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Making Meaningful Use Meaningful: The Final Meaningful Use Regulations And The Hazards Of Viewing Them In Isolation

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On July 13, 2010, the Centers for Medicare and Medicaid Services (CMS) pursuant to the American Recovery and Reinvestment Act of 2009 (ARRA) released the much-anticipated Final Rule for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (the Meaningful Use Final Rule). Simultaneously, the Office of the National Coordinator for Health Information Technology (ONCHIT) pursuant to the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) released its Final Rule on the initial standards, implementation specifications, and certification criteria for EHR and health information technology (HIT) (the Certification Criteria Final Rule). These two Final Rules establish what criteria and technical standards constitute the meaningful use of EHR technology required for a provider to be eligible for incentive payments.

Providers and HIT vendors will no doubt be inundated by interpretations of the criteria eligible professionals (EPs), eligible hospitals (EHs), and Critical Access Hospitals (CAHs) must meet in order to qualify for incentive payments. Filtering through this noise will be imperative—the Final Rules alone are over 1000 pages combined and CMS received over 2,400 comments on the proposed and interim rules.

Following the initial release of the rules on January 13, 2010, there was overwhelming pessimism throughout the healthcare industry regarding the achievement of meaningful use. A recent survey found that 80% of hospital chief information officers were concerned or very concerned about meeting meaningful use requirements, and 33% were concerned or very concerned that even the vendors are not ready for meaningful use.[1] The good news is that the Final Rules are more forgiving than the proposed rules. While the bar has

been lowered, even once-skeptical providers and vendors should nonetheless view meaningful use as a means to other ends rather than an end itself.

Below is a summary of the major requirements of the Final Rules including the criteria required to achieve meaningful use and relevant timelines, the incentive payments under the Medicare Fee-For Service (FFS) incentive program,[2] and the initial set of meaningful use EHR technology certification criteria. This is followed by a discussion of the role achieving meaningful use may play as an opportunity for a provider to position itself to successfully address an uncertain future in the healthcare industry. The question now presented to providers is not whether to seek meaningful use, but at what pace it should implement EHR and how to leverage meaningful use certification in dealing with other strategic goals.

What the Final Rules Say

The Meaningful Use Final Rule creates incentives under the Medicare FFS, Medicare Advantage (MA), and Medicaid programs for EPs, EHs, and CAHs to adopt and demonstrate meaningful use of certified EHR technology starting in 2011,[3] and includes payment adjustments under the Medicare FFS and MA programs for EPs, EHs, and CAHs who fail to adopt and demonstrate meaningful use after 2015. The three incentive programs while separate and distinct contain many common elements, particularly related to demonstrating the achievement of meaningful use.

The most significant change from the proposed rule is CMS' retreat from the all-or-nothing approach under the meaningful use criteria requirements.[4] In the Meaningful Use Final Rule, CMS requires that providers meet a core set of criteria, and then gives providers the ability to select certain other "menu" criteria to qualify for meaningful use.

The Meaningful Use Criteria and Incentive Timeline

According to HITECH, an EP or EH is considered a "meaningful user" of EHR if, during the specified reporting period, it:

1. Demonstrates use of certified EHR technology in a meaningful manner;
2. Demonstrates that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information in order to improve the quality of healthcare, such as promoting care coordination; *and*
3. Uses certified EHR technology to submit information to CMS on specified clinical quality measures and other measures.

To that end, CMS stood by its proposed phased-in, three-stage approach to implement the requirements for a provider to demonstrate meaningful use. While the Meaningful Use Final Rule includes the criteria for Stage 1, CMS has not yet proposed criteria for Stages 2

and 3. Although, CMS expects to update the meaningful use criteria on a biennial basis, with the Stage 2 criteria being released by the end of 2011 and the Stage 3 criteria being released by the end of 2013. The following table outlines how CMS anticipates applying the stages of meaningful use criteria in the first years of the program:

First Payment Year[5]	Criteria Required by Payment Year				
	2011	**2012**	**2013**	**2014**	**2015**
2011	Stage 1	Stage 1	Stage 2	Stage 2	TBD
2012		Stage 1	Stage 1	Stage 2	TBD
2013			Stage 1	Stage 1	TBD
2014				Stage 1	TBD

Importantly, after reviewing the comments received in response to the proposed rule, CMS lessened the burden on EPs, EHs, and CAHs seeking to establish meaningful use by requiring a core set of only 14 criteria objectives for EHs/CAHs and 15 criteria objectives for EPs (reduced from 23 for EHs/CAHs and 25 for EPs in the proposed rule) and a "menu" of 10 criteria objectives with associated measures of which providers are required to meet five of their choosing. CMS also lessened the measurement requirements associated with meeting the criteria objectives for several of the individual criteria. A quick reference guide to the Stage 1 criteria is available here.

CMS also simplified the rules for quality reporting. EPs will have to report data on three core quality measures in 2011 and 2012: blood-pressure level, tobacco use status, and adult weight screening and follow-up. There are alternate quality measures for providers to which the above quality measures do not apply: weight assessment and counseling for children, influenza immunization, and childhood immunization status. Notably, to meet the meaningful use requirements, EPs need only report the required clinical quality measures—they need not satisfy a minimum value for any of the clinical quality measures. Additionally, EPs also must choose three other measures from a list of 38 that it is able to incorporate into its EHRs. Similarly, by payment year 2011-2012, EHs and CAHs will be required to report on each of 15 clinical quality measures that are included in the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU).[6] Again, for EHs and CAHs, the report must only be made and a minimum value need not be satisfied initially.

For payment year 2011, a provider need only *attest* to the particulars relating to each quality measure. However, starting in payment year 2012, in addition to meeting requirements for meaningful use, Medicare EPs, EHs, and CAHs will be required to

electronically submit clinical quality measure results (numerators, denominators, exclusions) as calculated by certified EHR technology.

In the first payment year only, an EP or EH need only satisfy the Stage 1 criteria for any continuous 90-day period during the payment year in order to qualify for an incentive payment. After the initial payment year, however, the EP or EH must meet all of the Stage 1 criteria for the entire payment year. There also should be consideration given to meeting more than the minimum Stage 1 meaningful use criteria from the outset, as CMS has indicated that all Stage 1 criteria objectives, including all "menu" set objectives will likely be a required in later stages.

Basics of Meaningful Use Medicare FFS Incentive Payments - EPs

Under the Medicare FFS Incentive Program:

- Qualifying EPs[7] are entitled to receive incentives for up to five years, with payments beginning as early as 2011.
- No incentives will be paid after 2016.
- Incentive payments will be equal to 75% of Medicare allowable charges for covered professional services furnished by the EP in a payment year, subject to the incentive payment maximums.
- The aggregate maximum amount of total incentive payments that an EP can receive under the Medicare FFS incentive program is $44,000.
- If the EP "predominantly furnishes" (i.e., over 50% of professional services) services in a Health Professional Shortage Area (HPSA), the maximum annual incentive amounts are increased by 10%.
- EPs who become meaningful users after 2014 will not be eligible to receive incentive payments.

The following table shows the maximum incentive payment amounts available to EPs in a non-HPSA each year under the Medicare FFS incentive program:

Meaningful Use Established	EP Medicare Incentive Payment						
	2011	2012	2013	2014	2015	2016	Total
2011	$18,000	$12,000	$8,000	$4,000	$2000	0	$44,000
2012		$18,000	$12,000	$8,000	$4,000	$2,000	$44,000
2013			$15,000	$12,000	$8,000	$4,000	$39,000
2014				$12,000	$8,000	$4,000	$24,000
2015					0	0	0

Beginning in 2015, if an EP has not established meaningful use, the Medicare physician fee schedule amount for covered professional services furnished by the EP during the

year will be reduced by applying a sliding scale percentage reduction to the fee schedule amount that would otherwise apply. For 2015, an EP who does not meet the meaningful use requirements would receive only 99% of the Medicare fee schedule amount (or if the EP is also not a successful e-prescriber 98%); (ii) for 2016, only 98%; and (iii) for 2017 and beyond, only 97%.

Incentive payments under the Medicare FFS incentive program will be made in a single, consolidated annual payment through Medicare Administrative Contractors (MAC) or carriers. Incentive payments will be made on a rolling basis, such that as soon as the MAC ascertains that an EP successfully demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), incentive payments will be made. The incentive payments will be made to the Tax Identification Number (TIN) provided by the EP. For EPs associated with more than one practice, CMS requires that the EP select only one TIN to receive applicable EHR incentive payments. EPs are allowed to reassign incentive payments to an employer or an entity with which they have a valid employment agreement or contract providing for such reassignment.

Unlike EHs, which may participate in both the Medicare FFS and the Medicaid Incentive Programs, EPs may participate in only one program. CMS has proposed to allow each EP to designate its program of choice and to allow the EP to change its designation one time before 2014.

Basics of Meaningful Use Medicare FFS Incentive Payments - EHs[8]

Under the Medicare FFS incentive program:

- A qualifying EH[9] may receive incentive payments for up to four years, beginning October 2010.
- Fiscal year 2015 is the last year for which an EH can begin receiving incentive payments for meaningful use
- An EH can qualify to receive payments from both the Medicare and Medicaid EHR incentive programs
- Incentive payments for EHs are calculated based on the provider number used for cost reporting purposes, which is the CMS Certification Number (CCN) of the main provider (also referred to as OSCAR number).[10]

In determining incentive payment amounts, CMS has proposed that an EH's incentive payment be based on the hospital's Medicare Part A and MA inpatient bed days, total inpatient bed days, and charges for charity care, in accordance with the following formula:

Incentive Amount = [Initial Amount] x [Medicare Share] x [Transition Factor]

- Initial Amount = $2 million, + [$200 per inpatient for discharges between 1,150 and 23,000]
- Medicare Share = [M/(T*C)]
    - M = [# of Inpatient Bed Days for Part A Beneficiaries] + [# of Inpatient Bed Days for MA Beneficiaries]
    - T = [# of Total Inpatient Bed Days]
    - C = [Total Charges — Charges for Charity Care[11]]/[Total Charges]

The following table shows the applicable transition factors depending upon the year that an EH first qualifies for a Medicare FFS incentive payment:

Fiscal Year	Transition Factor by Fiscal Year That EH First Receives Incentive Payment				
	2011	**2012**	**2013**	**2014**	**2015**
2011	1.00				
2012	.75	1.00			
2013	.50	.75	1.00		
2014	.25	.50	.75	.75	
2015		.25	.50	.50	.50
2016			.25	.25	.25

CMS will determine incentive payments at the time of settling the 12-month cost report for the EH's fiscal year after the beginning of the payment year. The data used will be based on the hospital discharge and other data from that cost reporting period report once the hospital has qualified for meaningful use. Fiscal Intermediaries (FIs)/MACs will calculate incentive payments for qualifying EHs, and will disburse such payments on an interim basis once the EH has demonstrated meaningful use for the EHR reporting period.

Like EPs, EHs that do not meet the meaningful use requirements by 2015 and beyond will be subject to penalties in the form of reductions in Inpatient Prospective Payment System payments. EHs that do not meet the meaningful use requirements will incur 1/4, 1/2, and 3/4 reductions of their market basket updates in FY 2015, FY 2016, and FY 2017 and subsequent years, respectively. CAHs have a separate incentive calculation that can be explained upon request.

CMS also will conduct selected compliance reviews of EPs, EHs, and qualified CAHs who register for the incentive programs and who are recipients of incentive payments for the meaningful use of certified EHR technology.

The Certification Criteria of EHR Technology

In conjunction with the release of the Meaningful Use Final Rule, ONCHIT released the Certification Criteria Final Rule, which details the standards, implementation specifications, and certification criteria for EHR technology required for the Incentive Program's first stage (Certification Criteria). The modifications made by ONCHIT to the Certification Criteria Final Rule focused mainly on enhancing the clarity of the Interim Final Rule published on January 13, 2010. Providers, but especially vendors, will be pleased to hear that the general requirements, standards, and capabilities of certified EHR technology remain largely unaltered.

The Certification Criteria Final Rule lists the minimum capabilities EHR technology will be required to demonstrate in order to receive certification, which is required for a provider to meet the meaningful use requirements and thus receive incentive payments under the Meaningful Use Final Rule.

The Certification Criteria represent the floor of the EHR technology's capabilities required for the Incentive Programs; the minimum requirements that EHR technology must meet in order to achieve certification. It is not, however, intended to act as a limit on the use of additional functionality or capabilities of EHR technology generally. In fact, providers are encouraged, and in some ways expected, to innovate. Throughout the Certification Criteria Final Rule, ONCHIT highlights the fact that providers will aid in the development of future standards—that through the cooperative learning experiences among CMS, ONCHIT, providers, and vendors, "more meaningful" use will be the final result.

It is important to note that the Certification Criteria Final Rule is not intended to specify the conditions under which adopted Certification Criteria *must be used*. Instead, it specifies the minimum functionality an EHR *must demonstrate to attain certification*. Certifiable EHR technology need only be capable of demonstrating the ability to comply with the Certification Criteria. Given this, a provider may still use alternative standards or processes not contemplated by the Certification Criteria. For example, providers are required to submit lab results to public health agencies via HL7 version 2.5.1, but a provider could use a later released standard internally so long as it retains the ability to make submissions to public health authorities via the prescribed standard. It is, therefore, beyond the scope of the Certification Criteria Final Rule to mandate when, and to what extent, the capabilities of a certifiable EHR are used. ONCHIT anticipates that other regulatory rules, as well as the clinical and business needs of providers, will dictate when and how certified EHR technology's capabilities are used.

Under the Certification Criteria Final Rule, as was the case with the Interim Final Rule, certification of EHR technology can be approached in one of two ways: certification of

EHR technology as a "Complete EHR" that meets all of the required Certification Criteria or as an "EHR Module" that specifically addresses at least one certification criterion under the rule but less than all of them. EHR technology, therefore, can be certified to meet meaningful use *either* as a single Complete EHR *or* as a combination of certified EHR Modules addressing all of the individual Certification Criteria. A provider applying for the incentive payments need only show use of either Complete EHR or EHR Modules that, as a whole, satisfy all of the Certification Criteria.

This use of alternative methods throughout the Certification Criteria Final Rule was integrated throughout the Certification Criteria by ONCHIT to ensure a flexible approach. This was done to allow for greater use of healthcare information currently housed within informational silos—silos currently inaccessible across providers. The proposed goals of the Certification Criteria focus on capturing healthcare information electronically in a unified format. This will allow for healthcare information to be used for tracking key clinical decisions for care coordination purposes amongst providers, clinical decision support for individual patients, and the reporting of metrics for clinical quality measures that support and inform broader public health. The key health-related information required to support those goals requires that EHR technology include patient demographic and clinical health information such as allergies, medical history, and problem lists and has the capacity to:

- Provide clinical decision support to providers;
- Support computerized provider order entry;
- Capture, organize, and display information relevant to the provision of healthcare; and
- Exchange electronic health information with, and integrate such information from, both vertically and horizontally, other providers.

ONCHIT contemplates an evolving list of standards for continued compliance going forward. Alterations and updates for subsequent stages (Stages 2 and 3) will be released on a biennial basis with intermediate "Optional Criteria" in the years between (which are expected to foreshadow coming changes in each biennial release). On the horizon, then, will be a series of Optional Criteria preceding each new mandatory Stage. This phased-in approach is designed, and should provide, a vehicle for ongoing dialog between providers, vendors, and the healthcare community-at-large with ONCHIT on the topic of the meaningful use of Certified EHR Technology.

Beyond Meaningful Use—Leveraging the Meaningful Use Investment to Address a Changing Healthcare Industry

For many providers, achieving meaningful use will not be cheap or easy. However, providers should avoid simply comparing the raw incentive payments against the costs and time needed to achieve meaningful use in deciding how to approach the Final Rules.

Because certification will create a de facto industry standard, meaningful use will be a regulatory requirement or practical prerequisite across virtually all future developments in the healthcare industry. The same qualities that allow an HIT system to qualify for meaningful use can be leveraged in other government pilot projects, private payor initiatives, or hospital-physician alignment objectives. Whether a provider is tackling its strategic goals in reimbursement, infrastructure, operations, or alignment, a well-planned achievement of meaningful use will put it in a positional advantage.

For example, take the role meaningful use will play in the future of reimbursement models. The following are some of the new sources of revenue in which meaningful use, particularly its interoperability requirements, will play an integral part in fulfilling regulatory or private payor mandates: Accountable Care Organizations (ACOs) and other shared savings models; Medical Homes; Pay for Performance reporting; Regulatory Auditing; or other new incentive structures (e.g., new forms of bundling).

For all providers—even for the early-adopter providers for which achieving meaningful use was always a top priority—the issue then becomes how to strategically select a vendor and implement an HIT system that not only meets the various requirements of meaningful use, but also positions the provider to adapt to the new and unknown endeavors to come. Achieving meaningful use, therefore, presents providers with an opportunity to proactively navigate an uncertain future for the industry, but a shortsighted approach to achieving meaningful use could place a provider at a significant disadvantage in the ability to adapt to a changing marketplace.

The decisions facing providers are not as simple as selecting an HIT vendor. The approach to meaningful use will impact the future position of the provider in its dealings with regulators, private payors, and other providers.

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[1] PricewaterhouseCoopers Health Research Institute, *Ready or not: On the road to meaningful use of IHRs and health IT*, June 2010, *available at* http://www.pwc.com/us/en/....

[2] The authors intend to provide a follow-up analysis of the Medicaid and Medicare Advantage incentive programs.

[3] The first payment year for EPs is any calendar year (CY) beginning with CY 2011 and for EHs and CAHs is any fiscal year (FY) beginning with 2011.

[4] To view a summary of the initial proposed meaningful use rule, *Achieving "Meaningful Use" of Electronic Health Records: An Update from the Polsinelli Shughart Health Care Group*, Feb. 2010, click here.

[5] For purposes of incentive payments made to EHs, CMS defines a payment year and year of payment as "any fiscal year beginning with 2011." For EPs, CMS defines a payment year as "any calendar year beginning with 2011."

[6] The 15 RHQDAPU measures are: admitted patients' median time from emergency department (ED) arrival to ED departure; admission decision time to ED departure time for admitted patients; ischemic stroke patients prescribed antithrombotic therapy at hospital discharge; ischemic stroke – anticoagulation for a-fib/flutter; ischemic stroke – thrombolytic therapy for patients arriving within 2 hours of symptom onset; ischemic or hemorrhagic stroke – antithrombotic therapy by day 2; ischemic stroke – discharge on statins; ischemic or hemorrhagic stroke – stroke education; ischemic or hemorrhagic stroke – rehabilitation assessment; VTE prophylaxis within 24 hours of arrival; intensive care unit VTE prophylaxis; anticoagulation overlap therapy; platelet monitoring on unfractionated heparin; VTE discharge instructions; and incidence of potentially preventable VTE.

[7] Under the Meaningful Use Final Rule, hospital-based EPs are not eligible to receive the Medicare incentive payments. A hospital-based EP is an EP who furnishes 90% or more of his or her allowed services in a hospital inpatient or emergency department settings, including all settings that meet the definition of the main provider, department of a provider, or having a provider-based status.

[8] While not fully addressed here, the authors intend to provide further information on the incentive programs for CAHs in future analyses.

[9] A hospital eligible for the Medicare FFS incentive payments is a hospital paid under the hospital inpatient prospective payment system (IPPS) and that is located in one of the 50 states or the District of Columbia. Eligible hospitals do not include psychiatric, rehabilitation, long term care, children's or cancer hospitals, which are excluded from the IPPS.

[10] Of note, since the release of the Meaningful Use Final Rule, a bill with bipartisan support has already been introduced in the House and Senate to clarify that incentive payments are calculated based on each qualified hospital that is part of a multi-campus hospital system and not the hospital system as a whole. *See* HLW, vol. 8, no. 30 (Aug. 6, 2010) and HLW, vol. 8 no. 31 (Aug. 13, 2010).

[11] In performing this calculation, CMS will use charity care charges reported on line 20 of the pending final OMB approved Worksheet S-10. If data on charity care is not available, then the Secretary would use data on uncompensated care as a proxy. If the proxy data is not also available, then "C" would be equal to 1.