To: State of Missouri
Department of Social Services

From: Manatt Health Solutions

Subj.: CMS and ONC Rulemakings on EHR Incentive Programs

Date: January 19, 2010

On December 30, 2009, the Centers for Medicare & Medicaid Services (CMS) released its notice of proposed rulemaking on "meaningful use" of certified electronic health records (EHR NPRM) and the Office of the National Coordinator for Health Information Technology (ONC) released its complementary interim final rule on standards and certification criteria for certified EHR technology (Standards IFC).

The memorandum provides two types of information:

- A commentary on policy implications of the new rules, and
- A more detailed analysis of the rules' regulatory texts and preambles.

TABLE OF CONTENTS

POLICY COMMENTARY 1

DETAILED ANALYSIS

Part 1 Deploying Technological Tools to Achieve "Meaningful Use"

A. Basic Framework. 9
B. Stage 1 "Meaningful Use" Criteria 11
C. HIT Functionality Measures 11
D. Clinical Quality Measures 15
E Medicaid-Specific "Meaningful Use" Measures 19
F. Demonstrating "Meaningful Use" 19

Part 2 Why "Meaningful Use" Matters: ARRA Financial Incentives

A. Incentives for Hospitals 21
B. Incentives for Eligible Professionals 25
C. Issues Particular to Medicaid 29
D. Online Posting of "Meaningful Users" 31

Part 3 Identifying Technological Tools: ONC's Standards IFC

A. Key Definitions 32
B. Adopted Standards, Certification Criteria, and Implementation Specifications 33

APPENDICES

Appendix A — New Clinical Quality Measures Proposed for "Meaningful Use" A-1

Appendix B — Measure Group: Core for All EPs, Medicare or Medicaid A-6

Appendix C — Specialty Measures A-7

Appendix D — Proposed Clinical Quality Measures for Electronic Submission by Eligible Hospitals for Payment Year 2011-2012 ..... A-38

Appendix E — Proposed Alternative Medicaid Clinical Quality Measures for Medicaid Eligible Hospitals A-44

Appendix F — Certification Criteria A-46

Appendix G — Adopted Content Exchange and Vocabulary Standards A-58

Appendix H — Adopted Privacy and Security Standards A-61

Policy Commentary

CONTEXT

The American Recovery and Reinvestment Act of 2009 (ARRA or "the statute"), signed into law last February, set in motion the first significant federal health care funding opportunity for health information technology (Health IT). ARRA established the EHR Incentive Programs, which offer Medicare and Medicaid financial incentives for providers that adopt and engage in "meaningful use" of "certified EHR technology" (and impose reimbursement penalties on providers that do not). CMS estimates that the Medicare and Medicaid incentive programs will result in an aggregate $14.1 billion - $27.3 billion in net federal expenditures,[1] but the level of actual federal disbursements will hinge on what "meaningful use" means and how many providers can achieve it.

On December 30 the government took a significant step toward answering this question by setting forth comprehensive proposals that govern the distribution of ARRA "meaningful use" dollars. CMS acknowledges the complexities and challenges of defining "meaningful use." The agency's proposals exhibit flexibility on at least some key issues, such as by deferring deadlines for achieving "meaningful use" in the first payment year and by allowing providers to qualify for incentives under a more fluid "adoption year" approach. While open to comments on the rule as a whole, CMS identifies many individual issues on which it particularly seeks stakeholder input.

Comments on both rules are due March 15.[2] The Standards IFC rule takes effect February 12 (though, based on comments, ONC could make changes later), while "meaningful use" requirements become effective 60 days after publication of a final rule (CMS says it expects to publish such a rule "after March 2010").

OVERALL CONCLUSIONS

CMS's proposed "meaningful use" requirements risk being too much and too little:

- **Too Much.** The "meaningful use" rule overestimates the ability of current systems to support providers as they seek to integrate ambitious new EHR capabilities into their clinical routines and daily workflows. The rule makes overly aggressive assumptions—more aggressive than those of the federal HIT Policy Committee—about the EHR utilization and exchange thresholds that providers will actually be able to meet.

- **Too Little.** The rule underestimates the potential for new forms of health information exchange (HIE), instead acquiescing in the continued use of brittle and costly point-to-point interfaces. These interfaces are likely to saddle providers with mounting integration costs as "meaningful use" requirements become more stringent. As such, the rule misses a huge opportunity to advance broad-based, publically spirited health information exchange initiatives to share health information to support patient care, and instead chooses to support today's largely broken health information paradigm, which is dominated by proprietary networks, technological incumbents with large installed bases, and seemingly insurmountable barriers to achieving genuine interoperability.

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[1] This estimate is contained in CMS's regulatory impact analysis on the "meaningful use" proposed rule. The estimated range is substantially less than the $44.7 billion CMS previously assumed in its ARRA implementation plan.

[2] The rules will be published in the *Federal Register* on January 13, which will mark the start of the 60-day comment periods.

In all, the rule's approach proceeds from a worldview about how EHR and HIE markets can, will, and should develop—a worldview that, in key areas, places bets that many may view as questionable.

POLICY IMPLICATIONS OF "MEANINGFUL USE": THE BASIC TERMINOLOGY

The EHR NPRM relies on its own specialized vocabulary. Here are the key terms:

1. **Certified EHR:** *The item of technology that an Eligible Professional (EP) or Eligible Hospital (EH) must meaningfully use in order to qualify for financial incentives (and avoid reimbursement penalties).*

   - Context: ONC, in its Standards IFC, specifies certification criteria to which an EHR must conform in order to be the base tool EPs and EHs need to potentially qualify as a "meaningful user."

   - Specifics: To be eligible for certification, an EHR must include certain patient demographic and clinical information and must have the capacity to carry out specified functions. A separate ONC regulation will address the selection of certifying bodies and the process they will use to apply the criteria to EHRs.

2. **Stages 1-3:** *Three graduated stages for implementing "meaningful use" and EHR certification requirements.*

   - Context: The EHR NPRM addresses only Stage 1 requirements. Separate rulemakings will address the requirements for Stage 2 and Stage 3.

   - Specifics: Stage 1 requirements focus on use of certified EHR technology, both to electronically capture health information in coded format and to submit quality measures information to CMS. Electronic submission of quality measures information is not proposed for 2011, but CMS says it plans to require such electronic submissions for 2012 and subsequent years.

3. **Objective:** *The Objectives an EP or EH must meet to be a "meaningful user."*

   - Context: An Objective represents a relatively broad aspiration that, standing alone, is susceptible to different interpretations as to whether it is achieved.

   - Specifics: The EHR NPRM contemplates a multiyear framework in which Objectives become progressively more exacting as the program moves through Stages 1 through 3. CMS's current proposed rule specifies Objectives for Stage 1 alone, but subsequent rulemakings will specify Objectives for Stages 2 and 3. Some Objectives are identical for EPs and EHs, while others differ.

4. **Measure:** *The benchmark against which an EP or EH demonstrates that an Objective is met.*

   - Context: A Measure is intended to be concrete enough to demonstrate an Objective's achievement (or not).

   - Specifics: Under the EHR NPRM, each Objective has a corresponding Measure. To be a "meaningful user," EPs and EHs must use a certified EHR to satisfy all Objectives and all Measures.

POLICY IMPLICATIONS OF "MEANINGFUL USE": THE BASIC ARCHITECTURE

The EHR NPRM runs over 550 pages, but at its core is an architecture that flows from a handful of key assumptions. One such assumption—termed by CMS "a significant departure" from the HIT Policy Committee's recommendations—is that "meaningful use" Objectives and Measures should be more tightly linked. To forge this tighter linkage, the proposed rule puts in place, in effect, three categories of Measures, each with markings that suggest longer-term CMS policy motivations:

1. **Category: Functional Measures That Rely Solely on Capabilities Included as Part of Certified EHR Technology**

   - Description: "Meaningful use" Measures in this first category place substantial reliance on the inherent capabilities of the certified EHR itself (as specified in accord with ONC's criteria). Under the EHR NPRM, providers can achieve some of these Measures with relatively little effort; an EP or EH need only enable the relevant EHR capability. For other Measures, the provider must use the capability and quantify this use. For all the Measures in this category, CMS assumes that there is not a reliance on the electronic exchange of information.

   - Example: For the Stage 1 Objective, "Maintain Active Medication List," CMS sets as the corresponding Measure the following:

     > At least 80 percent of all unique patients seen by the eligible professional or admitted by the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded in structured data.

     Other Stage 1 Measures with similar use/quantification requirements include those pertaining to computer order entry, problem lists, active medication allergy lists, recorded demographics, and recorded and charted vital signs.

   - Manatt Commentary: Measures that reflect these kinds of EHR use/quantification requirements assume that providers can (in CMS's words) "continuously utilize" EHR capabilities and make them "part of the daily work process." Consistent with these assumptions, the EHR NPRM requires high thresholds for utilization of certain EHR functionalities. Indeed, for each of the ten Objectives that CMS cites as relying "solely on a capability included as part of certified EHR technology," the required utilization threshold for the associated Measure is 80 percent. Thus, as one example, a provider would be required to use certified EHR technology to perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care. Though CMS views 80-percent thresholds as representing reasonable progress toward full compliance, while still allowing sufficient flexibility to accommodate technical and other hindrances, the bottom-line result is that providers will not reach these "meaningful use" levels without significant changes in existing workflows and development of internal compliance programs.

2. **Category: Functional Measures That Require Health Information Exchange**

   - Description: Measures in this category contemplate a provider's use of certified EHR technology to effect the electronic exchange of information from third-party data sources.

- Examples: For the Stage 1 Objective, "Incorporate Clinical Lab-Test Results into EHR as Structured Data," the corresponding Measure is the following:

  > At least 50 percent of all clinical laboratory results ordered by the eligible professional or by an authorized provider of the eligible hospital . . . whose results are in either . . . a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

  Other Stage 1 Measures with similar information exchange requirements include those pertaining to e-prescribing and insurance eligibility and claims. The proposed rule also requires providers to conduct isolated, one-time tests of an EHR's capability to exchange clinical and certain other types of information, such as problem lists, medication lists, allergies and diagnostic test results among providers of care and patient-authorized entities electronically.

- Manatt Commentary: Most of the Measures in this category have very high exchange thresholds (75% - 80%) that are out of line with the current state of practice. For example, in 2008, the overall rate of prescriptions routed electronically, as a percentage of prescriptions eligible for electronic routing, was 6.6 percent.[3] Such data stand in jarring contrast to the rulemaking's assumptions for the level of exchange possible in the current market:

  - *For Prescriptions*: "While this Measure does rely on the electronic exchange of information based on public input previously discussed and our own experiences with e-Rx programs, we believe this is the most robust exchange currently occurring and propose 75% as an achievable threshold for Stage 1 criteria of meaningful use."

  - *For Laboratories*: "We are cognizant that in most areas of the country the infrastructure necessary to support such exchange is still being developed. Therefore, we believe that 80 percent is too high a threshold for Stage 1 criteria of meaningful use. We propose 50 percent as the threshold based on our discussions with EHR vendors, current EHR users and laboratories."

  The effect of such high Stage 1 thresholds appears to be to encourage the establishment of multiple, expensive point-to-point connections to the large laboratory chains and e-prescribing hubs. It can be anticipated from the design of this new rule that EHR vendors will seek to create proprietary interfaces that connect themselves, their customers, and the sources of lab and pharmacy information. Moreover, as providers experience every day, it can be further anticipated that the integration costs of these initiatives will be passed on to the provider in a combination of up-front fees and ongoing transaction fees. From a provider and policy point of view, the evolution of networks in this fashion is likely to create a wholly unaffordable, illiquid information infrastructure that ultimately works against our shared goals of care coordination, quality improvement, and cost-efficiency.

  While it is true that there is nothing in the proposed rule that prevents regional or state-based HIE initiatives from creating a lower cost, more far-reaching, more equitable platform for exchanging pharmacy and lab data, the success of these early public-private exchange efforts is likely to be significantly impeded by the market confusion created as a result of competing private initiatives, the goals of which largely relate to increasing profitability of data suppliers and control over information by data recipients. As such, the EHR NPRM perpetuates a world of information silos, providing incentives to adopt current systems, which, once adopted, will be

[3] SureScripts. National Progress Report on E-Prescribing. 2008.

difficult to dislodge because of the substantial investments required to standardize interfaces and install other system upgrades.

Effects of these misplaced incentives will become starkly evident if Stages 2 and 3 encompass broader HIE requirements, such as clinical decision support (CDS) systems that require integration of laboratory results with medication history and other sources of information. The technology in which providers invested for Stage 1 will likely be incompatible with such later-year requirements, leaving as the only practical alternative custom development and integration at the point of the EHR itself—the point where provider costs are high and system-wide leverage low.

3. **Category: Quality Measures Based on Reporting of Clinical Information**

- Description: For the final category of "meaningful use" Measures, CMS proposes to require reporting of information on measures of clinical quality (though not electronically before 2012). Many of these clinical quality measures, but not all, are included in Medicare's physician and inpatient hospital quality reporting programs. For "meaningful use" purposes, an EP must report a core set of clinical quality measures, as well as (to the extent applicable) a specialty-specific set of measures. EPs and EHs are required to report on Measures for all patients, not just Medicare and Medicaid beneficiaries.

- Example: An EH must report its "[o]verall inpatient 30-day hospital readmission rate."

- Manatt Commentary: The Stage 1 requirement that measures be reported for all patients, not just Medicare and Medicaid beneficiaries, may be challenging for those providers that have tailored their reporting systems to the quality and pay-for-performance requirements of individual payers. For measures not part of existing reporting regimes, data may need to be gathered manually–a disadvantage that could accrue, disproportionately and paradoxically, to hospitals that have already made substantial investments in inpatient EHR systems.

  Beyond problematic Stage 1 requirements, straws in the wind make quality reporting a worrisome area for the future. It is a relatively short step to go from a requirement to report an experiential result to a requirement to achieve a care outcome. Thus, a Stage 1 requirement for reporting a hospital's 30-day readmission rate (the example above) is not so far removed from demonstrating a "10% reduction in 30-day readmission rate"—an actual HIT Policy Committee recommendation for Stage 2.

  The proposed rule provides indications that clinical quality measures could be used to enforce a vision of the future health care system. For example, while the statute states that an EP or EH must use certified EHR "to submit . . . information . . . on such quality measures and such other measures" as CMS may select, the EHR NPRM proposes to define "clinical quality measures" to mean:

  > Measures of processes, experience, and/or *outcomes* of patient care, observations or treatment that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable and timely care. (Emphasis ours.)

  Language like this suggests that Stages 2 and 3 will nudge "meaningful use" more clearly toward health care outcomes.

POLICY IMPLICATIONS OF "MEANINGFUL USE": KEY CROSS-CUTTING THEMES

Cutting across the EHR NPRM are a number of important policy themes:

1. **Tepid Support for Forward-Looking HIE**

   The problematic assumptions underlying "meaningful use" Measures that rely on HIE (discussed above) are symptomatic of a broader policy misjudgment—one that represents a sin of omission. By refraining from adopting a more focused vision of how the HIE market should develop and evolve, the rule makes possible too many technological futures and gives a leg up to the status quo—a fractured system that has confounded interoperability and fueled communications, knowledge, and care-delivery gaps.

   For example, CMS accords state and regional HIE efforts a degree of recognition that is no more than lukewarm. To be sure, the proposed regulation qualifies organizations that support HIE for targeted Medicaid-related incentives for promoting certified EHRs and, in so doing, cites their ability to "reduce the need for costly point-to-point interfaces between different EHR tools" and provide "a more scalable model of health information exchange." But these advantages having been duly noted, CMS then proceeds to make possible, even encourage, a future marked by non-scalable, point-to-point interfaces.

   CMS's approach can be characterized as "working from the outside in": attempting to create HIE based on interoperable networks constructed by installing large numbers of stand-alone applications, such as EHRs, at the "outside," then slowly moving "in," toward the network, initially via proprietary, independent network services for such areas as laboratory results and e-prescribing. The assumption is that these independent networks will, over time, gracefully integrate and become interoperable, causing HIE to thrive. The broad thread of experience has generally supported the opposite view, from mobile phone networks (recall the need for regulation to enable consumers to keep their phone number when switching providers) to early online services (such as the initial AOL and Prodigy services) to other examples of history's technological cul-de-sacs.

   In contrast, Internet-based systems can be characterized as "working from the inside out": specifying a small, precise set of protocols that ***everyone*** has to implement, thereby ensuring that anyone who "connects" achieves interoperability with everyone else. If the agency focused on the critical protocols and conditioned "meaningful use" on ***all providers*** implementing them, then, by definition, we would leapfrog the silos of the past and make all EHRs interoperable.

   In sum, CMS's ultimate goals are admirable, but the agency would have a stronger, more forward-looking proposal if it placed clearer policy support behind an open, Internet-based architecture that reflects appropriate federal, state, and regional roles.

2. **Mixed Message on Clinical Decision Support (CDS)**

   At first blush, the proposed regulation provides a strong signal for the use of CDS tools. For Stage 1, CMS proposes "implementing CDS tools to facilitate disease and medication management." While the HIT Policy Committee recommended that providers implement only one clinical decision support rule, the EHR NPRM calls for implementation of five rules.

   Viewed in another light, however, the signals are less clear. First, there is a lack of specificity about which of the hundreds of decision support rules EPs and EHs should choose. Second, the proposed regulation suggests an overly narrow approach to the nature of decision support itself. Because CMS defines CDS as "HIT functionality that builds upon the foundation of an EHR," some may interpret

decision support functions to be limited to data available from a single point of care. While some certified EHRs include clinical decision support functionality, that functionality is limited if it doesn't access information from a broad array of providers involved in a patient's care. Current EHRs are not built to exchange data with other provider EHR systems unless connected through an HIE. Consequently, they are not able to incorporate data from multiple sources (e.g., claims, laboratory data, patient-supplied data, or disease management system) and have relatively unsophisticated clinical logic capabilities. The net result is that they have relatively limited CDS capabilities with relatively high false positive messaging rates.

3. **Limitation on Who Can Play**

CMS proposes to interpret narrowly the definitions of qualifying EHs and EPs, as established by ARRA. The most obvious example is CMS's proposal regarding "hospital-based" physicians, which, under ARRA, are excluded from the EHR incentives. Many stakeholders have argued that only physicians who provide support for hospital services, such as pathologists and radiologists, should qualify as "hospital-based," while physicians who perform services in outpatient departments that could just as easily be furnished in a physician's office, such as primary care doctors, should not be considered "hospital-based."

CMS, however, proposes that any physician who performs 90 percent of his or her services in a hospital inpatient or outpatient setting would qualify as "hospital-based," regardless of the type of services performed. This potentially will shut out broad swaths of primary care practitioners who practice in hospital-based outpatient clinics and members of faculty practice plans of academic medical centers.

Another example is the rule's proposed definition of EH for purposes of the Medicaid incentives. Although the statute states that "acute care" hospitals may qualify for incentives, CMS proposes to limit program participation to acute care hospitals with an average length of stay of 25 days or fewer. In effect, this would prohibit hospitals that are classified as long-term care hospitals under the Medicare program from receiving Medicaid incentives.

4. **Flexibility in Adoption Requirements**

CMS proposes that providers would progress through Stages 1 – 3 based on the payment year they begin "meaningful use," rather than imposing the same "meaningful use" standards on all providers in a given year. For example, an EP who begins "meaningful use" in 2011 would have to meet Stage 2 criteria in 2013, while an EP who adopts in payment year 2013 would not reach Stage 2 until 2014. Thus, late adopters would not face more stringent criteria in the first year of adoption than early adopters. However, CMS proposes to require that these late adopters progress more quickly through the stages, so that all providers would be in Stage 3 by 2015.

5. **Continued Emphasis on Patient Engagement**

The regulation maintains the HIT Policy Committee's emphasis on engaging patients and families in their health care and provides clarity regarding what will be considered "timely" access to patient health information. For example, CMS proposes that providers be required to send reminders to patients, per patient preference, for preventive/follow-up care, as well as proposing that patients be provided with an electronic copy of their health information within 48 hours after a request. Further, EPs would be required to provide patients with "timely" electronic access to health information (such as through a patient portal) within 96 hours after the information becomes available to the EP.

It is also important to note that for Stage 1, CMS proposes *not* to adopt the HIT Policy Committee's recommendation that providers furnish those under their care with patient-specific education resources. On the one hand, this can be viewed as inconsistent with empowering patients with relevant, actionable and culturally competent information regarding their condition. On the other hand, CMS's stated intention to ensure exploration of the issue for "future meaningful use" stages is a further indication that CMS recognizes patient engagement as a key pillar of managing quality and cost of care.

6. Relatively Little Say for States

The role of the states is significantly minimized in defining "meaningful use" for Medicaid purposes. The statute sets the Medicare definition of "meaningful use" as a floor, but authorizes states to establish additional criteria for the Medicaid EHR Incentive Program. Medicaid is a federal-state partnership, and states play prominent roles in supporting HIT adoption and HIE, as acknowledged by the considerable federal investment in statewide HIE planning.

The authority to articulate state priorities through "meaningful use" has been viewed as an important lever to encourage and advance statewide HIE. However, some stakeholders might view the scope and impact of this authority as significantly curtailed by CMS's proposed policy that state-specific "meaningful use" criteria apply solely to EPs and children's hospitals. Children's hospitals are a small subset of providers, and only a limited group of practitioners will qualify as EPs under the Medicaid EHR Incentive Program (because 30 percent of their caseload must be made up of Medicaid recipients to be eligible). Thus, this proposed policy sets the bar for "meaningful use" as the Medicare standard for the majority of providers eligible for incentive funds.

Detailed Analysis

Part 1: Deploying Technological Tools to Achieve "Meaningful Use"

A. Basic Framework

ARRA specifies three requirements for "meaningful use": 1) using certified EHR technology in a meaningful manner (which includes e-prescribing for EPs); 2) connecting a certified EHR in a manner that provides for the electronic exchange of health information to improve the quality of care; and 3) using the technology to submit to CMS information on clinical quality measures and other measures selected by CMS.

DEFINITIONS

To implement these core requirements, CMS proposes several fundamental definitions.

- Meaningful EHR User. An EP or EH who, for an EHR Reporting Period for a Payment Year, demonstrates "meaningful use" of a certified EHR technology in the form and manner consistent with CMS standards.

  These standards would take the form of a phased series of Objectives and Measures, as described more fully below.

- Payment Year. For EPs, any calendar year beginning with 2011. For EHs, any fiscal year (FY) beginning with 2011.

  The "first Payment Year" would mean the first calendar or federal FY for which an EP or EH, respectively, receives an incentive payment.

- EHR Reporting Period. For the first Payment Year only, CMS proposes to define "EHR Reporting Period" to mean any continuous 90-day period within a Payment Year in which an EP or EH successfully demonstrates "meaningful use" of certified EHR technology. EPs or EHs may choose to start their EHR Reporting Period on any date beginning with the first day of the Payment Year that allows for the 90-day period to be completed by the last day of the Payment Year. For the second Payment Year and all subsequent Payment Years, the EHR Reporting Period would be the entire Payment Year.

KEY CONCEPTS

Phased Approach to "Meaningful Use"
As discussed in the Executive Summary, CMS proposes a phased, incremental approach of adoption of certified EHR technology across three Stages. CMS describes these Stages as reflecting reasonable criteria based on currently available technology and provider practice experience that build over time into a more robust definition of "meaningful use," consistent with anticipated development of technology and health IT infrastructure. As discussed further below, in the EHR NPRM, CMS proposes specific Objectives and Measures only for Stage 1. CMS plans to establish Stage 2 and Stage 3 criteria through future rulemaking processes.

CMS describes each Stage as follows:

- Stage 1 "meaningful use" criteria focus on 1) capturing health information in a coded format, 2) using the information to track key clinical conditions, 3) communicating captured information for care coordination purposes, and 4) reporting of clinical quality measures and public health information.
- Stage 2 criteria would likely expand upon Stage 1 criteria in the areas of disease management, clinical decision support, medication management, support for patient access to their health information, transitions in care, quality measurement, research, and bidirectional communication with public health agencies. For Stage 2, CMS may also consider applying the criteria more broadly to both the inpatient and outpatient hospital settings. CMS expects to propose Stage 2 criteria by the end of 2011.
- Stage 3 criteria would likely focus on achieving improvements in quality, safety and efficiency, focusing on decision support for national high-priority conditions, patient access to self-management tools, access to comprehensive patient data, and improving population health outcomes. CMS expects to propose Stage 3 criteria by the end of 2013.

Payment Year v. Adoption Year
In order to account for differences in the current level of HIT adoption and implementation across providers and to encourage adoption and use of certified EHRs regardless of relative maturity of EHR technology and systems, CMS proposes to allow EPs and EHs to align specific Stages of "meaningful use" criteria to the year that they begin seeking incentive payments. This approach permits participants in their first Payment Year to meet only Stage 1 criteria in order to qualify for the incentive payments, thereby preventing increasingly strict criteria from discouraging late adopters' participation while rewarding providers who adopt EHRs early with a longer phase-in period to reach Stage 3 criteria. This approach also aims to bring all EPs and EHs to the same level of "meaningful use" by 2015.

The following table lays out the timeline for moving through the Stages, depending on the first Payment Year:

First Payment Year	**Payment Year**				
	2011	**2012**	**2013**	**2014**	****2015+**
2011	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3
2012		Stage 1	Stage 1	Stage 2	Stage 3
2013			Stage 1	Stage 2	Stage 3
2014				Stage 1	Stage 3
*2015+					Stage 3

* Avoids payment penalties only for EPs in the Medicare EHR Incentive Program.
** Stage 3 criteria of "meaningful use" or a subsequent update to the criteria if one is established through future rulemaking.

Under the EHR NPRM, Medicaid EPs, and EHs that qualify for an incentive payment for adopting, implementing, or upgrading EHRs in their first Payment Year would follow the same "meaningful use" progression described in the table above as if their second Payment Year were their first Payment Year. For example, if a Medicaid EP received an incentive for its first Payment Year in 2012 for adopting, implementing, or upgrading certified EHR technology, it would progress through the Stages of "meaningful use" as if its first Payment Year were 2013. Thus, the EP would be subject to Stage 1 requirements in 2013, Stage 2 requirements in 2014, and Stage 3 requirements in 2015.

Common Definition of "Meaningful Use" Under Medicare and Medicaid
As described more fully below, CMS proposes that the Medicare "meaningful use" criteria serve as a minimum standard, or floor, for the Medicaid program. States would be permitted, with CMS approval, to implement additional Objectives or amend existing Measures, provided that the state-proposed alternatives further promote the use of EHRs and do not require additional functionality beyond that required of certified EHR technology.

B. Stage 1 "Meaningful Use" Criteria

In proposing "meaningful use" requirements, CMS adopts the basic structure reflected in the recommendations of the HIT Policy Committee—the federal advisory committee tasked with making recommendations to the Secretary of the Department of Health & Human Services (HHS) regarding a definition for "meaningful use." This structure is composed of specific Objectives grouped under care goals, which are in turn grouped under health outcomes policy priorities.

CMS proposes that to qualify as a "meaningful EHR user" in 2011, an EP or EH must demonstrate that it meets all of the Objectives and their associated Measures set forth as Stage 1 criteria. For Stage 1, CMS proposes 25 Objectives and related Measures for EPs and 23 for EHs. CMS proposes that each Objective must be satisfied by an individual EP as determined by a unique National Provider Identifier (NPI) and an individual hospital as determined by a unique CMS certification number (CCN).

COMPARISON WITH HIT POLICY COMMITTEE RECOMMENDATIONS

With limited exceptions, CMS accepted the Objectives recommended by the HIT Policy Committee. CMS proposes not to adopt the HIT Policy Committee's recommendations to establish Objectives for "recording of advanced directives," "document a progress note for each encounter," and "provide access to patient-specific education resources upon request." In other instances, CMS accepted recommended Objectives with some modifications in order to make the Objectives more specific or stringent. For example, CMS proposes requiring implementation of five clinical decision support rules relevant to specialty or high clinical priority, while the HIT Policy Committee recommended only one clinical decision support rule.

While the Objectives generally follow HIT Policy Committee recommendations, the proposed Measures set forth by CMS represent a significant departure from the recommendations in that CMS proposes explicitly linking each Measure to an Objective.

The EHR NPRM groups Measures into two categories: HIT Functionality Measures and clinical quality measures.

C. HIT Functionality Measures

The HIT Functionality Measures proposed by CMS can be divided into three categories: 1) Measures that rely solely on capabilities included as part of certified EHR technology (i.e., do not require HIE), 2) Measures that require HIE, and 3) one security Measure.

1. **Measures That Rely Solely on Capabilities Included as Part of Certified EHR Technology**. A number of HIT functionality Measures require only that a functionality included as part of certified EHR technology be enabled and/or utilized in order to meet a Measure threshold, and do not require the electronic exchange of information.

1(a). *Measures That Rely Solely on Enabling a Feature of Certified EHR Technology*. The following proposed HIT Functionality Measures require only that functionality included as part of EHR be enabled:

Stage 1 Objectives		Stage 1 Measures
EPs	EHs	
Implement drug-drug, drug-allergy, drug-formulary checks	Implement drug-drug, drug-allergy, drug-formulary checks	The EP/EH has enabled this functionality
Implement five clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement five clinical decision support rules related to a high-priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement five clinical decision support rules relevant to the clinical quality metrics the EP/EH is responsible for reporting

1(b). *Measures That Require Incorporation of EHR Functionality Into the Provider's "Daily Work Process."*

Stage 1 Objectives		Stage 1 Measures
EPs	EHs	
Use CPOE	Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)	For EPs, CPOE is used for at least 80% of all orders For EHs, CPOE is used for 10% of all orders
Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of "none" recorded as structured data
Maintain active medication list	Maintain active medication list	At least 80% of all unique patients seen by the EP or admitted to the EH have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data
Maintain active medication allergy list	Maintain active medication allergy list	At least 80% of all unique patients seen by the EP or admitted to the EH have at least one entry (or an indication of "none" if the patient has no medication allergies) recorded as structured data
Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	At least 80% of all unique patients 13 years old or older seen by the EP or admitted to the EH have "smoking status" recorded

Stage 1 Objectives		Stage 1 Measures
EPs	EHs	
Record demographics: o preferred language o insurance type o gender o race o ethnicity o date of birth	Record demographics: o preferred language o insurance type o gender o race o ethnicity o date of birth o date and cause of death in the event of mortality	At least 80% of all unique patients seen by the EP or admitted to the EH have demographics recorded as structured data
Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for children 2-20 years, including BMI	Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for children 2-20 years, including BMI	For at least 80% of all unique patients aged 2 and over seen by the EP or admitted to the EH, record blood pressure and BMI; additionally plot growth chart for children aged 2-20
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate at least one report listing patients of the EP or EH with a specific condition
Send reminders to patients, per patient preference, for preventive/follow-up care	N/A	Reminder sent to at least 50% of all unique patients seen by the EP that are aged 50 or over
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request	At least 80% of all patients who request an electronic copy of their health information are provided with it within 48 hours
N/A	Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request	At least 80% of all patients who are discharged from an EH and who request an electronic copy of their discharge instructions and procedures are provided with it
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP	N/A	At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information
Provide clinical summaries for patients for each office visit	N/A	Clinical summaries are provided for at least 80% of all office visits
Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation for at least 80% of relevant encounters and transitions of care
Provide summary-of-care record for each transition of care and referral	Provide summary-of-care record for each transition of care and referral	Provide summary-of-care record for at least 80% of transitions of care and referrals

2. **Measures That Require HIE.** A number of proposed Objectives and associated Measures rely on the electronic exchange of information. These can be subdivided into two categories: 1) Measures that rely on the electronic exchange of information for which CMS assumes that adequate HIE exists to enable the attainment of specific performance Measure thresholds, and 2) Measures that rely on the electronic exchange of information for which CMS assumes that inadequate HIE infrastructure exists to support the attainment of specific Measure thresholds and for which testing is required.

2(a). *Measures That Rely On the Electronic Exchange of Information for Which CMS Assumes That Adequate HIE Infrastructure Exists.*

Stage 1 Objectives		Stage 1 Measures
EPs	EHs	
Generate and transmit permissible prescriptions electronically (eRx)	N/A	At least 75% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology
Incorporate clinical lab test results into EHR as structured data	Incorporate clinical lab test results into EHR as structured data	At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data
Check insurance eligibility electronically from public and private payers	Check insurance eligibility electronically from public and private payers	Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the EH
Submit claims electronically to public and private payers	Submit claims electronically to public and private payers	At least 80% of all claims filed electronically by the EP or the EH

2(b). *Measures That Rely On the Electronic Exchange of Information for Which CMS Assumes That Adequate HIE Infrastructure Does* ***Not*** *Exist.*

Stage 1 Objectives		Stage 1 Measures
EPs	EHs	
Capability to submit electronic data to immunization registries and actual submission where required and accepted	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Performed at least one test of a certified EHR technology's capacity to submit electronic data to immunization registries
Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Performed at least one test of a certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or EH submits such information have the capacity to receive the information electronically)

Stage 1 Objectives		Stage 1 Measures
EPs	EHs	
N/A	Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received	Performed at least one test of an EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which EH submits such information have the capacity to receive the information electronically)
Capability to exchange key clinical information (for example, problem list, medication list, 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, allergies, diagnostic test results), among providers of care and patient-authorized entities electronically	Performed at least one test of a certified EHR technology's capacity to electronically exchange key clinical information

3. **Security Measure.**

Stage 1 Objectives		Stage 1 Measures
EPs	EHs	
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 [under the HIPAA Security Rule] and implement security updates as necessary

Though CMS excludes the electronic exchange of structured information from many Stage 1 Objectives or proposes what it perceives to be "relatively low performance measure thresholds" for Measures that do rely on the electronic exchange of structured data, the agency says it plans to adjust its requirements as the capabilities of HIE infrastructure evolve. Specifically, the agency anticipates raising these low thresholds and redefining Objectives to include electronic data exchange in future rulemaking. For example, CMS says it specifically intends to require the electronic transmission of orders entered through CPOE for Stage 2 criteria.

D. Clinical Quality Measures

The third core requirement of "meaningful use" is that an EP or EH use certified EHR technology to submit information "on such clinical quality measures and such other measures" as CMS shall select. However, applicable statutory provisions specify that CMS is not permitted to require the electronic reporting of such information unless it "has the capacity to accept the information electronically."

CMS, in the EHR NPRM, invokes this latter provision, stating that the agency, for 2011, lacks the capacity to accept quality-related information electronically and thus, for this one year, requires EPs and EHs to use certified EHRs to capture data and calculate results, but, for submission, requires use of attestation. CMS also says that, for 2012, "meaningful use" will require electronic submission of quality measures information. Thus, CMS proposes substantially different Stage 1 approaches for 2011 and 2012.

KEY CONCEPTS

Definition of "Clinical Quality Measures"
CMS proposes to define "clinical quality measures" to mean "measures of processes, experience, and/or *outcomes of patient care, observations or treatment* that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable and timely care." (Emphasis supplied.)

> *Manatt Commentary: The definition's inclusion of "outcomes" could engender controversy among those stakeholders that believe that while the "meaningful use" statute permits CMS to require electronic submission of quality-related information, it does not permit the agency to require actual achievement of quality Objectives.*

Scope of Reporting
CMS proposes that EPs and EHs report information on specified quality measures for which they have applicable cases, as determined across all patients, not just Medicare and Medicaid beneficiaries.

> *Manatt Commentary: Implementing reporting for all patients may prove challenging for those providers that have tailored their reporting systems to the quality and pay-for-performance requirements of individual payers.*

Consistency Between Medicare and Medicaid
CMS notes that states may require reporting of clinical quality measures to demonstrate Medicaid "meaningful use." CMS proposes that quality measures adopted for purposes of Medicare also apply in Medicaid, though the agency identifies separate, alternative Medicaid measures for eligible hospitals with patient populations not reflective of the clinical characteristics represented by the Medicare measures.

Relationship to NQF Measures
The statute requires CMS, in selecting clinical quality measures, to give preference to measures endorsed by the National Quality Forum (NQF). However, the statute does not actually require use of NQF-endorsed measures, and in some instances CMS has selected non-NQF measures. Specifically, of the 90 Stage 1 measures that CMS proposes (described below), 79 are NQF-endorsed and 11 are not.

> *Manatt Commentary: For the 11 measures not endorsed by NQF —five applicable to EP services, six to services of EHs—there will be no consistent specifications for collecting clinical data, requiring providers to supply their own or CMS to provide further guidance.*

Relationship to PQRI, RHQDAPU Measures
The statute requires CMS to avoid the reporting of measures that is "redundant or duplicative" of reporting required under Medicare's Physician Quality Reporting Initiative (PQRI) or Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) programs. The statute does not limit actual measures selected to those included in PQRI and RHQDAPU.

In the EHR NPRM, CMS proposes to require that "meaningful EHR users" report a number of measures that also must be reported under PQRI, RHQDAPU, and other programs. CMS says it believes it complies with the statute's non-duplication requirements because the agency's goal—to be achieved "as soon as practicable"—is to require use of EHRs to consolidate the reporting of quality measures for purposes of PQRI, RHQDAPU, and "meaningful use." For 2012 the agency proposes that using certified EHR to report a given quality measure for "meaningful use" purposes satisfies any other quality-reporting requirements for this same measure.

Manatt Commentary: Despite the substantial overlap with PQRI and RHQDAPU measures, CMS's "meaningful use" proposals also contemplate reporting of information on several "new" measures—that is, measures that have neither been required nor actively considered in the PQRI or RHQDAPU programs. These "new" measures, depicted at Appendix A, hold particular significance, for they suggest emerging CMS policy priorities. Indeed, at least some of these measures, such as the non-risk-adjusted 30-day readmission rates for acute myocardial infarction (AMI), heart failure, or pneumonia, and the separate all-cause readmission index are likely to be controversial with providers. Non-risk-adjusted measures are difficult to interpret, and there would be numerous ways to define the all-cause readmission index.

Relationship to HHS and CMS Priorities
CMS proposes to apply several other criteria when selecting clinical quality measures. The agency proposes to consider measures that promote CMS and HHS priorities related to improved quality and efficiency of care, such as prevention, management of chronic conditions, high-cost and high-volume conditions, elimination of health disparities, healthcare-associated infections and other conditions, improved care coordination, improved efficiency, improved patient and family experience of care, improved end-of-life/palliative care, effective management of acute and chronic care episodes of care, and reduced unwarranted geographic variation in quality and efficiency.

CMS says it may also include measures that relate to known gaps in PQRI or that have been recommended by other committees under the Federal Advisory Committee Act, such as the HIT Policy Committee.

QUALITY MEASURES PROPOSED BY CMS

Proposed Stage 1 Measures for EPs
CMS proposes that for Stage 1, EPs submit information on two sets of quality measures—one set, designated "core," for which all EPs would make submissions, and another set to be selected by EPs themselves, based on specialty.

CMS proposes three core measures, and they pertain to tobacco use, blood pressure, and drugs to be avoided in the elderly. These measures are depicted at Appendix B.

In addition to submitting information on core measures, an EP would also make submissions on measures included in one of 15 specialty-designed sets. For example, an EP who is a cardiologist would submit information on the core measures, as well as on the measures in the set for cardiology.

Once an EP selected a specialty-specific measure group for 2011, the EP could not alter this choice for 2012. CMS acknowledges that some EPs' practices may not correspond to a specialty designation and indicates that for these EPs exemptions from reporting specialty-oriented measures will be available.

The specialty-specific sets of measures are depicted at Appendix C.

Proposed Stage 1 Measures for EHs
CMS proposes that for Stage 1, EHs submit information on a single set of quality measures, as depicted at Appendix D, though, as noted above, CMS proposes to permit Medicaid-eligible hospitals to submit information on an alternative set of quality measures for purposes of determining "meaningful use" under that program. This alternative set of measures is depicted at Appendix E.

Manatt Commentary: Many hospitals will be able to leverage reporting already developed and systematized for RHQDAPU compliance. However, many of the proposed CMS "meaningful use" measures, while endorsed by NQF or recognized by the Joint Commission, are not included in the RHQDAPU-required set. For these kinds of measures, EHs will need to do the reporting manually. Paradoxically, the need for manual reporting will be less disadvantageous for many EHs for ambulatory measures (where EHRs are less widely adopted, requiring manual submission anyway) than for inpatient measures (where manual submission will require a shift from more widely adopted but RHQDAPU-focused EHRs).

REPORTING AND IMPLEMENTATION

Payment Years 2011 and 2012

As noted above, CMS proposes to defer electronic reporting of information on quality measures until 2012. Consistent with such a deferral is the fact that of the 90 proposed Stage 1 clinical quality measures that CMS proposes, only 9 have the electronic reporting specifications needed for transmission through EHRs.

For 2012, CMS proposes to require electronic reporting, regardless of whether 2012 is a provider's first or second Payment Year. The agency acknowledges that the paucity of current measures with electronic reporting specifications means that, for 2012, the overall number of applicable measures (assuming a requirement of electronic submission) will decline.

To its plans for 2012, CMS adds this hedge: "[I]f the Secretary does not have the capacity to accept the information on clinical quality measures electronically in 2012 . . . we will continue to rely on an attestation method for reporting of clinical quality measures."

Key elements of CMS's 2011 through 2012 plan are the following:

- Measures for 2011 and 2012 become effective 60 days after publication of the final "meaningful use" rule. No additional 2011 or 2012 measures become effective, absent a new notice-and-comment rulemaking.
- As needed, CMS would make technical changes to the measures, such as revisions to the measures' detailed specifications. These changes would be made public through postings to CMS's website. There would be no comment opportunity.
- Posting of final specifications for all 2011 measures would be targeted for no later than April 1, 2010. For 2012 measures, the target date would be April 1, 2011.
- CMS would post, as they become available, electronic specifications for submitting information on measures for 2012.
- For 2012, EPs and EHs would use certified EHR technology to submit information electronically through one of three means: logging into a CMS-designated portal, submitting information through an HIE organization, or submitting information through "registries."

Manatt Commentary: A key question is whether CMS's final option would allow providers to leverage the clinical data already being reported to proprietary databases maintained by medical specialty societies.

Payment Years After 2012

CMS says that for years after 2012, it expects the number of measures for which electronic reporting will be required to "rapidly expand." The agency says it intends to consider additional measures from the 2010 PQRI program for use in both the Medicare and Medicaid EHR Incentive Programs. In addition, for Medicaid, CMS says it will consider clinical quality measures in the areas of pediatric care, long-term care, obstetrics, dental care/oral health, and mental health and substance abuse.

Manatt Commentary: CMS's initiatives are likely to spur and accelerate other efforts to identify EHR-based measures for "meaningful use." The HIT Policy Committee has made recommendations on measure topics for 2013 and 2015. In addition, in 2010, the NQF plans to endorse a "starter" set of EHR-based performance measures that reflect effective or "meaningful" use of HIT functions for measurement and improvement. More broadly, NQF is developing a set of HIT-sensitive criteria that could influence the future direction of measures selection.

E. Medicaid-Specific "Meaningful Use" Measures

ARRA specifies that states may base evaluation of Medicaid "meaningful use" on the Medicare "meaningful use" criteria established by CMS. However, the statute also specifically requires states to ensure that populations with unique needs, such as children, are appropriately addressed in Medicaid "meaningful use" criteria, though this requirement is not further explained. CMS does not provide additional detail or guidance concerning types of initiatives or considerations that would demonstrate state compliance with this requirement, though CMS does propose to require states to annually report on these efforts and provide quantitative data.

CMS proposes to allow the application of Medicare "meaningful use" criteria to Medicaid, but with the inclusion of alternative Medicaid-specific clinical quality measures for use by Medicaid hospitals. States are further explicitly permitted under the proposal to add elements to the Medicare "meaningful use" definition, though CMS prohibits additional Medicaid "meaningful use" criteria that would require additional EHR functionality, and the agency strongly discourages measures that require providers to assume additional financial burdens. Examples of CMS-suggested areas for state consideration include requirements for providers to participate in HIE and to establish links for immunization, lead screening, and newborn screening registries.

CMS has also proposed to deem any EH that satisfies the requirements for being a "meaningful EHR user" under the Medicare EHR program as a "meaningful EHR user" under the Medicaid EHR Incentive Program.

Manatt Commentary: In effect, this proposal exempts EHs from needing to meet state-specific "meaningful use" definitions and limits the application and impact of state-specific "meaningful use" criteria.

F. Demonstrating "Meaningful Use"

DEMONSTRATION BY ATTESTATION

CMS proposes that for Payment Year 2011, EPs and EHs would demonstrate that they satisfy each of the proposed "meaningful use" Objectives and Measures through attestation. For Payment Years beginning in CY and FY 2012, CMS proposes that EPs and EHs directly submit clinical quality measures to CMS (or to the states for those professionals participating in the Medicaid EHR Incentive Program) through certified EHR technology, but continue to attest to meeting all other Measures.

Specifically, CMS proposes that EPs and EHs provide attestation through a secure mechanism, such as through claims-based reporting or an online portal. Under the EHR NPRM, an EP or EH (through a one-time attestation performed following the completion of the EHR Reporting Period for a given Payment Year) would identify the certified EHR technology they are using and the results of their performance on all the Measures associated with the Objectives for "meaningful use."

CMS said it based its choice of attestation as a method for demonstrating Stage 1 criteria on a current lack of ability to allow for more automated and/or documented options for demonstrating "meaningful use" through existing HIT products. However, as HIT matures, CMS said it expects to move more Measures away from being demonstrated through attestation and to increasingly base demonstration on automated reporting by certified EHR technology (for example, through use of such technology for direct reporting of both clinical and nonclinical measures, such as HIT Functionality Measures, and documented participation in HIE).

Finally, in addition to requiring electronic reporting of clinical quality measures in Payment Year 2012 in Medicare and Medicaid, CMS proposes that it (and/or the states) test options to utilize existing and emerging HIT products and infrastructure capabilities to satisfy other Objectives of the "meaningful use" definition. Optional testing could involve the use of registries or the direct electronic reporting of additional Measures associated with the Objectives of the "meaningful use" definition.

MULTIPLE PRACTICE LOCATIONS

In order to ensure that EPs who see patients in multiple practices/locations and for whom certified EHR technology is not available at each location can meet Measure thresholds, CMS proposes that all Measures be limited to actions taken at practices "equipped" with certified EHR technology. A practice/location is considered "equipped" if certified EHR technology is available at the start of the EHR Reporting Period.

Further, CMS proposes that to be a "meaningful EHR user," 50 percent or more of an EP's patient encounters during a given EHR Reporting Period must occur at a practice/location equipped with certified EHR technology. EPs who do not conduct 50 percent of their patient encounters in any one practice/location may meet the 50 percent threshold through a combination of practices/locations.

Part 2: Why "Meaningful Use" Matters: ARRA Financial Incentives

A. Incentives for Hospitals

MEDICARE INCENTIVES

IPPS Hospital Incentives
ARRA provided for incentive payments under the Medicare hospital inpatient prospective payment system (IPPS); IPPS-excluded hospitals, such as inpatient rehabilitation facilities and long-term care hospitals, are not eligible. Hospitals located in Puerto Rico and other territories and possessions also are not eligible for the incentives.

The statute established a basic payment formula under which EHs will receive their Medicare share (based on Part A and Part C inpatient days) of a $2 million base amount plus graduated per-discharge payments ($200 per discharge for the 1,150th through 23,000th discharge). The incentive payments also increase relative to the amount of charity care provided by the EH.

Expressed as a formula, the basic payment amount for IPPS EH incentives will be calculated as follows:

$$(\$2{,}000{,}000 + DischargeAmount)\left(MedicareDays \big/ InpatientDays\left((TotalCharges - CharityCharges) \big/ TotalCharges\right)\right)$$

Incentive payments will be available for four years, but phased down each year. EHs will receive 100 percent of the basic payment amount in the first year, but the amount will be reduced by 25 percent each year after that. Payments begin in federal fiscal year (FY) 2011, but EHs will have until FY 2015 to begin "meaningful use" of certified EHR technology and still receive incentive payments. However, if an EH waits until FY 2014 or 2015, it will not receive incentive payments for the full four years and will be paid lower aggregate payments.

Beginning in FY 2015, EHs that fail to demonstrate meaningful EHR use will be penalized with a reduced IPPS market basket update (MBU), although this penalty may be waived by CMS if compliance with the requirements for being a "meaningful EHR user" would result in a "significant hardship," such as in the case of an EH in a rural area without sufficient Internet access.[4] EHs subject to the penalty will have their MBU reduced by one-third in FY 2015, two-thirds in FY 2016, and will receive no MBU in FY 2017 and subsequent years.

[4] ARRA does not define "significant hardship," leaving it to CMS to define the term. In the EHR NPRM, CMS declined to propose a definition, instead stating that it will define the term in "a future rulemaking prior to the 2015 effective date" of the payment penalties.

The following table summarizes these provisions.

First Payment Year	Percentage of Basic Payment Amount							MBU Reduction
	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	Total	
FY 2011	100	75	50	25	0	0	250	
FY 2012		100	75	50	25	0	250	
FY 2013			100	75	50	25	250	
FY 2014				75	50	25	150	
FY 2015					50	25	75	1/3
FY 2016							0	2/3
FY 2017+							0	No MBU

CAH Incentives

ARRA also included special payment provisions for critical access hospitals (CAHs). A CAH is a small (less than 15 inpatient beds), short-stay, rural hospital that is the sole hospital in a community or otherwise designated as a "necessary provider." CAHs are exempted from the IPPS and paid under Medicare based on 101 percent of the Medicare share of their reasonable costs. Therefore, even without the ARRA incentive provisions, CAHs would be reimbursed 101 percent of their Medicare share of capital and operating costs incurred for implementing EHRs.

ARRA created two forms of payment enhancement for CAHs that adopt certified EHR technology. First, CAHs will be reimbursed based on a significantly higher Medicare share for the costs for the "purchase of certified EHR technology." Under current CAH reimbursement rules, the Medicare share for a CAH is based on straight Medicare Part A utilization (that is, Medicare Part A days divided by total days). Under ARRA's EHR incentive provisions, payments will be based on the same Medicare share that is used for the EHR incentives under the IPPS—which takes into account charity care and Medicare Advantage (Part C) days—plus 20 percentage points. CMS, however, clarifies in the EHR NPRM that the Medicare share cannot exceed 100 percent.

Second, CAHs will be permitted to depreciate their capital expenses in a single year. Typically, costs for purchased software and hardware must be depreciated over a useful life of three or five years. Thus this provision will allow front-loaded reimbursement for capital expenses. CAHs also will be permitted to expense capital expenditures for the purchase of certified EHR technology from previous years to the extent they have not already been depreciated.

Both of these provisions are time-limited. They apply for a maximum of four years and will not be available for cost reporting periods beginning on or after calendar year 2016.

CMS proposes to define the "reasonable costs for the purchase of certified EHR technology" as the reasonable acquisition costs—excluding any depreciation and interest expenses associated with the acquisition—incurred for the purchase of depreciable assets, such as computers and associated software,

necessary to administer certified EHR technology. Because only "depreciable assets" are included in this definition, enhanced reimbursement would not appear to be available for operating expenses or leased or rented hardware or software because these costs are expensed in a single year. However, CMS does not address this issue specifically in the EHR NPRM.

CMS also does not discuss whether costs of ambulatory EHRs could potentially be reimbursed under the incentive provisions. CMS makes clear that the ARRA provisions apply only to the operating and capital costs of inpatient CAH services, but does not address whether some or all of the capital costs of an ambulatory EHR can be allocated as costs of inpatient CAH services.

CAHs also will be subject to Medicare payment penalties. CAHs that fail to become "meaningful users" of certified EHR systems will be paid only 100.66 percent of their reasonable costs in FY 2015, 100.33 percent in FY 2016, and 100 percent in FY 2017 and later years. Like IPPS EHs, CAHs will not be subject to these penalties if they demonstrate "significant hardship," which, as discussed above, CMS proposes to leave undefined for the time being.

Interaction with RHQDAPU
ARRA also made changes to the RHQDAPU program under the IPPS,[5] presumably to reflect the fact that quality measure reporting is a requirement of "meaningful use." Currently EHs are subject to a 2-percentage-point reduction in their MBU if they fail to submit quality data under the RHQDAPU program. Beginning in FY 2015 (the first year of payment penalties for failure to engage in "meaningful use" of certified EHR technology), the penalty for failure to participate in RHQDAPU is a one-quarter reduction in the MBU, which, except in the extraordinary case of an MBU of 8 percent or more, reduces the RHQDAPU penalty.

To integrate the two penalty provisions, CMS proposes to divide the MBU into two portions, with one-quarter subject to the RHQDAPU penalty and three-quarters subject to the EHR penalty. For example, if the MBU were 2.0 percent, the RHQDAPU penalty would apply to .5 percentage points and the EHR penalty would apply to 1.5 percentage points. In this example, in FY 2015, an EH would receive only a 1.0 percent update if it failed both to participate in RHQDAPU and engage in "meaningful use" of certified EHR technology. The RHQDAPU penalty would be .5 percentage points. The EHR penalty would also be .5 percentage points, which is one-third (the EHR penalty for 2015) of 1.5.

Multi-Campus Hospitals
If a health system has multiple EHs on different campuses, but some or all of the EHs bill under the same CMS certification number (CCN) (also known as the "provider number"), CMS will base EHR incentive payments on data from the CCNs, rather than data from each EH campus. ARRA does not address this issue, merely referring to incentive payments to "hospitals." Somewhat surprisingly, CMS does not specifically mention multi-campus EHs in the EHR NPRM. However, CMS makes clear that, for both CAHs and IPPS EHs, payments will be calculated based on "the CCN of the main provider."

Interim Payments and Reconciliation
CMS proposes to use data regarding each EH's discharges, inpatient days, and charges for charity care from the cost reporting period that ends during the FY prior to the Payment Year to calculate an "interim" EHR incentive payment. During cost report settlement, CMS would adjust these interim payments based on data from the cost reporting period that ended during the Payment Year.

CMS does not address when EHR incentive payments would be disbursed to IPPS EHs. Because interim payments would be based on data from the cost reporting period prior to the Payment Year, presumably payments could be made as soon as an EH's fiscal intermediary (FI) or Medicare Administrative Contractor

[5] CAHs do not participate in RHQDAPU.

(MAC) receives and processes the EH's attestation that it engaged in "meaningful use" of a certified EHR during the EHR Reporting Period.

CMS does address timing for disbursement of payments to CAHs. CMS proposes that a "prompt interim payment" would be made after 1) the CAH submits the necessary documentation to support the computation of the incentive payment amount and 2) CMS or the CAH's FI or MAC reviews the documentation and determines the amount of the interim payment.

Payments Through MAOs
The vast majority of EHs will receive their payments from their FIs or MACs through the original Medicare fee-for-service (FFS) program. However, an EH will receive its incentive payments from a Medicare Advantage Organization (MAO) if 1) the EH is under common corporate governance with the MAO, 2) the EH serves enrollees of plans offered by the MAO, and 3) no more than one-third of the discharges or bed days of Medicare beneficiaries for the year are paid for under the original FFS program. If an EH receives payments from the MAO, the MAO must provide EHR incentives in a "similar manner" as they would be paid under the original FFS program.

MEDICAID INCENTIVES

ARRA authorized a 100 percent federal match for incentives under state Medicaid programs to encourage EHs and EPs to purchase, implement, and operate certified EHR technology. Hospitals eligible under Medicare and Medicaid EHR Incentive Program rules may receive both payments. In contrast, dually eligible professionals must choose between the Medicare and Medicaid EHR incentive payments.

Eligibility
Medicaid incentive payments are available to acute care hospitals for which at least 10 percent of patient volume[6] is attributable to Medicaid recipients, as well as to children's hospitals. ARRA does not define either of these hospital types.

CMS, in the EHR NPRM, defines "acute care hospital" for Medicaid purposes as a health care facility that has an average length of patient stay of 25 days or fewer, as well as a Medicare CCN bearing the last four digits in the series 0001-0879. CMS projects that this definition captures short-term general hospitals and 11 cancer hospitals. CCNs for CAHs fall outside of this range, so they would not be eligible for Medicaid incentive payments.

> *Manatt Commentary: This provision prohibits hospitals that are classified as long-term care hospitals (LTCHs) under the Medicare program from receiving Medicaid incentives. It is consistent with long-standing CMS skepticism regarding the high Medicare profit margins of LTCHs. However, in many parts of the country, hospitals that provide the same services as LTCHs are certified as acute care hospitals and would qualify for the Medicaid incentives. Thus CMS is arguably singling out LTCHs for exclusion from Medicaid incentives solely due to how they classify themselves for Medicare payment purposes.*

CMS proposes two definitions of "children's hospital," either of which an EH may satisfy. One proposed definition would encompass a separately certified children's hospital with a Medicare CCN that bears the last four digits in the series 3300-3339. The other definition would capture free-standing EHs that furnish services exclusively to individuals under age 21. A children's wing of a general hospital would not qualify for Medicaid EHR incentive payments under either definition.

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[6] The CMS EHR NPRM's provisions on Medicaid patient volume are discussed below in connection with EPs. Patient volume would be determined in the same manner for EPs and EHs.

Payment Methodology
The cap on matching funds for Medicaid EH incentive payments is based on the formula for Medicare EHR incentive payments, but with a Medicaid utilization factor substituted for the Medicare utilization factor. In the EHR NPRM, CMS addresses the following statutory issues pertaining to this formula:

- Sources of Data. Like under the Medicare program, data would be derived from the hospital cost reporting period that ends during the FY prior to the FY that serves as the Payment Year. States should assume discharges for an individual EH based on the most recent three years of available data from an auditable data source. Auditable data sources include Medicare or Medicaid cost reports, Medicaid Management Information System (MMIS) payment and utilization information, and EH financial statements and accounting records.
- Total Inpatient Days. Only inpatient bed days would be counted, not substitute services or in-lieu-of services days.
- Transition Factor. Although the Medicare EHR Incentive Program applies a transition factor of zero for Medicare EHs for which the first Payment Year is after 2013, this reduction in payment would not apply for the Medicaid EHR Incentive Program.

ARRA does not set payment caps for individual years, but rather a cap on total dollars across the payment cycle, which may not exceed six years. However, payments in any one year cannot exceed 50 percent of the total payment cap, and payment in any two years cannot exceed 90 percent of this limit. No payment may be made if the first year of adoption is later than 2016.

B. Incentives for Eligible Professionals

MEDICARE INCENTIVES

Payments Under the PFS
Medicare payments are also available for EPs that are paid under the physician fee schedule (PFS). EPs are those professionals that are defined as "physicians" under the Medicare statute, which includes doctors of medicine and osteopathy and, for certain limited purposes, dentists, podiatrists, optometrists, and chiropractors.

Medicare payments will be calculated on an individual-practitioner basis. For each year under the EHR Incentive Program, an EP will receive 75 percent of the EP's total "allowed charges" (that is, the amounts Medicare pays under the PFS) during the Payment Year, subject to a cap. The payment limit for the first year depends on when the EP begins "meaningful use" of an EHR system. If the first year is 2011 or 2012, the cap is $18,000; if it is 2013, the cap is $15,000. The cap is lowered to $12,000 in the second year, $8,000 in the third, $4,000 in the fourth, and $2,000 in the fifth. EPs who begin "meaningful use" of an EHR system in 2014 will be paid as if they started in 2013, but will forgo the first-year payment. No incentive payments will be available to EPs who begin "meaningful use" in 2015 or later, and CMS will stop making incentive payments altogether in 2017.

EPs who do not adopt Certified EHR technology are subject to financial penalties for designated years. In 2015, noncompliant EPs will see their Medicare payments under the PFS cut by 1 percent across the board. This penalty increases to 2 percent in 2016 and 3 percent in 2017 and subsequent years.

Putting these rules together, the chart below lists the limits on total incentive payment amounts under the incentive payment program and payment penalties, depending on first year of "meaningful use":

Adoption Year	Maximum Payment							PFS Penalty
	2011	2012	2013	2014	2015	2016	Total	
2011	$18,000	$12,000	$8,000	$4,000	$2,000	$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	1%
2016							$0	2%
2017+							$0	3%

The payment limits will be 10 percent higher for an EP who "predominantly" furnishes services in a designated health professional shortage area (HPSA). CMS proposes to define "predominantly" as EPs who furnish more than 50 percent of their services in an HPSA.

Hospital-Based EPs
A significant limitation on the EP incentive payments is that "hospital-based" EPs are not eligible. Under ARRA, a hospital-based EP is one "who furnishes substantially all of [his or her] services in a hospital setting (whether inpatient or outpatient)" and "through the use of the facilities and equipment, including qualified electronic health records, of the hospital." The determination of whether an EP is hospital-based is to be made "on the basis of the site of service . . . and without regard to any employment or billing arrangement between the eligible professional and any other provider." ARRA leaves CMS with broad discretion to establish criteria regarding what qualifies as furnishing "substantially all" of an EP's services in a "hospital setting."

CMS proposes to define "substantially all" as furnishing at least 90 percent of services in an inpatient or outpatient EH setting. CMS would make this determination using place of services (POS) codes—specifically, all services paid for under claims with POS codes 21 (inpatient hospital), 22 (outpatient hospital), and 23 (emergency room, hospital) would be considered services furnished in an inpatient or outpatient hospital setting. Services provided in a provider-based outpatient department would count toward the 90 percent threshold.

> *Manatt Commentary: This proposed definition has significant potential to limit the availability of EHR incentive payments to EPs who are members of faculty practice plans of academic medical centers. Furthermore, primary care physicians who furnish at least 90 percent of their services in provider-based clinics would not qualify for incentive payments. In fact, CMS notes that, under its proposed definition, 27 percent of all physicians and 12-13 percent of family practitioners would be considered hospital-based. However, as CMS also observes, this inclusive definition of "substantially all" would also exclude a larger number of EPs from the Medicare payment penalties that begin in 2015.*

Interaction With E-Prescribing Program
An EP who receives EHR incentive payments through the Medicare program is ineligible to be paid incentives under CMS's existing Medicare E-Prescribing Incentive Program. However, the same would not be true for EPs who receive EHR incentive payments through the Medicaid program. They could receive payments under both the Medicaid EHR Incentive Program and the Medicare E-Prescribing Incentive Program.

Group Practices
ARRA authorized CMS to provide for "alternative means" of demonstrating "meaningful use" by EPs in group practices. In the EHR NPRM, CMS does not propose to establish such "alternative means." Rather, each EP would be required to demonstrate "meaningful use" individually. Despite this, CMS proposes that, if an EP receives a payment under the Medicare EHR Incentive Program, the EP or group practice would be ineligible to receive payments under the E-Prescribing Incentive Program.

> *Manatt Commentary: It is not entirely clear whether CMS is proposing that an EP who receives EHR incentives would disqualify every individual EP in his or her group practice from receiving payments under the E-Prescribing Incentive Program or would merely render the group practice ineligible to qualify for e-prescribing incentives as a group.*

Timing of Payment
CMS proposes to make payments on a rolling basis. The EP's carrier or MAC would be authorized to make an incentive payment "as soon as" it has ascertained that an EP has 1) demonstrated "meaningful use" for the applicable EHR Reporting Period, and 2) reached the threshold for maximum payment. Thus, in 2011, CMS would make an incentive payment once the EP had demonstrated "meaningful use" and had at least $24,000 in allowed charges under the PFS (because the $18,000 cap for 2015 is 75 percent of $24,000). If a qualifying EP's allowed charges did not reach the threshold for maximum payment during the Payment Year, then the carrier/MAC would disburse the incentive payment to the qualifying EP in the year following Payment Year based on 75 percent of the EP's allowed charges.

Payment Through MAOs
Under limited circumstances, EPs would be paid through MAOs. Unlike under the incentive provisions for IPPS hospitals, payment by MAOs to EPs would be in addition to the payments received through carriers and MACs under the original FFS program. An EP would be paid through an MAO only if:

- The EP is either:
  - Employed by the MAO, or
  - Employed by, or a partner of, an entity that through contract with the MAO furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of the MAO;
- The EP furnishes at least 80 percent of his or her services to Medicare beneficiaries to enrollees of the MAO; and
- The EP furnishes at least 20 hours of patient care services per week on average.

In general, MAOs must make payments in a "similar manner" as under the original FFS program. However, an EP may receive EHR incentives only through the MAO, and may not receive payments through the FFS program, if it has earned less than the maximum EHR incentives under the FFS program.

MEDICAID INCENTIVES

Eligibility
The following professionals qualify as EPs for purposes of Medicaid incentive payments:

- Physicians
- Dentists
- Certified nurse-midwives
- Nurse practitioners
- Physician assistants to the extent that they practice in a rural health clinic (RHC) that is led by a physician assistant or practice in a federally qualified health center (FQHC) that is led by a physician assistant

Incentive payments are available only to three categories of EPs:

- Those who are not hospital-based (using the same definition as under the Medicare provisions) and have at least 30 percent of their patient volume attributable to Medicaid patients;
- Those who are pediatricians and are not hospital-based and have at least 20 percent Medicaid patient volume; or
- Those who "practice predominantly" in FQHCs or RHCs and have at least 30 percent of their patient volume attributable to "needy individuals," which include Medicaid recipients, Children's Health Insurance Program (CHIP) recipients, patients furnished with uncompensated care, and patients whose charges are reduced by the provider based on income considerations. CMS proposes to define "practices predominantly" to refer to situations in which 50 percent of an EP's total patient encounters over a period of six months occur as an FQHC or RHC.

Volume Threshold

CMS, with a stated aim of capturing the highest number of Medicaid practitioners potentially eligible for the program, proposes use of the following formula to determine whether EPs or EHs satisfy the volume criterion:

$$\frac{\text{Total Medicaid patient encounters in any representative 90-day period in the preceding calendar year}}{\text{All patient encounters for the same provider over the same 90-day period}} * 100$$

CMS says that its intent is not to prescribe rigid standards but instead to use a more flexible "plain meaning" test in applying this methodology. CMS also permits states to propose alternative approaches.

Payment Methodology

Federal matching funds for incentive payments to EPs are available up to the lesser of a fixed annual dollar amount or 85 percent of the federally determined "net average allowable costs" of EHRs. The fixed dollar amounts are a) $21,250 for the first year of payment, which may not be later than 2016, and b) $8,500 for subsequent years, which may not be made after 2021 or for more than five years.[7] In addition, EPs must be responsible for 15 percent of their costs.

"Net average allowable costs" for the first year are the average costs for the purchase and initial implementation or upgrade of EHR technology, including support service and training. For subsequent years, they are the average costs of operation, maintenance, and use of EHR technology. ARRA directed CMS to conduct a study to determine these amounts and the EHR NPRM addresses studies reviewed by the agency and provides a proposed definition and accompanying rationale. While it was conceivable that CMS could set "net average allowable costs" caps lower than the fixed dollar amounts designated in the statute, CMS proposes a definition that would permit EPs to access full payments up to the statutorily specified caps.

[7] Therefore, EPs can receive a total of six years of payments; one year at $21,250, plus five years at $8,500.

Under these formulas, as depicted in the table below, the maximum that an EP may receive over six years is $63,750.

Eligible Professional	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
Physician	$21,250	$8,500	$8,500	$8,500	$8,500	$8,500	$63,750
Certified Nurse-Midwife	$21,250	$8,500	$8,500	$8,500	$8,500	$8,500	$63,750
Dentist	$21,250	$8,500	$8,500	$8,500	$8,500	$8,500	$63,750
Nurse Practitioner	$21,250	$8,500	$8,500	$8,500	$8,500	$8,500	$63,750
Physician Assistant	$21,250	$ 8,500	$ 8,500	$ 8,500	$ 8,500	$ 8,500	$63,750
Pediatrician	$14,167	$5,667	$5,667	$5,667	$5,667	$5,667	$42,502

One-Time Switch Between Medicare and Medicaid
CMS proposes that EPs be able to make a one-time switch between EHR Incentive Programs prior to 2015. Under certain circumstances, EPs may be able to marginally exceed the aggregate payment cap under the Medicaid EHR Incentive Program. Therefore, CMS proposes to limit the incentive payments available to the maximum incentive payment the EP could receive under the Medicaid EHR Incentive Program.

Eligibility for Six Years of Payment
If a provider has already completed adopting, implementing, or upgrading a certified EHR system in the first year, then the provider, for all subsequent years (up to a total of five years), must demonstrate "meaningful use." The EHR NPRM clarifies that all Medicaid EPs are able to access six years of payment, even if they are able to demonstrate "meaningful use" in the first year of payment.

C. Issues Particular to Medicaid

IMPLEMENTATION DATES

While ARRA specifies an implementation date for the Medicare EHR Incentive Program, no such requirement exists for the Medicaid EHR Incentive Program. CMS previously indicated that it did not expect implementation of the Medicaid Incentive Program prior to January 2011.[8] However, in the EHR NPRM, CMS proposes to allow states to make Medicaid incentive payments in 2010 for those EPs and EHs that are engaged in efforts to adopt, implement, or upgrade EHR technology. In proposing this change, CMS cited the goal of facilitating provider access to capital and supporting providers' abilities to meet "meaningful use." criteria in successive years. However, CMS indicated that this flexibility extends only to efforts to adopt/implement/upgrade technology and that it will not allow states to make "early" incentive payments to EPs and EHs that demonstrate "meaningful use."

[8] CMS Media Fact Sheet: "Medicare and Medicaid Health Information Technology: Title IV of the American Recovery and Reinvestment Act," Centers for Medicare & Medicaid Services, June 16, 2009.

Providers must first satisfy "meaningful use" requirements by 2016 in order to receive any payments. Furthermore, in contrast to the Medicare provisions, ARRA does not mandate Medicaid payment penalties for providers who do not meaningfully use EHRs, though nothing in the statute would prohibit state Medicaid agencies from imposing penalties on noncompliant providers.

ADOPT, IMPLEMENT, UPGRADE

To receive first-year Medicaid incentive payments, ARRA requires only that providers demonstrate that they are engaged in efforts to "adopt, implement, or upgrade" certified EHRs. The EHR NPRM provides further definitional texture:

- *Adopt*. Actual purchase/acquisition and installation of EHRs;
- *Implement*. Utilization of EHRs, such as staff training, EHR data entry, and establishment of data exchange agreements; and
- *Upgrade*. Expansion of EHR functionality, such as through the addition of clinical decision support or maintenance.

After the first year, EPs must engage in "meaningful use" of certified EHR technology to be eligible for incentive payments.

STATE ADMINISTRATION

Administrative Activities
ARRA authorizes a 90 percent federal match to support state administration of the Medicaid EHR Incentive Program. States must demonstrate compliance with three criteria articulated under ARRA in order to receive federal matching funds for administration of EHR incentive payments:

- The state uses the funds for purposes of administering the incentive payments, including the tracking of "meaningful use" of certified EHR technology by Medicaid providers;
- The state conducts adequate oversight of the EHR Incentive Program, including routine tracking of "meaningful use" attestations and reporting mechanisms; and
- The state pursues initiatives to encourage adoption of certified EHR technology to promote health care quality and the exchange of health care information under Medicaid, subject to applicable laws and regulations governing such exchange, while ensuring privacy and security of data provided to its data exchange partners.

In connection with these activities, CMS proposes to require that states implement an electronic system for provider registration and collect specific data elements to fulfill obligations for tracking incentive payments and preventing duplication with Medicare incentive payments for EPs. While the EHR NPRM provides some specificity around the tracking and oversight activities – articulating state responsibilities related program integrity, financial oversight, and provider appeals – CMS remained notably silent on the "initiatives to encourage adoption of certified EHR technology to promote health care quality and the exchange of healthcare information...."

Access to Administrative Funds
CMS previously issued sub-regulatory guidance, through a letter to State Medicaid Directors ("SMD letter"), describing the processes that states are required to complete to access administrative funds. The guidance primarily focused on the initial planning activities to be conducted by states and the planning documents to be submitted for federal approval. (Subsequently, CMS approved initial planning documents for 13 states.)

The proposed rule codifies this previous guidance, and provides additional specifications on the federal approval processes and state administrative responsibilities. Consistent with prior indications by CMS, states will be required to submit a Planning-Advanced Planning Document (P-APD), State Medicaid Health IT Plan (SMHP), and Implementation-Advanced Planning Document (I-APD) to access administrative funds.

Prior to the issuance of the EHR NPRM, CMS had only discussed allowing prospective access to 90 percent of FFP funds for state administrative activities related to the Medicaid EHR Incentive Program. Significantly, CMS, in the EHR NPRM, proposes to allow claims for reasonable administrative costs to run retroactively to the date of enactment of ARRA (February 18, 2009). For such claims, states must be able to show that they have begun initial planning stages of moving the state in the direction of "meaningful use" and may request CMS approval for these funds through the Advanced Planning Document process.

Providers Near State Borders
CMS's proposal also addresses another complexity of the Medicaid program, noting that Medicaid providers located on state borders may be eligible to receive incentive payments from multiple states. To simplify state administration, CMS proposes to require Medicaid providers annually to elect the state from which they will access Medicaid incentive payments.

Pass-Through Organization
In connection with Medicaid incentive payments to EPs, ARRA permits payment of incentives to state-designated "entities promoting the adoption of certified EHR technology," provided that the arrangements are voluntary and that the state-designated entity retains no more than 5 percent of the payment. The CMS regulatory preamble specifically identifies the qualifications of HIE organizations for this role, noting the value they offer in efficiently and affordably moving electronic clinical and administrative data in furtherance of quality improvement and public health goals.

D. Online Posting of "Meaningful Users"

Under ARRA, CMS is required to list online providers who are receiving Medicare EHR incentive payments. In the EHR NPRM, CMS proposes to collect the information necessary to post the name, business address, and business phone numbers of all EPs, IPPS hospitals, and CAHs participating in the Medicare EHR Incentive Program and to post this information on the CMS website.

Part 3: Identifying Technological Tools: ONC's Standards IFC

ONC's interim final rule with comment period (IFC) sets initial standards, implementation specifications, and certification criteria for certified EHR technology.[9] The initial set of certification criteria adopted by ONC specify the capabilities and related standards required of certified EHR technology in order to support EPs' and EHs' achievement of the proposed Stage 1 "meaningful use" criteria under the Medicare and Medicaid EHR Incentive Programs. Under the IFC, the certification criteria will be used to test and certify EHR technology; however, ONC plans to issue in the first quarter of 2010 a separate NPRM establishing specific policies for the certification of Health IT systems and the process by which a certification body becomes authorized to certify EHR technology.

ONC views the set of certification criteria adopted in the IFC as the first step in an iterative, incremental approach to standards adoption that requires a process for harmonizing both current and future standards and in which certification criteria evolve to meet changing needs. Specifically, ONC expects to adopt future certification criteria concurrently and in support of a transition to Stage 2 and Stage 3 "meaningful use" criteria in the Medicare and Medicaid EHR Incentive Programs. In doing so, ONC anticipates increasing the level of specificity of certification criteria (including phasing out certain alternative standards adopted in the initial set), and requiring greater capabilities of certified EHR technology (including the ability to exchange electronic health information across disparate care settings and among many different types of health IT).

> *Manatt Commentary: One of ONC's most important assumptions underlying this approach is that multiple standards can be tolerated today in order to accelerate the installation of certified EHRs, with these standards being harmonized and more tightly constrained later to increase interoperability and enable HIE through EHR compliance with these newer standards. Experience with EHR installations to date does not support this assumption. EHR installations require significant investment in software and in process redesign. Such investments cannot be jettisoned easily, and therefore providers are likely to stick with their initial choice of EHR, since they will be relying on that vendor to achieve the "meaningful use" requirements. Moreover, providers will likely seek market leaders, accelerating forces toward vendor consolidation. A likely outcome is the emergence of one to three large, dominant vendors in Stage 1 that become even more entrenched as Stages 2 and 3 approach due to the providers' sunk costs and difficulty of replacement. As a result, providers and their vendors will be incented to persuade ONC to limit efforts to "up the bar" in order to hold down their costs. If the providers and vendors cannot or will not invest to meet Stage 2 or later requirements, ONC (and CMS) will face a difficult choice: "lower the bar" by delaying or abandoning adoption of more restrictive standards or greatly increasing costs to providers that will have to either pay custom development costs to their vendor or attempt to replace their vendor; or fail or be significantly delayed in achieving Stage 2 and/or 3 "meaningful use" requirements.*

A. Key Definitions

ONC adopts the following baseline definitions:

- Certified EHR Technology. "A Complete EHR or a combination of EHR Modules, each of which:
  1) Meets the requirements included in the definition of Qualified EHR; and
  2) Has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary."

[9] The IFC will become effective February 12, 2010, 30 days after publication in the *Federal Register*. It will be open to a 60-day period of public comment, which ends on March 15, 2010. ONC plans to issue a "final" (rather than interim) final rule early in 2010.

- Qualified EHR. "An electronic record of health-related information on an individual that:
  1) Includes patient demographic and clinical health information, such as medical history and problem lists; and
  2) Has the capacity:
     i) to provide clinical decision support;
     ii) to support physician order entry;
     iii) to capture and query information relevant to health care quality; and
     iv) to exchange electronic health information with, and integrate such information from, other sources."

  ONC notes that this definition sets only the floor for the capabilities that certified EHR technology must include, as ONC adopts certification criteria that require capabilities beyond those specified in this definition and that EHR systems must additionally meet to be considered certified EHR technology.

- EHR Module. Any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by ONC.

- Complete EHR. EHR technology that has been developed to meet all applicable certification criteria adopted by ONC.

  ONC does not intend for the term Complete EHR to limit the capabilities included in such a system, but rather to signify EHR technology that can perform all of the applicable capabilities required by certification criteria. ONC expects that some Complete EHRs will have capabilities beyond those addressed by certification criteria.

An EHR Module could be an interface or other software program that provides the capability to exchange electronic health information, an open source software program that enables online access to health information maintained by an EHR, a clinical decision support rules engine, a software program used to submit public health information to relevant agencies, or a quality measure reporting service or software program. Thus, an EP or EH could create a combination of products and services that, taken together, meets the definition of certified EHR technology; however, the provider will have the responsibility of ensuring that the selected certified EHR Modules are capable of working together to enable the provider's achievement of "meaningful use."

> *Manatt Commentary: Only the most well-resourced providers will have the sophistication to piece together EHR Modules so as to meet all certification requirements. At least in the early years of the EHR Incentive Programs, most EPs and EHs will tend to select vendors' Complete EHR products. It is unlikely that this will change in the later years since there will be considerable prior investment in the initially chosen Complete EHR, creating a "land grab" environment over the next 12-36 months, with a small number of EHR products capturing the lion's share of the market. The winners will be those that can offer a Complete EHR and support over the next 6-12 months when most of the critical decisions about products will be made.*

B. Adopted Standards, Certification Criteria, and Implementation Specifications

ONC divides its criteria into three categories: standards, implementation specifications, and certification criteria. As defined by ONC, a standard is a "technical, functional, or performance-based rule, condition, requirement or specification that stipulates instructions, fields, codes, data, materials, characteristics." Implementation specifications are "specific requirements for implementing a standard," and certification

criteria are "criteria to establish that technology meets standards and implementation specifications." One way of looking at these categories is that standards are the fundamental rules for structuring information into EHRs and carrying out electronic communications, while implementation specifications are the detailed instructions on how to do so. The certification criteria ONC adopts in the IFC directly tie standards and implementation specifications to the "meaningful use" Objectives that CMS proposes to adopt for Phase 1 of the EHR Incentive Programs.

ADOPTED CERTIFICATION CRITERIA

In order to guide its approach to developing certification criteria, ONC established the following goals:

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability;
- Support the evolution and timely maintenance of adopted standards;
- Promote technical innovation using adopted standards;
- Encourage participation and adoption by all vendors, including small businesses;
- Keep implementation costs as low as reasonably possible;
- Consider best practices, experiences, policies, frameworks, and the input of the HIT Policy Committee and HIT Standards Committee in current and future standards;
- Enable mechanisms, such as the National Health Information Network, to serve as a test-bed for innovation and an open-source reference implementation of best practices; and
- To the extent possible, adopt standards that are modular and not interdependent.

The certification criteria adopted by ONC describe **both** the required capabilities certified EHR technology must include and, where applicable, the standard(s) that must be used by those capabilities. Accordingly, the IFC first discusses adopted certification criteria and then the various standards referenced by the adopted certification criteria.

A complete table showing all adopted certification criteria, which lists Stage 1 "Meaningful Use" Objectives and corresponding certification criteria, is attached as Appendix F.

ADOPTED STANDARDS

ONC has organized adopted standards into the following four categories:

- Vocabulary Standards (standardized nomenclature and code sets used to describe clinical problems and procedures, medications, and allergies);
- Content Exchange Standards (standards used to share clinical information, such as clinical summaries, prescriptions, and structured electronic documents);
- Transport Standards (standards used to establish a common, predictable, secure communication protocol between systems);
- Privacy and Security Standards (authentication, access control, and transmission security) which relate to and span across all other types of standards.

ONC chose to adopt alternative standards for certain purposes and has limited the adoption of specific vocabulary standards in this initial set to a few instances. However, ONC expects that, to enhance interoperability and support later Stages of "meaningful use," it will be essential that the agency adopt specific standards, vocabularies, and codes sets in the future.

Manatt Commentary: The standards adopted by ONC will allow virtually all of the existing EHR products of major vendors to qualify as "certified" EHR technology. Although this may limit interoperability—at least in the short term—ONC chose not to disrupt the market by imposing aggressive standardization.

To paraphrase text from the Policy Commentary, while the ultimate goals are admirable, it would have a stronger, more forward-looking proposal if it placed clearer policy support behind an open, Internet-based architecture that reflects appropriate federal, state, and regional roles. This approach could be characterized as "working from the outside in": attempting to create HIE based on interoperable EHRs constructed by getting large numbers of stand-alone EHRs installed at the "outside," then slowly moving "in" toward the network, in this case by starting with the multiple standards currently used (or no standard in many cases) in Stage 1 and then adopting increasingly restrictive standards for Stages 2 and 3 to promote interoperability. As noted above, this is a challenging path to success and one that history does not support.

The Internet can be characterized as "working from the inside out": specifying a small, precise set of protocols that **everyone** *had to implement and therefore by definition anyone "connecting" had to interoperate with everyone else. "Internet" is literally shorthand for "inter-network." While desirable, "inter-network" exchange was difficult until Internet Protocols were developed. Nearly 40 years hence, the approach continues to demonstrate unmatched scale and interoperability. Our suggestion would be to focus on those critical protocols, and demand that* **everyone** *implement them. Then all EHRs would be interoperable by definition.*

Transport Standards
With respect to transport standards, ONC has adopted Simple Object Access Protocol (SOAP) version 1.2 and Representation State Transfer (REST) to provide standard ways for systems to interact with one another.

CMS also clarifies the difference between "transport standard" and "content exchange standard" as some stakeholders use the terms interchangeably: transport standards are not domain-specific, while content exchange standards are (for example, SOAP and REST can be used by other industries to exchange information while the CCD, a content exchange standard, cannot).

Content Exchange and Vocabulary Standards
A comprehensive table demonstrating the content exchange and vocabulary standards adopted for each applicable exchange purpose is available at Appendix G.

Privacy and Security Standards
After considering the recommendations of the HIT Standards Committee, ONC has chosen to adopt specific standards to be used in certified EHR technology for certain capabilities. For other capabilities, ONC has not adopted specific standards due to a belief that such capabilities can be addressed through various approaches and in order to avoid preclusion of future innovation.

Further, ONC emphasizes that the IFC focuses solely on the capabilities of certified EHR technology and does not change existing HIPAA requirements, guarantee compliance with those requirements, or absolve any provider from having to comply with applicable HIPAA provisions. While capabilities provided in certified EHR technology may aid an EP or EH in improving technical safeguards or meeting some HIPAA requirements, the use of certified EHR technology alone does not equate to compliance with HIPAA rules. A table demonstrating the adopted privacy and security standards is available at Appendix H.

ADOPTED IMPLEMENTATION SPECIFICATIONS

Though ARRA requires that ONC adopt implementation specifications in addition to standards and certification criteria, ONC does not believe that sufficiently mature implementation specifications exist to adopt to support "meaningful use" Stage 1. Thus, under the IFC, ONC adopts only two implementation specifications:

- For quality reporting: The Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry; and
- For eligibility transactions for health plans: Phase 1 of the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE).

Further, ONC seeks public comment as to whether there are in fact implementation specifications that are industry-tested, widely used and/or would not present a significant burden if adopted.

> *Manatt Commentary: By adopting only two implementation specifications, ONC missed an opportunity to promote interoperability at the early stages of HIT adoption.*
>
> *Furthermore, ONC appears to have adopted the PQRI implementation specification for both EH and EP quality reporting. However, ONC does not acknowledge that the PQRI program is a physician-only program or discuss whether the PQRI implementation specification is appropriate for hospital reporting of quality measures.*