



16758	<b>Proposed Measure 3:</b> Patient-generated health data or data from a non-clinical setting
16760	Common Clinical Data Set (CCD)
16760	Implantable Device List/Unique Device Identifier (UDI)
16772	EHR Technology Certification Requirements for Reporting of CQMs
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16775	*relative to the HITECH Act (not necessarily able to make headway by commenting on the CMS NPRM)

16779	F. The Medicaid EHR Incentive Program; 1. EHR Reporting Period for First Year of Meaningful Use
16793	Patient Volume Fraction
16807	ONC-ACB Requirements
N/A	CEHRT Definitions
N/A	General Comments
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**NPRM Wording in Question**

In addition, we propose changes to the EHR reporting period, timelines, and structure of the Medicare and Medicaid EHR Incentive Programs.

Simply proposing that paper-based formats would not be required or allowed .....for Stage 3 meaningful use.

Requirement in General

requesting public comment on definition of prescription

APIs may be enabled

Should the data require verification by an authorized provider?

Should the incorporation of the data be automated?

Should there be structured data elements available for this data as fields in an EHR?

Should the data be incorporated in the CEHRT with or without provider verification?

Should the provenance of the data be recorded in all cases and for all types of data?

We also seek comment on whether this proposed measure should have a denominator limited to patients with whom the provider has multiple encounters, such as unique patients seen by the provider two or more times during the EHR reporting period.

We also seek comment on whether this measure should be divided into two distinct measures. The first measure would include only the specific sub-category of patient-generated health data, or data generated predominantly through patient self-monitoring rather than by a provider. The second measure would include all other data from a non-clinical setting. This would result in the objective including four measures with providers having an option of which two measures to focus on for the EHR reporting period

Stage 3 includes requirements for specifications included in CCDS

We request comment on whether we have overlooked the need for or feasibility of requiring this functionality.

We specifically seek comment on this issue of a plan to increase the number of CQMs to which an EHR is certified.

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...exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years.

The 90-day reporting period

Patient Volume for Meaningful Use calculation

"...obtain a record of all adaptations and updates, including changes to user-facing aspects, made to certified health IT, on a monthly basis each calendar year..."

CEHRT Definitions

Reconciliation

Practice Policies

**Comments:**

The timeline in Stage 3 of one (1) business day for Clinical Summaries/Visit Summaries is very challenging for some providers to complete and sign their notes in a busy clinic. It should be at least 2 business days taking into account that some providers also perform surgeries/procedures and may be in surgery all day after a busy clinic the day prior and are unable to get to their clinic notes to complete within one business day.

We recommend that paper based formats still be allowed for objectives and measures. Our patient population may not have access to IT-based resources.

There would be significant development and cost burden for our organization to develop automated measure calculations that do not scale to a national government health-providing entity.

We recommend not using OTC medications as they do not have an NDC code and it would be hard to standardize.

We are not sure how this would impact our organization since we are the vendor of our own electronic health record. Would we be required to supply the thousands of APIs or agree to support connections from hundreds of other vendors?

This is dependent on the type of patient-generated health data, and it is recommended that this be evaluated by type of information, rather than putting all patient-generated health data into one category. For instance, in behavioral health settings, standardized patient self-report measures are commonly used, and these are data elements that are generated by the patient and responses are never changed or verified by the provider. The data being captured is understood as representing the patient's perspective, and is used as a patient report tool

This again depends on the type of patient-generated data being considered. To the extent that automation can streamline integration and usability, it is desirable. But, it can't be determined at the highest level of "non-clinical" or patient-generated. Specific classes of information need to be addressed based on their characteristics

There should be structured data elements available for this patient-generated health data as fields in an EHR.

This is dependent on the type of patient-generated health data being considered.

It may be more critical for some types of data; it is not recommended to combine all patient-generated and all "non-clinical" data into one category and set the same standards at the highest level. Standards need to be set at a level that is more descriptive of the type of data.

Patients with only a single encounter should be eliminated from this measure.

We support dividing this measure into two distinct measures. There may be significant variation in practice types as to whether they collaborate with “non-clinical” providers, which might influence how they meet this proposed measure

Stage 3 calls for the EP to incorporate an electronic summary of care document from a source OTHER than the provider's EHR. We are unclear what IT implications this would have on our EHR system.

The requirement to be able to capture, parse, and store UDI data is extremely important for the reasons mentioned in the document (most specifically, tracking and recall purposes). Secondly, as FDA moves toward applying the UDI concept to items not implanted and eventually to medications, this requirement will lay the groundwork for EHRs in the future to be able to capture, parse, store, transmit, and report the UDIs for anything that contains a UDI (including medication or device recalls).

The proposed increase in number of Clinical Quality Measures (CQMs) is extremely aggressive, especially for our organization that has an alternate, more organizationally appropriate, specific measures to build from which this work for CQMs would deter. Our organization has over 150 measures on its eQMs Priority Development List, compiled to meet the new core sets for 2015 for The Joint Commission In-Patient ORYX, the requirements for CMS Hospital Care reporting in the Choice Act, and for the migration of HEDIS measures from EPRP - new measures in response to new guidelines.

Additionally, rules surrounding Medicaid reporting CQMs does not scale to a national government, health-providing entity like ours that encompasses multiple states. We would appreciate the opportunity to discuss the VA eQMs with CMS.

The VA has part-time providers that treat non-Medicaid/Medicare patients in many facilities, yet these patients are included in the denominator of the overall patient volume fraction for purposes of calculating CMS incentives and penalties. We request that VA patients be removed from the denominator as these part-time providers are significantly impacted by their inability to receive CMS incentives. This in turn may cause a VA staffing and recruitment issue resulting in fewer providers willing to work part-time for the VA negatively impacting patient care by increasing wait time.

Though the "lack of control over the availability of CEHRT for EPs practicing in multiple locations" was finalized as a hardship exception in the Stage 2 final rule, and no changes are made to this exception in the NPRM for 2015, it is important to note sections 1848(a)(7)(B) of the HITECH Act provides that the Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment in CY 2015 and subsequent calendar years, "but in no case may an EP be granted an exception for more than 5 years".

The VA will have to pursue a greater avenue than an exception, given an exception cannot surpass 5 years, to protect its part-time providers if the VA does not provide a CEHRT to its part-time providers and it hinders them from reaching 50% use to demonstrate MU.



The first time reporting for ambulatory clinic and hospital providers/clinicians/non-clinical end-users requires a large adjustment and learning curve and is also a challenging time for the IT department to make necessary changes to meet these requirements and be able to create methods to pull decretit data if not already in place to report to CMS. There is a large amount of continual training and constant monitoring that is required for everyone involved. The 90-day continuous reporting period for the first reporting year will allow time for adjustments, improvements, training, and changes to be made to meet the numerous mandated requirements in a safe and efficient manner.

In an effort to remove the impact to the Department of Veteran Affairs (VA's) part-time providers, who while treating non-Medicaid/Medicare patients in the VA facilities, would be penalized for not reaching expected meaningful use calculations to receive their EHR incentive payments if VA patients were included in the denominator of the overall patient volume fraction. The VA requests the removal of said patients from the denominator of said calculation to ensure the part-time provider, a significant resource for the veteran and Veteran Affairs, a significant resource is encouraged to continue to provide services to VA.

There is a high impact of cost to our organization in use of tax dollars for monthly maintenance of a vendor in order to comply to this criteria. Additionally, it would require us to maintain a separate environment for compliance testing further increasing tax payer costs to comply with this requirement.

As a Federal, non-Medicaid/Medicare provider, the certification definitions provided by ONC and CMS do not fit the veteran healthcare-providing agency. VA seeks a certified EHR definition for the validation of a qualified EHR system, certified to interoperability features to support interaction between the VA and outside facilities. We request to have a certification for technical interoperable which excludes automated measures and clinical quality measures.

Despite the complexities around the difficulty of meeting the Stage 2 requirements for care summary exchange at transition of care and patient record sharing, the thresholds have been significantly increased. We are concerned in particular with the requirements to perform medication, allergy, and problem list reconciliation for 80% of TOCs and referrals.

Stage 3 adds structured and codified data elements that require information based on State and Federal Regs (e.g. in some states you cannot ask if guns are kept in the home, MU requires you ask how often a patient goes to church). We are not sure if our current federal regs opt us out of this or do we have to be able to collect from each state. We need to make sure this would not requie breaking any existing laws.