



LegalNotes

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LegalNotes is a regular online *Aligning Forces for Quality* (AF4Q) publication that provides readers with short, readable summaries of developments in the law that collectively shape the broader legal environment for efforts to improve quality, reduce health care disparities, and improve the transparency of price and quality information.

HIT Adoption and the American Recovery and Reinvestment Act of 2009: Examining the Concept of “Meaningful Use”

Introduction

This installment of **LegalNotes** focuses on the concept of “meaningful use” of electronic health records and the key considerations that will underlie proposed rules expected to be issued by the Center for Medicare and Medicaid Services (CMS) by the end of December 2009. The goal is to provide the AF4Q communities with background information in advance of the proposed rule as an aid to understanding its provisions when published.

When the proposed rule is issued, the Legal Barriers team will send out the rule as well as a rapid analysis. We anticipate a 60-day comment period from the date that the rule is published. Because commenting on any proposed rule—especially this one—is so important, the Legal Barriers team also will coordinate preparation of a sample comment that will be sent to all members of the AF4Q community by the end of January 2010. This will help each community develop community-specific comments, and the Legal Barriers team is also prepared to help any community that would like assistance in developing its comments.

Public comments received by a federal agency on rules as consequential as the meaningful use regulations are incredibly important, and because the definition of meaningful use is so critical for the AF4Q communities, filing comments is strongly recommended.

Background and Overview

It is important to begin by placing the definition of meaningful use in context. While the policy will evolve over a long time period, the law that undergirds this policy reflects an enormous achievement: the establishment of a formal national health policy that moves the health care system into an electronic information age.

The Health Information Technology for Economic and Clinical Act of 2009 (HITECH), part of the American Recovery and Reinvestment Act of 2009 (ARRA)¹, authorizes approximately \$49 billion to incentivize adoption and meaningful use of certified electronic health records by Medicare and Medicaid providers. Included in this appropriation is both grant funding and Medicare/Medicaid incentive payments.

ARRA authorizes payment of financial incentives to certain classes of Medicare and Medicaid participating physicians, hospitals, health professionals² and health care entities. Covered entities are eligible for incentive payments during the 2011-2015 time periods³ if they can demonstrate adoption and meaningful use of certified electronic health record (EHR) technology.⁴ Similarly, the Medicaid provisions target additional health care providers with high-volume Medicaid practices, as well as certain providers with a high volume of “needy” patients. Eligible providers include physicians, dentists, nurse mid-wives and nurse practitioners, or physician assistants (practicing in a federally qualified health center or rural health clinic led by a physician assistant), who either have a patient volume that is 30 percent Medicaid or who practice in a federally qualified health center or rural health clinic with a patient volume that is 30 percent needy.⁵ The only eligible hospitals are

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children's hospitals and acute care hospitals whose patient volume is 10 percent Medicaid.⁶

Under the Act, near-term financial incentives transition to "adjustments" in the long term, in the form of Medicare provider payment reductions that rise successively beginning in 2015.⁷ CMS is in charge of the incentive program and its regulations by law must be issued by the end of 2009.⁸ While the CMS definition will be binding on Medicare providers, state Medicaid agencies have the flexibility under the law to develop alternative definitions.⁹

The final Medicare definition of meaningful use, as well as how state Medicaid programs approach the issue, can be expected to have a major impact on AF4Q communities. But the basic challenge in developing a meaningful use standard, guided by the terms of the legislation itself, can be stated as follows: A strong standard that requires evidence of advanced use of technology in order to receive the incentive payments may result in limited adoption among providers, at least in the initial years before penalties for non-adoption kick in; by contrast, setting the meaningful use bar too low means that adoption may yield very little in the way of measurable improvement in quality and information. Thus, the definition essentially will guide AF4Q communities on the formal federal policy that undergirds their own work. To the extent that the initial definition may produce limited actual data results in the short-term, AF4Q communities may want to consider ways to take maximum advantage of this definition and to find ways to encourage their community providers to build more rapidly on these early strides.

Meaningful Use Defined in Law

The statute sets the following core definition of "meaningful users:"

In general.—[A]n eligible professional shall be treated as a meaningful * * * user [of an EHR] * * * if each of the following requirements is met: (i) *Meaningful use of certified EHR technology.*—The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that * * * the professional is using certified EHR technology in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary. (ii) *Information exchange.*—The eligible professional demonstrates to the satisfaction of the Secretary * * * that during such period such certified EHR technology is connected in a manner that provides, * * * in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care

coordination. (iii) *Reporting on measures using EHR.*— * * * the eligible professional submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary . . .¹⁰

(emphasis added)

Thus, the statute contains three measures: demonstrating that the technology in use is certified; connectivity that provides for exchange of information; and the ability to report on measures using EHRs. (The third measure is conditioned on the ability of the Secretary to receive information electronically.) Within these three criteria, there obviously is a vast range of performance possibilities. For example, if certification standards are relatively modest, then adoption will yield relatively modest capabilities. If data exchange requirements are modest, then only limited types of data may be exchanged. And similarly, if reporting expectations are modest, very modest amounts of data may be reported.

Recognizing the inherent tension raised by where to set the performance bar, the statute authorizes the Secretary to require "more stringent" measures over time,¹¹ suggesting an assumption on Congress' part that the early phases of meaningful use will focus on adoption of certified technology and relatively simple use. The statute also directs the Secretary, in selecting clinical quality measures, to give preference to measures endorsed by a non-profit, consensus-based "entity" that they have contracted with under Section 1890 of the Social Security Act,¹² such as the National Quality Forum,¹³ and to publish the measures to be used in the Federal Register.¹⁴ The statute further prohibits the Secretary from requiring the reporting of measures unless she has the capacity to accept the information electronically while at the same time permitting the piloting of electronic information acceptance systems.¹⁵

Thus, three key issues will be worth watching when the rules appear: first, *the parameters of certified EHR technology*, second, *the meaning of exchanging information to improve the quality of health care*, and third, *the meaning of reporting information on the clinical quality measures and other measures* selected by the Secretary.

ONCHIT Activities

In carrying out its duties under the law, the Office of the National Coordinator for Health Information Technology (ONCHIT) has assembled a panel of experts, referred to as the Health Information Technology Policy Committee (HIT Policy Committee) to both hold hearings and make recommendations. Based on public meetings and input from various stakeholders, the HIT Policy Committee created three drafts of a matrix identifying the general

care goals, objectives and measures for 2011, 2013 and 2015.¹⁶ The matrix serves as a guide for defining meaningful use.

The HIT Policy Committee's draft identifies five "health outcomes policy priorities" for conceptualizing health care transformation. The goals include the following: (1) improve quality, safety, efficiency and reduce health disparities; (2) engage patients and families; (3) improve care coordination; (4) improve population and public health; and (5) ensure adequate privacy and security protections for personal health information.

Specific goals are identified for each priority. For example, for the first priority of improving quality, safety, efficiency and reducing health disparities, the meaningful use goals include the following: (1) provide access to comprehensive patient health data for the patient's health care team; (2) use evidence-based order sets and computer-based order entry (CPOE); (3) apply clinical decision support at the point of care; (4) generate lists of patients who need care and then use them to reach out to patients; and (5) report to patient registries for quality improvement, public reporting, etc.

Each set of goals contains specific objectives, which in turn are broken down by year (through the three-stage process identified in the matrix: 2011, 2013 and 2015), and then again by provider type (eligible providers and hospitals). The aim is to create meaningful use measurements that, as the statute suggests, become "more stringent" over time, in order to ensure not only that adoption is achieved, but that over time, adoption yields greater results in efficiency and quality.

Defining What it Means to be a Meaningful User of Certified EHRs

Two concepts form an essential part of the discussion of meaningful use: adoption of a certified EHR and meaningful use of the EHR.

Certified EHR Technology

ARRA uses the Health Insurance Portability and Accountability Act (HIPAA) definition of a qualified health record¹⁷ to define "certified EHR technology."¹⁸ Under HIPAA, a qualified electronic health record means 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; 2) has the capacity to provide clinical decision support, to enable physician order entry, and to capture and query information relevant to health care quality; and 3) to exchange electronic health information with, and integrate such information from other sources.¹⁹ ARRA requires the U.S. Department of Health and Human Services to work with the National Institute of Standards and Technology (NIST) to define certification criteria²⁰ as well as a process by which adherence to standards will be measured.

NIST sets the standard, but the Certification Commission for Health Information Technology (CCHIT), responsible for testing and ensuring the conformity of commercial Health Information Technology (HIT) products, will be the sole transitional certifying body through final rulemaking.²¹

Because the legislation defines the critical characteristics of an EHR, it is expected that the regulations will reflect these core elements. How the critical characteristics are defined is important because existing EHR technology varies in its comprehensiveness. For instance, between 8-12 percent of U.S. hospitals have a basic EHR system, and only 1.5 percent of U.S. hospitals have a comprehensive EHR system (present in all clinical units).²² Further, computerized provider-order entry for medications, a requirement under ARRA, has been implemented in only 17 percent of U.S. hospitals.²³ A basic system (present in at least one clinical unit) is capable of: 1) tracking the majority of all clinical documentation (most test results, but not imaging results); and 2) very limited computerized provider-order entry, including medications, but excluding laboratory, consults and nursing orders.

Critical Elements of Meaningful Use

In implementing the statutory elements of meaningful use, the regulations must monitor several phases of provider HIT activity. First, providers must implement electronic prescribing.²⁴ Second, providers must report on clinical quality measures, and any other clinical quality measure deemed appropriate by the Secretary.²⁵ Finally, providers must use the technology to improve the quality of health care.²⁶ As noted, the statute specifically mentions care coordination as an example of such an improvement.

Thus, the law raises two key questions: First, what does improving the quality of health care mean? Second, how can technology be used to improve the quality of health care in an effective manner?

The meaningful application of electronic prescribing, interoperability and quality metrics is dependent on the context in which their application is framed. ARRA approaches the discussion of meaningful use principally from an administrative and claims practices perspective, focusing on provider capability at the individual practice level. However, because the law does not define "quality" or "exchange" to reach only provider-specific clinical care settings, the definition of meaningful use could encompass broader activities such as reporting to a patient registry or interacting with patients' personal health records.

In this context, an essential component of the definition of meaningful use could be the concept of interoperability and 1) providers' ability to communicate with patients; 2) public health; and 3) agencies and entities that are engaged in activities relevant to the health of patients and community preventive efforts, such as

public health programs that offer measures and report on progress in managing diabetes in high risk communities.

Future Considerations

Advancing the Technology While Advancing Use

Two highly related tensions arise in the consideration of requiring the adoption of new technologies. The first is how aggressively to define meaningful use, while the second is how aggressively to press the evolution of the technology. Clearly, the faster the technology evolves, the higher the bar can be moved. Concomitantly, the more that providers clamor for technology advances because they become adopters of the basic technology and begin to sense what it can do, the faster the technology can be expected to evolve. And the more that entities external to the clinical care setting itself—public health agencies, payers, health care regulatory bodies, consumers and others—come to expect certain types of information about health care, meaningful use and meaningful use technology will advance.

It is clear that the nation has a long way to go. Estimates suggest that approximately less than 15 percent of providers currently use EHRs and that a smaller proportion are meaningful users in the sense that they are using the technology to improve health care quality or exchange information.²⁷ The evidence indicates that providers are not now using HIT in a manner that affects overall population health, system costs or system quality. Instead they are using the technology to carry out discrete, individual procedures. Implicit in HITECH is a vision of technology that is sufficiently sophisticated, adoption that is sufficiently widespread, and results that are sufficiently amassed and used outside the immediate clinical care setting to begin to make a real population level difference in quality and cost. Thus, further considerations for policy development to promote efficient provider use of HIT include uniformity in the manner in which information is transferred, the maintenance of EHRs as legal medical records and ensuring the accuracy of user input, the maintenance of file integrity, and the production of documentable paper trails.

The Cost of Adoption and Use

An additional challenge is overcoming the sense among providers that the business benefits of adoption and use will accrue not to them, but instead to insurers and patients, and that uses aimed at reducing inefficiencies will adversely affect the financial aspects of practice. Smaller clinical practices may be unable to afford to implement the new technologies even with the aid of the incentives. (Funding for initial HIT adoption is available under Medicaid but not under Medicare.) Furthermore, Medicaid incentives are limited

to certain subsets of health care providers for the allowable costs of EHR technology and implementation and certain categories of hospitals for the allowable costs of EHR technology only. (As described, certain specialty care hospitals²⁸ and eligible providers with specific Medicaid patient volumes or who practice in a federally qualified health center or rural health clinic with a specific Medicaid patient volume.²⁹) Providers who do not qualify for funding for the initial adoption of HIT will face upfront costs for adoption that may not be balanced by the incentives available under Medicare.

Adoption and Health Disparities

ARRA requires that the federal infrastructure improve efforts to reduce health care disparities.³⁰ In developing meaningful use policy, ONCHIT is expected to address how technology will affect “communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured and medically underserved.”³¹ In response, current drafts of meaningful use criteria released by the HIT Policy Committee reflect a commitment towards the “collection of patient demographic data, including, at a minimum, race, ethnicity, primary language, and gender information,”³² and promoting technologies that address the needs of vulnerable populations.³³

Concluding Thoughts

AF4Q community initiatives turn in great part on the selection and implementation of quality measures, the collection of data, and provider and community feedback. Ultimately, the concept of meaningful use becomes the public policy engine that will propel these efforts forward. As with many aspects of public policy, communities should not be surprised if the initial bar is set lower than what would be optimal in terms of achieving AF4Q goals. It is often the case that regulatory standards reflect relatively modest goals, precisely because they are binding regulatory standards and must not be so stringent as to exclude much of the target population or interest whose performance is the subject of the rules.

Over time, the concept of meaningful use will grow more stringent, and the fact that the rule will establish a national floor for meaningful use of EHR technology represents a fundamental advance in American health care. Even if the initial definitions are modest, it is in the direct interest of AF4Q communities to encourage widespread adoption among Medicare providers while working closely with state Medicaid programs to ensure effective implementation, since those providers whose services may be most relevant to the reduction of population health disparities will be most affected by the course of Medicaid implementation.

- ¹ The American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5, 111th Cong., 1st sess. (2009).
- ² ARRA, § 4101(a) (adding new section 1848(o)(1) to the Social Security Act (42 U.S.C. 1395w-4).
- ³ ARRA, § 4101(a) (adding new section 1848(o)(1)(E) to the Social Security Act (42 U.S.C. 1395w-4).
- ⁴ ARRA, § 3000(1).
- ⁵ ARRA, § 4201(a)(2) (adding new section 1903(t)(2)(A) to the Social Security Act (42 U.S.C. 1396b).
- ⁶ ARRA, § 4201(a)(2) (adding new section 1903(t)(2)(B) to the Social Security Act (42 U.S.C. 1396b).
- ⁷ ARRA, § 4101(b).
- ⁸ ARRA, § 3004(b)(1).
- ⁹ ARRA, § 4201(a)(2) (adding new section 1903(t)(1)(6)(C)(i)(II) to the Social Security Act (42 U.S.C. 1396b).
- ¹⁰ ARRA, § 4101(a) (adding new section 1848(2)(A)(i-iii) to the Social Security Act (42 U.S.C. 1395w-4).
- ¹¹ ARRA, § 4101(a) (adding new section 1848(2)(A) to the Social Security Act (42 U.S.C. 1395w-4).
- ¹² Social Security Act, § 1890 (42 U.S.C. 1395aaa).
- ¹³ ARRA, § 4101(a) (adding new section 1848(2)(B)(i)(I) to the Social Security Act (42 U.S.C. 1395w-4).
- ¹⁴ ARRA, § 4101(a) (adding new section 1848(2)(B)(i)(II) to the Social Security Act (42 U.S.C. 1395w-4).
- ¹⁵ ARRA, § 4101(a) (adding new section 1848(2)(B)(ii) to the Social Security Act (42 U.S.C. 1395w-4).
- ¹⁶ U.S. Department of Health and Human Services, Health IT Policy Council Recommendations to National Coordinator for Defining Meaningful Use: Final-August 2009, http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_888532_0_0_18/FINAL%20MU%20RECOMMENDATIONS%20TABLE.pdf (accessed December 22, 2009).
- ¹⁷ The Public Health Service Act (PHSA), 58 Stat. 682, 42. 13. U.S.C. 3000(13).
- ¹⁸ ARRA, § 3000(3)(13).
- ¹⁹ The Public Health Service Act (PHSA), 58 Stat. 682, 42. 13. U.S.C. § 300j-33).
- ²⁰ ARRA, § 3001(c)(3)(A).
- ²¹ U.S. Department of Health and Human Services, Health IT Policy Committee August 14, 2009 Meeting Transcript, http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11113_890820_0_0_18/HITpolicy_transcript_081409.pdf (accessed December 22, 2009).
- ²² Jha AK, DesRoches CM, Campbell EG, Donelan K, Rao SR, Ferris TG, Shields A, Rosenbaum S, Blumenthal D., Use of Electronic Health Records in U.S. Hospitals, *N Engl J Med.* 2009 Apr 16;360(16):1628-38.
- ²³ Jha AK, DesRoches CM, Campbell EG, Donelan K, Rao SR, Ferris TG, Shields A, Rosenbaum S, Blumenthal D., Use of Electronic Health Records in U.S. Hospitals, *N Engl J Med.* 2009 Apr 16;360(16):1628-38.
- ²⁴ ARRA, § 4101(a) (adding new section 1848(o)(2)(i) to the Social Security Act (42 U.S.C. 1395w-4).
- ²⁵ ARRA, § 4101(a) (adding new section 1848(o)(1)(iii) to the Social Security Act (42 U.S.C. 1395w-4).
- ²⁶ ARRA, § 4101(a) (adding new section 1848(o)(1)(ii) to the Social Security Act (42 U.S.C. 1395w-4).
- ²⁷ Catherine M. DesRoches, Dr.P.H., Eric G. Campbell, Ph.D., Sowmya R. Rao, Ph.D., Karen Donelan, Sc.D., Timothy G. Ferris, M.D., M.P.H., Ashish Jha, M.D., M.P.H., Rainu Kaushal, M.D., M.P.H., Douglas E. Levy, Ph.D., Sara Rosenbaum, J.D., Alexandra E. Shields, Ph.D., and David Blumenthal, M.D., M.P.P., Electronic Health Records in Ambulatory Care – A National Survey of Physicians, *N Engl J Med.* 2008 July 359:50-60.
- ²⁸ ARRA, § 4201(a)(2) (adding new section 1903(t)(2)(B) to the Social Security Act (42 U.S.C. 1396b).
- ²⁹ ARRA, § 4201(a)(2) (adding new section 1903(t)(2)(A) to the Social Security Act (42 U.S.C. 1396b).
- ³⁰ ARRA, § 3001(b)(2), ARRA, § 3001(b)(3).
- ³¹ ARRA, § 3001(c)(5)(C).
- ³² ARRA, § 3002(b)(2)(B)(vii).
- ³³ ARRA, § 3002(b)(2)(B)(viii).