

Some Tout CMS' Proposed "Meaningful Use" Definition for Use of Electronic Health Records As Too Ambitious

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Just in time for the New Year, the Department of Health and Human Services (HHS), through the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), released two sets of much-anticipated federal regulations dealing with healthcare providers' implementation of electronic health records (EHR) systems. As part of the American Recovery and Reinvestment Act of 2009 (ARRA),¹ hospitals, physicians groups, and other healthcare providers who adopt the "meaningful use" of EHRs will be eligible to receive financial incentives in the form of higher Medicare and Medicaid reimbursement rates.² However, those incentives will not be available until later this year or early 2011; thus, providers must absorb the upfront capital investment cited by physicians and hospitals as the main barrier to EHR implementation. As a result, some companies are offering physician practices and other providers interest-free or low-interest loans to absorb some of the cost.³ On December 30, 2009, CMS announced proposed rules to implement the "meaningful use" criteria governing the EHR programs.⁴ In a related announcement, a second set of regulations has been proposed by the ONC to set standards and certification criteria that the EHRs must meet in order to receive incentive payments.⁵ Both sets of rules were published in the *Federal Register* on January 13, 2009, and will be open for public comments for a 60-day period.

Background

The health information technology (HIT) provisions of the ARRA are found primarily in Title IV of the legislation, known as the Health Information Technology for Economic and Clinical Health Act (HITECH).⁶ Pursuant to the HITECH Act, physicians and

¹ Pub. L. No. 111-05, H.R. 1, 111th Cong. (2009) (enacted).

² See Centers for Medicare & Medicaid Servs., *Fact Sheets: Medicare and Medicaid Health Information Technology: Title IV of The American Recovery and Reinvestment Act*, June 16, 2009, <http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3466&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>.

³ See Bruce Japsen, *Electronic Medical Records: Extra Payments Designed to Get More Doctors on Board*, CHICAGO TRIB., Jan. 7, 2010, <http://www.chicagotribune.com/health/chi-thu-notebook-docs-0107-jan07,0,4357681.story>.

⁴ Centers for Medicare & Medicaid Servs., Press Release, *CMS and ONC Issue Regulations Proposing a Definition of Meaningful Use and Setting Standards for Electronic Health Record Incentive Program*, Dec. 30, 2009, <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3561&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>.

⁵ *Id.* See also David Burda, 'Meaningful Use' Criteria Released, MODERN HEALTHCARE.COM, Dec. 30, 2009, <http://www.modernhealthcare.com/article/20091230/FREE/312309969>.

⁶ See Centers for Medicare & Medicaid Servs., *Fact Sheets: Details For: Medicare and Medicaid Health Information Technology: Title IV of the American Recovery and Reinvestment Act*, June 16, 2009, <http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3466&intNumPerPage>.

hospitals that implement the “meaningful use” of EHRs during calendar years 2010 to 2014 will be eligible to receive higher Medicare and Medicaid incentive payments.⁷ Additionally, federal matching funds will be available to states to support administrative costs associated with the HITECH Act’s provisions.⁸ Providers that do not implement EHR programs may incur financial penalties in the form of lower Medicare reimbursement rates beginning in 2015.⁹

ARRA’s Definition of “Meaningful Use”

The ARRA defines the term “meaningful use” broadly and without much detail so as to advise healthcare providers on proper implementation of EHR systems. The ARRA sets forth three broad requirements:

1. [d]emonstrating to the Secretary of Health and Human Services (HHS) that certified technology is being used “in a meaningful manner;”
2. [d]emonstrating that the technology is connected in a manner that provides for the electronic exchange of health information; and
3. [u]sing the EHR to submit clinical quality measures selected by the Secretary.¹⁰

ARRA grants the Secretary of HHS discretion to define the terms in more detail; in an effort to do exactly that, a federal advisory committee, the HIT Policy Committee, was established to offer advice and suggestions about what constitutes “meaningful use.”¹¹

On June 16, 2009, the HIT Policy Committee released its initial recommendations.¹² Though the 22 objectives/recommendations did not include a formal definition of “meaningful use,” they were a first step in an ongoing process. Most of the objectives cited by the committee covered inpatient and outpatient care, including:

- using Computerized Provider Order Entry (CPOE) for all order types including medications;
- generating and transmitting permissible prescriptions electronically;
- maintaining an active medication/allergy list;
- sending reminders to patients (according to their preferences) for preventative and follow-up care;
- documenting a progress note for each encounter;
- providing patients with an electronic copy or electronic access to clinical

⁷ *Id.*; see also Ron Scott, *ARRA Provides Incentives for “Meaningful Use” of Electronic Health Records* 14:5 UPDATE ON HEALTH at *3 (May 2009).

⁸ *Id.*

⁹ *Id.*

¹⁰ See Pub. L. No. 111-05, H.R. 1, Sec. 4101(a)(2)(A), 111th Cong. (2009) (enacted); Rick Pollack, Exec. V.P. of Am. Hosp. Ass’n, Letter to David Blumenthal, Nat. Coord. for Health Info. Tech., June 26, 2009, available at <http://www.aha.org/aha/letter/2009/090626-cl-hit-meaningful-use.pdf>.

¹¹ U.S. Dep’t of Health & Human Servs., Press Release, *Process Begins to Define “Meaningful Use” of Electronic Health Records*, June 16, 2009, <http://www.hhs.gov/news/press/2009pres/06/20090616a.html>.

¹² *Id.*

- exchanging key clinical information among care providers.¹³

In a June 2009 letter to David Blumenthal, M.D., national coordinator for the HIT Policy Committee, the American Hospital Association (AHA) said the Committee's timelines for achieving full implementation of some of the objectives was simply "not achievable."¹⁴ Instead, the association urged the Committee and CMS to develop a "meaningful use" timeframe that begins with fewer functional requirements and extends the transition to a fully functional EHR system beyond 2015.¹⁵ The association agreed with the Committee that clinical documentation of patient demographics, problem lists and medication lists, discharge summaries, and lab results and other diagnostic tests were achievable functionalities by 2011, but noted that other functions such as nursing documentation assessments, electronic access by pharmacists to formularies, and medication bar coding should not be added until 2013.¹⁶

Proposed "Meaningful Use" Regulations

The proposed rule would define meaningful use for the Medicare EHR incentive programs. It proposes two definitions: the first would apply to eligible professionals participating in the Medicare fee-for-service and the Medicare Advantage EHR incentive programs. The second proposed definition would apply to eligible hospitals and critical access hospitals.¹⁷ These definitions also would serve as the minimum standard for eligible professionals and eligible hospitals participating in the Medicaid EHR incentive program. The rule proposes that states could request CMS approval to implement additional meaningful use measures, as appropriate, but could not request approval of fewer or less rigorous meaningful use measures than required by the rule.¹⁸

Under the "meaningful use" regulations¹⁹ announced on December 30, 2009, healthcare providers must use EHRs to improve the quality, safety and efficiency of healthcare services; reduce healthcare disparities; engage patients and their families; improve the coordination of care; improve public health; and ensure the privacy and security of personal medical information pursuant to specific objectives set forth in the regulations.²⁰ To effectuate these goals, CMS' proposed rule will utilize three stages to phase in specific EHR criteria.

¹³ Joseph Goedert, *First Look at "Meaningful Use,"* HEALTH DATA MGT., June 16, 2009, http://www.healthdatamanagement.com/news/meaningful_use-38487-1.html. ("This is the beginning of a conversation that will continue for some time," said David Blumenthal).

¹⁴ Rick Pollack, Exec. V.P. of Am. Hosp. Ass'n, Letter to David Blumenthal, Nat. Coord. for Health Info. Tech., June 26, 2009, available at <http://www.aha.org/aha/letter/2009/090626-cl-hit-meaningful-use.pdf>.

¹⁵ *Id.*; see also Am. Health Lawyers Ass'n, *Health Information Technology Stakeholders Comment on Draft Definition of "Meaningful Use" of EHRs*, HEALTH LAWYERS WEEKLY, July 10, 2009.

¹⁶ *Id.*

¹⁷ See CMS Press Release, *supra* note 4.

¹⁸ *Id.*

¹⁹ 42 C.F.R. Pts. 412, 413, 422 and 495 (Dec. 30, 2009), available at <http://www.modernhealthcare.com/assets/pdf/CH680921230.PDF>.

²⁰ Burda, *supra* note 5.

Stage 1

Stage 1, which begins in 2011, the proposed 25 objectives and measures for eligible professionals (EPs) and 23 objectives and measures for eligible hospitals focuses on electronically capturing health information in a coded format, using that information to track key clinical conditions, communicating the information for care coordination purposes, and initiating the reporting of clinical quality measures and public health information.²¹ These specific objectives for EPs and hospitals must be met in order to demonstrate that they are meaningful users.²² In 2012, CMS proposes requiring the direct submission of clinical quality measures to CMS through EHR technology.²³

Stage 2

Beginning in 2013, Stage 2 would expand upon Stage 1 criteria and encourage the utilization of information exchange using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results (such as blood tests, microbiology, urinalysis, pulmonary function tests and other data needed to diagnose and treat disease).²⁴ Stage 2 will also focus more heavily in the areas of disease management, clinical decision support, medication management, support for patient access to their health information, transitions in care, quality measurement and research, and bi-directional communication with public health agencies.²⁵ CMS may additionally consider applying the criteria more broadly to both the inpatient and outpatient hospital settings.

Stage 3

Beginning in 2015, Stage 3 will 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.²⁶

Reaction to the Proposed Rule

There has been mixed reaction to the nearly 700 pages of proposed rules regarding the future of healthcare information technology – over 500 pages devoted solely to the

²¹ Centers for Medicare & Medicaid Servs., Press Release, *CMS Proposes Definition of Meaningful Use of Certified Electronic Health Records (EHR) Technology*, Dec. 30, 2009, <http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3564&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>. See also *HealthcareTechnologyNews, Meaningful Use Criteria*, Jan. 3, 2010, <http://news.avancehealth.com/2010/01/meaningful-use-criteria.html>.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

“meaningful use” criteria.²⁷ The American Hospital Association (AHA) issued a statement indicating its lack of favor with the proposed rules. The release stated, in part:

America's hospitals have serious concerns that the new health information technology rules severely limit hospitals' ability to access federal financing for health information technology that is used to improve patient care...While health information technology holds great promise in improving care, widespread efforts toward adoption will be hindered unless key provisions in these rules are addressed...The intent behind the stimulus funds was to recognize the important efforts hospitals and physicians have undertaken to improve care and to stimulate greater use of health information technology and EHRs. However, the rules released yesterday create a stringent definition of "meaningful use" that doesn't recognize these important efforts and would unfairly penalize many hospitals. A more commonsense approach would reward the progress hospitals and physicians already have made toward adopting EHRs.²⁸

The statement went further to add that the proposed “meaningful use” rule “fails to recognize how modern hospitals are organized and how care is delivered.”²⁹ Don May, vice president for policy at the AHA, said the HIT Policy Committee spent too much time listening to panels of experts who advised it on needed criteria and not enough time focused on talking with providers in the field on how the proposed rules might affect their day-to-day operations.³⁰

“They did a lot of detailed work very quickly and I think they've come up with a pretty good ideal system, but we don't think it's a starting system,” May said. “If you raise the bar so high and hospitals can't hit that and they have no reason to do that, this rule may actually provide a disincentive for those hospitals that are on the wrong side of the digital divide.”³¹

Equally direct was a statement by the Medical Group Management Association which said the proposed rules were “overly complex and that medical groups will confront significant challenges trying to meet the program requirements.”³² However, Chicago-

²⁷ See Joseph Cohn, *Meaningful Use IT Rules Get Mixed Reaction*, MODERNPHYSICIAN.COM, Jan. 4, 2010, <http://www.modernphysician.com/apps/pbcs.dll/article?AID=/20100104/MODERNPHYSICIAN/301049913/-1>.

²⁸ Rick Pollack, Exec. V.P., Am. Hosp. Ass'n, *AHA Statement on Proposed Rules on 'Meaningful Use' and Health Information Technology Funding*, Dec. 31, 2009, available at <http://www.aha.org/aha/press-release/2009/091231-pr-hit.html>.

²⁹ *Id.*

³⁰ Joseph Conn, *Proposed EHR Rule Might Be Too Ambitious: Experts*, MODERN HEALTHCARE.COM, Jan. 13, 2010, <http://www.modernhealthcare.com/apps/pbcs.dll/article?AID=/20100113/REG/301139953/1029#>.

³¹ *Id.*

³² Cohn, *supra* note 27. See also *Provider Groups: EHR Rule Misses Mark*, HEALTHDATA MGT., Jan. 4, 2010, available at http://www.healthdatamanagement.com/news/meaningful_use_stimulus_EHR_HITECH_certification-39604-1.html?zkPrintable=true.

based Healthcare Information and Management Systems Society stated that “there is much more to applaud than criticize.”³³

Conclusion

There is a great deal at stake in formulating, as well as implementing, the new regulations and significant discussions will be held and comments to be submitted during the 60-day public comment period. In addition, CMS and ONC must flesh out regulations regarding the requirements and other definitions for EHR systems as well as certification criteria that will be used to allow healthcare providers to pass muster with the federal agencies and begin to receive incentive payments. Between \$14.1 billion and \$27.3 billion has been earmarked by the ARRA for the EHR programs. **For additional information on CMS’ other proposed requirements for EHR incentive programs, see *Health Law Perspectives* article: CMS Proposes Rule for Electronic Health Record Standards and Specifications.**

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³³ *Id.*