from payment adjustments.

## Comments on Proposed Changes to Meaningful Use Timeline and the Use of CEHRT

Reporting in 2014	<p>CMS is proposing to allow EPs, EH/CAHs that could not fully implement 2014 Edition CEHRT availability to continue to use 2011 Edition CEHRT for the EHR reporting periods in CY 2014 and FY 2014. These proposed alternatives are for providers that could not fully implement 2014 Edition CEHRT to meet MU for the duration of an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability. CMS is proposing this change for 2014 only and maintains the existing policy that all providers must use 2014 Edition CEHRT for the EHR reporting periods in CY 2015, FY 2015 and in subsequent years or until new certification requirements are adopted.</p> <p>Under Medicaid for 2014, providers must adopt, implement, or upgrade to 2014 Edition CEHRT only.</p>
Using 2011 Edition CEHRT only	<p>CMS is proposing that all EPs, EH/CAHs that use only 2011 Edition CEHRT for their EHR reporting period in 2014 must meet the MU objectives and associated measures for Stage 1 that were applicable for the 2013 payment year, regardless of their current stage.</p> <p>CMS will refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 that were applicable for 2013 as the “2013 Stage 1 objectives and measures,” and we will refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 that are applicable for 2014 as the “2014 Stage 1 objectives and measures.” Providers who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.</p>
Using a Combination of 2011 and 2014 Edition CEHRT	<p>CMS is proposing that all EPs, eligible hospitals, and CAHs using a combination of 2011 Edition CEHRT and 2014 Edition CEHRT for their EHR reporting period in 2014 may choose to meet the 2013 Stage 1 objectives and measures or the 2014 Stage 1 objectives and measures, or if they are scheduled to begin Stage 2 in 2014, they may choose to meet the Stage 2 objectives and associated measures under 42 CFR 495.6. Providers who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.</p>
Using 2014 Edition CEHRT for 2014 Stage	<p>Providers who are scheduled to begin Stage 2 for the 2014 EHR reporting period but are unable to fully implement all the functions of their 2014 Edition CEHRT required for Stage 2 objectives and measures due to delays in 2014 Edition CEHRT availability would</p>

<p>1 Objectives and Measures in 2014 for Providers Scheduled To Begin Stage 2</p>	<p>have the option of using 2014 Edition CEHRT to attest to the 2014 Stage 1 objectives and measures for the 2014 EHR reporting period. Providers who are scheduled to begin Stage 2 in 2014 who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures. Providers that were scheduled to begin Stage 2 in 2014 that instead meet the Stage 1 criteria in 2014 will be required to begin Stage 2 in 2015. All providers, except those in their first year of demonstrating meaningful use, are required to have a full year EHR reporting period. In addition, in 2015, all providers are required to have 2014 Edition CEHRT in order to successfully demonstrate meaningful use.</p>
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**Kentucky Comments:**

Kentucky urges CMS to define the phrase *fully implement* for all of the recommendations found within the NPRM stated above. If providers choose to attest that they are unable to fully implement 2014 Edition CEHRT because of delays, this is a major system change within the KY Medicaid EHR Incentive Program State Level Registry that would require developers to implement several provisions to the Medicaid attestation system, hence requiring additional time and resources. This begs the question, how would Medicare receive this information from Kentucky dual-eligible providers or Medicare only providers? Kentucky urges more clarification with specific details. If providers attest that they are unable to fully implement their CEHRT, what type(s) of documentation would be needed to verify the validity of the attestation? Kentucky recommends that the phrase *fully implemented* is clearly defined and proper guidance is distributed by the CMS and ONC with specific documents to support their attestation.

The technical difficulties and the variability of CEHRT Editions will also cause greater issues with interoperability, namely in regards to transitions of care/summary of care. The timing of the proposed rule in relation to last quarter attestations also creates great confusion as it affects providers’ reporting periods. Kentucky recommends delaying the onset of Stage 2 in order to allow providers to fully adopt certified technology and use it in a meaningful way.

Kentucky would also like greater clarification on providers that have adopted 2014 CEHRT and are live on the version. Would providers use 2014 Stage 1 objectives or Stage 2 objectives? This poses confusion with providers seeking to move forward with their attestations in 2014.

Kentucky providers have noted that the demand for certification of EHR systems far surpasses the supply of resources from the certifying bodies—largely due to the CCHIT removal from the ONC certification process. Providers have been held up for their upgrades/installations due to the overwhelming amount of work from certifying bodies such as Drummond, thus restricting providers from implementing their certified EHR technology and attesting to Meaningful Use. Additional clarification is needed for the 2015 optional certification as well. Because some providers have currently implemented 2014 technology, Kentucky recommends that Meaningful Use is pushed

back one year and begins in 2015. Kentucky also recommends that the 2015 MU reporting period would last 90 days and provides the option for providers to choose any three-month quarter for an EHR reporting period.

If the proposed rule is approved, the KHIE does not see a valid reason or business case for establishing interoperability with 2011 EHR vendors who have not yet developed public health reporting interfaces. For Kentucky, this represents 21 EHR vendors used by eligible professionals and hospitals throughout the state. Of the EHR vendors that are 2014 certified, many still have not developed the interfaces required for public health reporting.

Kentucky recommends that the option to attest to 2013 Program Rules be extended to include all EHR Incentive Program participants, including participants who adopt, implement, or upgrade certified technology, as well as participants who have 2014 certified software that do not contain all of the requisite components to support 2014 federal and state rules.

Kentucky recommends that under Medicaid in 2014, providers must adopt, implement, or upgrade to 2011 and/or 2014 Edition CEHRT systems. Allowing providers to utilize 2011 and 2014 systems in 2014 will cause less difficulty with attestation systems and public health reporting objectives, among others. Allowing providers to attest to MU with 2011 and 2014 software is inequitable for providers that AIU in 2014 and Kentucky feels that all providers should be held to the same standards across the board.

<p>Extension of Stage 2</p>	<p>CMS is proposing that Stage 3 would begin in CY 2017 for EPs and FY 2017 for eligible hospitals and CAHs that first became meaningful users in 2011 or 2012.</p> <p>This proposed change would allow EPs, eligible hospitals, and CAHs that first became meaningful users in 2011 or 2012 to begin Stage 3 on January 1, 2017 (EPs) and October 1, 2016 (eligible hospitals and CAHs).</p>
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**Kentucky Comments:**

Kentucky feels that Stage 2 should be pushed back one year, starting in 2015, and allows providers to forgo the attestation in 2014 without penalty. Kentucky also recommends that an exclusion and expanded hardship exemptions of the Meaningful Use program is needed until Stage 3. We recommend that providers continue to implement their certified technology, train their staff on meaningfully using the technology and develop workflows/processes to support the implementation plan within a reasonable timeframe. Under the proposed rule, although a reprieve is given to hospitals, we feel that providers will not be ready for Meaningful Use Stage 2. Kentucky also recommends that less changes or provisions be made to the Stage 3 objectives. The changes of technology and objectives from Stage 1 to Stage 2 were vast and created significant confusion among providers and vendors. In addition, the market and technological capabilities did not align with the objectives outlined in stage 2. Kentucky feels that a gradual increase of objectives/thresholds would more appropriately align with provider’s adoption rates and ability to implement CEHRT systems to use in a meaningful way moving forward.

Clinical Quality Measure Submission in 2014

The method of CQM submission under this proposal would depend on the edition of CEHRT a provider uses to record, calculate, and report its clinical quality measures for the selected EHR reporting period in 2014. If a provider elects to use only 2011 Edition CEHRT for its EHR reporting period in 2014, the provider would be required to report CQMs by attestation as follows:

EPs would report from the set of 44 measures and according to the reporting criteria finalized in the Stage 1 final rule (75 FR 44386 through 44411)—++Three core/alternate core;

++Three additional measures; and

++The reporting period would be any continuous 90 days within CY 2014 for EPs that are demonstrating meaningful use for the first time or a 3-month CY quarter for EPs that have previously demonstrated meaningful use.

Eligible hospitals and CAHs would report all 15 measures finalized in the Stage 1 final rule (75 FR 44411 through 44422). The reporting period would be any continuous 90 days within FY 2014 for hospitals that are demonstrating meaningful use for the first time or a 3-month FY quarter for hospitals that have previously demonstrated meaningful use.

If a provider elects to use a combination of 2011 Edition and 2014 Edition CEHRT and chooses to attest to the 2013 Stage 1 objectives and measures for its EHR reporting period in 2014, the provider would be required to report CQMs by attestation using the same measure sets and reporting criteria outlined earlier for providers who elect to use only 2011 Edition CEHRT for their EHR reporting periods in 2014.

Providers may attest to data for the CQMs derived exclusively from the 2011 Edition CEHRT for the portion of the reporting period in which 2011 Edition CEHRT was in place.

If a provider elects to use a combination of 2011 Edition and 2014 Edition CEHRT and chooses to attest to the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures, the provider would be required to submit CQMs in accordance with the requirements and policies established for clinical quality measure reporting for 2014 in the Stage 2 final rule and subsequent rulemakings.

A provider must submit CQMs in accordance with the requirements and policies established for 2014 in those rulemakings if the provider elects to use only 2014 Edition CEHRT for the entire duration of its EHR reporting period in 2014, regardless of the stage of meaningful use that the provider chooses to meet.

**Kentucky Comments:**

Kentucky feels there has been a lack of guidance on the topic of CQMs. As it states, for CQM reporting, providers must refer to their state policy, however, if providers do not have 2014 CEHRT they will be unable submit electronically. This is a challenge for the KY Medicaid EHR Incentive Program as it will require major website changes that will require both accepting electronic submissions and manual attestations. Additionally, several providers to date have had issues with generating a QRDA III file for CQM submissions. Several providers struggle with aligning CQM requirements with the inpatient quality reporting system as the specifications continue to change and thus presenting barriers to clinical data analytics.

<p>Revision to the CEHRT Definition for Additional Flexibility in 2014</p>	<p>ONC is proposing to revise the CEHRT definition to change certain Federal fiscal year (FY)/calendar year (CY) cutoffs in paragraphs (1) and (2) of the CEHRT definition under <a href="#">45 CFR 170.102</a>. These FY/CY cutoffs were finalized in ONC's 2014 Edition final rule.</p> <p>ONC is proposing to modify the CEHRT definition at 45 CFR 170.102 to replace the following</p> <ul style="list-style-type: none"> <li>• “2013” with “2014” in the first sentence of paragraph (1).</li> <li>• “FY and CY 2014” with “FY and CY 2015” in paragraph (1) (i) and (1) (iii).</li> <li>• “2014” with “2015” in the first sentence of paragraph (2).</li> </ul> <p>The revision will make the first day of FY 2015 (for eligible hospitals and CAHs) and CY 2015 (for eligible professionals) the new required start date for exclusive use of 2014 Edition certified Complete EHRs and EHR Modules to meet the CEHRT definition.</p>
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**Kentucky Comments:**

Kentucky encourages that the ONC reevaluate the certification tests that were performed and make improvements based on those tests. Specifically, KY has encountered issues with the manner in which EHR vendors were certified for incorporating the summary of care records.