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"Meaningful Use" Rule: A Preliminary Analysis
Prepared by Manatt Health Solutions for athenahealth

On July 13, 2010, the Centers for Medicare and Medicaid Services (CMS) issued its final rule on the Electronic Health Record (EHR) Incentive Programs under Medicare and Medicaid, which were created by the Health Information Technology for Economic and Clinical Health Act (HITECH).[1] Beginning in 2011, the EHR Incentive Programs provide Medicare and Medicaid financial incentives for providers that engage in "meaningful use" of "certified EHR technology" and, beginning in 2015, impose Medicare payment penalties on providers that do not.[2]

In this final rule, CMS sticks with the framework it proposed in its December 30, 2009 notice of proposed rulemaking (NPRM), but makes some concessions that are intended make meaningful use more achievable for providers. CMS received over 2,000 comments on the NPRM, and much of the 864-page final rule is devoted to responding to these comments. Manatt Health Solutions offers the following reactions based on their review to date of this final rule:

- *No "Big Ideas."* A number of commenters had suggested "alternative pathways" to eligibility under the EHR Incentive Programs, such as through participation in a "qualified" health information exchange or by achieving meaningful use as a health system instead of on a hospital-by-hospital basis. CMS did not adopt any of these suggestions.

- *Only Stage 1 Criteria Addressed.* Consistent with the approach CMS took in the NPRM, CMS addresses only Stage 1 of meaningful use in this final rule. CMS envisions three stages of meaningful use—but plans to address the other two stages in future rulemaking. The lone exception is CMS's decision, discussed below, to adopt Stage 2 criteria for computerized provider order entry (CPOE). Many commenters voiced concern that providers needed additional guidance regarding future stages of meaningful use to make informed purchasing decisions. CMS rejected these comments, taking the position that "one of the greatest benefits of the phased stage approach is the ability to consider the impact and lessons of the prior stage when formulating a new stage."

- *More Flexible Approach to Achieving Meaningful Use.* CMS will allow providers to qualify as meaningful users without meeting each meaningful use measure.
    - In the NPRM, CMS proposed 25 meaningful use measures for eligible professionals (EP) and 23 for hospitals.
        - CMS was criticized for its proposed "all or nothing" approach, under which providers would have been required to satisfy each of the proposed meaningful use measures to be eligible for incentive payments.
    - In this final rule, CMS divides the measures into a "core set," all of which providers must satisfy, and a "menu set," out of which providers must satisfy only 5 out of 10 measures.
        - The "core set" has 15 measures for EPs and 14 measures for hospitals.
        - The "menu set" has 10 measures each for EPs and hospitals.
        - Providers must choose at least one measures from the "menu set" that is related to improving population and public health.
        - We have attached as Attachment 1 to this client advisory a table listing the "core set" and "menu set" of measures.
    - CMS chose not to adopt the two proposed meaningful use measures related to administrative transactions in either the "core set" or "menu set."

- *Reduced Thresholds For Meaningful Use Measures.* As was expected by many stakeholders, CMS lowered the bar for several meaningful use measures.
    - For example, in this final rule, CMS is requiring EPs to engage in e-prescribing for 40 percent of prescriptions. CMS had originally proposed a 75-percent threshold.
    - CMS reduced the threshold for entering laboratory results into EHRs from 50 percent to 40 percent.
    - CMS drastically lowered the bar for reporting of clinical quality measures.

[1] HITECH was contained within the American Recovery and Reinvestment Act of 2009.
[2] The Office of the National Coordinator for Health Information Technology simultaneously issued a complementary final rule on standards for certified EHR technology. This advisory does not address this other final rule, but Manatt will be preparing a summary of the standards and certification final rule.

        - EPs will be required to report only 3 core quality measures and choose an additional 3 measures from a set of 38. CMS had proposed that EPs report on a core set of 3 clinical quality measures, plus an additional set of clinical quality measures based on the EP's specialty.
        - CMS reduced from 43 to 15 the number of clinical quality measures that hospitals need to report.

- *"Outside In" Approach to HIE.* CMS's approach in the NPRM was criticized by some as limiting the long-term potential for robust health information exchange (HIE) by proposing an "outside in" framework based on establishing interoperable networks constructed by installing large numbers of stand-alone applications, such as EHRs, then incrementally encouraging HIE through proprietary, independent network services for such areas as laboratory results and e-prescribing. Some commenters suggested that an "inside out" approach would better foster HIE—such as by establishing an Internet-based system under which CMS and ONC would establish a set of protocols that everyone has to implement, thereby ensuring that anyone who "connects" achieves interoperability with everyone else. With such a set of protocols in place, these commenters argued that providers would be better able to reach outside of their own practice sites and connect with all other providers operating under the same protocols. In contrast, the "outside in" approach may have a tendency to entrench point-to-point communications within independent networks. However, in this final rule, CMS finalizes the "outside in" approach that it proposed.

- *Role of States.* CMS took a number of steps that will likely limit the role of states in defining meaningful use.
    - CMS finalized its proposal to deem a hospital to be a meaningful user for Medicaid purposes if it meets the Medicare meaningful use criteria.
    - CMS restricted the ability of state Medicaid agencies to adopt additional meaningful use criteria. Under this final rule, states will be permitted to adopt only four specific additional meaningful use measures identified by CMS. All four are related to reporting to public health agencies and data registries.
        - Furthermore, CMS makes clear that states cannot require participation in state HIEs as a meaningful use measure.
    - States will not be allowed to require reporting of Medicaid-specific quality measures. CMS had proposed a list of such Medicaid-specific measures, but chose not to adopt the list in this final rule.
    - States will not be allowed to make incentive payments prior to January 2011. In the NPRM, CMS had proposed to give states the option to implement their Medicaid incentive programs in 2010.

- *Changes to CPOE.* Despite protests from commenters, CMS went forward with its proposal to require CPOE in Stage 1 of meaningful use—and included CPOE in the "core set" of measures.
    - In the NPRM, CMS had proposed CPOE thresholds of 80 percent for EPs and 10 percent for hospitals. Many commenters argued that CPOE tends to be the last EHR functionality implemented into provider workflows for both hospitals and EPs. These commenters took the position that CPOE should be deferred to a future stage.
    - In this final rule, CMS reduced the CPOE threshold for EPs to 30 percent, raised the threshold for hospitals to 30 percent.
        - However, only medication orders will count toward the measurement; CMS had originally proposed to include orders for laboratory tests and diagnostic imaging as well.
        - In addition, emergency room services will be included in the hospital measurement. CMS had originally proposed to base the hospital CPOE measure solely on inpatient services. Many commenters recommended expanding the measure to the emergency room as well as inpatient services because hospitals tend to implement CPOE in the emergency room setting before the inpatient setting. CMS agreed with these commenters and adopted their recommendation.
    - CMS will require a 60 percent CPOE threshold in Stage 2. Notably, this is the only Stage 2 measure that CMS addresses in this final rule.

- *Revised Definition of Hospital-Based.* In response to legislation passed subsequent to CMS's issuance of the NPRM, CMS revised the definition of hospital-based EPs so that services EPs furnish in hospital outpatient departments will not qualify as hospital-based. Under HITECH, hospital-based EPs are not eligible to participate in the EHR Incentive Programs. CMS had originally proposed to define hospital-based EPs as EPs who furnish substantially all of their services in inpatient, emergency room, and provider-based outpatient settings because the definition of hospital-based under HITECH, as originally enacted, referred to "inpatient or outpatient" services. However, the Continuing Extension Act of 2010, enacted on April 15, 2010, amended HITECH to eliminate references to hospital outpatient settings. Accordingly, in this final rule, CMS defines hospital-based EPs as EPs who furnish substantially all of their services in inpatient or emergency room settings.
    - Surprisingly, as discussed below, this change to the definition of hospital-based, which would be expected to allow many more EPs to participate in the EHR Incentive Programs, does not appear to have increased CMS's estimate of federal outlays under the program.

- *No Relief for Multi-Campus Hospitals.* CMS finalizes its proposal to define a hospital based on its provider number. Health systems that operate multiple distinct hospitals under a single provider number had argued that each distinct hospital should be separately eligible for EHR incentives, but CMS rejected these arguments.

- *Mixed Results For Non-IPPS Hospitals.*
    - Under the NPRM, only hospitals paid under the Medicare Inpatient Prospective Payment System (IPPS) and critical access hospitals (CAH) would have been eligible for Medicare incentives, and only IPPS hospitals, cancer hospitals, and children's hospitals would be eligible for Medicaid incentives. Some commenters argued that other hospital types—such as long-term care hospitals and inpatient rehabilitation facilities—should be eligible for incentives, and that CAHs should be eligible for Medicaid incentives.
    - Under the final rule, CAHs will be eligible for Medicaid incentives, but CMS declined to make any other changes to the hospital types eligible for participation.

- *Little Change In Impact Analysis.* Despite narrowing the definition of "hospital-based" and lowering the bar for meaningful use, CMS's assessment of the impact of the final rule is strikingly similar to its impact analysis in the NPRM.
    - In the "regulatory impact analysis" in this final rule, CMS estimates total net federal outlays for the EHR Incentive Programs to be between $9.7 and $27.4 billion. CMS projects that, by 2015, between 66.4 and 92.6 percent of hospitals and 21 and 53 percent of EPs will be meaningful users under the Medicare program.
    - In the NPRM, CMS estimated a range of net federal outlays between $14.1 and $27.3 billion. By 2015, between 77.8 and 93.6 percent of hospitals and 21 and 53 percent of EPs were projected to be meaningful users under the Medicare program.
    - Based on our review to date, it is unclear why the changes CMS adopted in this final rule did not increase, even marginally, the estimated federal outlays and program participation.

The final rule is available online at: http://www.ofr.gov/OFRUpload/OFRData/2010-17207_PI.pdf.

Appendix 1: Final Meaningful Use Measures

CORE SET			
Health Outcomes Policy Priority	Stage 1 Objectives		Stage 1 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
Improving quality, safety, efficiency, and reducing health disparities	Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE
	Implement drug-drug and drug-allergy interaction checks	Implement drug-drug and drug-allergy interaction checks	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period
	Generate and transmit permissible prescriptions electronically (eRx)		More than 40% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology
	Record demographics o preferred language o gender o race o ethnicity o date of birth	Record demographics o preferred language o gender o race o ethnicity o date of birth o date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data
	Maintain an up-to-date problem list of current and active diagnoses	Maintain an up-to-date problem list of current and active diagnoses	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data
	Maintain active medication list	Maintain active medication list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data
	Maintain active medication allergy list	Maintain active medication allergy list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data
	Record and chart changes in vital signs: o Height	Record and chart changes in vital signs: o Height	For more than 50% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's or

	o Weight o Blood pressure o Calculate and display BMI o Plot and display growth charts for children 2-20 years, including BMI	o Weight o Blood pressure o Calculate and display BMI o Plot and display growth charts for children 2-20 years, including BMI	CAH's inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structured data
	Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	More than 50% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data
	Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance that rule	Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule	Implement one clinical decision support rule
	Report ambulatory clinical quality measures to CMS or the States	Report hospital clinical quality measures to CMS or the States	For 2011, provide aggregate numerator, denominator, and exclusions through attestation as discussed in section II(A)(3) of this final rule
			For 2012, electronically submit the clinical quality measures as discussed in section II(A)(3) of this final rule

Engage patients and families in their health care	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days
		Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request	More than 50% of all patients who are discharged from an eligible hospital or CAH's inpatient department or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it
	Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients for more than 50% of all office visits within 3 business days
Improve care coordination	Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information
Ensure adequate privacy and security protections for personal health information	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process

MENU SET			
Health Outcomes Policy Priority	**Stage 1 Objectives**		**Stage 1 Measures**
	Eligible Professionals	**Eligible Hospitals and CAHs**	
Improving quality, safety, efficiency, and reducing health disparities	Implement drug-formulary checks	Implement drug-formulary checks	The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period
		Record advance directives for patients 65 years old or older	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) have an indication of an advance directive status recorded
	Incorporate clinical lab-test results into certified EHR technology as structured data	Incorporate clinical lab-test results into certified EHR technology as structured data	More than 40% of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition
	Send reminders to patients per patient preference for preventive/ follow up care		More than 20% of all unique patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period
Engage patients and families in their health care	Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP		More than 10% of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold

			certain information
	Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	More than 10% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources
Improve care coordination	The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)
	The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals
Improve population and public health	Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)
		Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)

	Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice	Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)