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Information Technology

Health IT Incentives in Stimulus Law: More Details Needed About What Qualifies

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The Health Information Technology for Economic and Clinical Health Act (HITECH) portion of the American Recovery and Reinvestment Act of 2009 (ARRA)[1] will provide much-desired funding for physicians and hospitals to invest in health information technology (health IT), which many claim will total over $35 billion over the next five years. But HITECH gives a great deal of discretion to the U.S. Department of Health and Human Services (HHS) when implementing the new law and most of the regulations expected under HITECH are still being drafted.

Falling within one of the definitions of eligible provider under HITECH does not assure that a provider will receive incentive payments. Nor does the purchase of a certified electronic health record. HITECH provides for incentive payments to eligible providers only if they meet several other requirements in the new law, many of which are the subject of great debate as HHS drafts regulations. Many unresolved issues will have a significant impact on provider ability to participate in and benefit from the incentive programs. Therefore, it is too soon to make many business decisions about health IT investments if incentive payments are desired.

Under the current timeline final regulations will not become effective until next spring. A notice of proposed rulemaking on meaningful use is expected to be released by the Centers for Medicare & Medicaid Services (CMS) at the end of 2009. There will be a 60-day comment period; then CMS will take time to process comments and issue the final rule. That is expected in mid- to late spring 2010. There is ''no definitive guidance for providers'' before then.[2]

There are several points at which HHS can leverage their discretion to maximize the positive impact of health IT deployment: It can do rulemaking on the definitions related to the technology, *e.g.*, by linking technology requirements and capabilities to improving outcomes. It can provide guidelines for certification categories and processes that enable innovative technologies to be certified as being tools to support desired outcomes, such as patient-centered records to

[1] Pub. L. No. 111-5, 123 Stat. 115-521 (2009).

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[2] National Coordinator for Health IT Dr. David Blumenthal, in a media call Aug. 20, 2009.

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support chronic care management. And there is the development of the ''meaningful use'' requirements on which most of the industry has focused.

The criteria for these requirements will determine the scope of health IT adoption as well as the effectiveness of the federal health IT initiative in achieving the goals of health care reform. Set the bar low, and you likely increase the rate of adoption, but the impact on health care quality and cost could be less. Set the bar high, and adoption will be slower, but the positive impact on health care quality and cost could be greater.

HITECH creates incentives for providers under both the Medicare and the Medicaid programs.[3] While payments will be made for the meaningful use of qualified technology under each program, the programs themselves will be very different. After a brief description of the two programs,[4] the uncertainties that remain regarding meaningful use are outlined.

Brief Description of Funding Sources for Providers Under HITECH

Medicare

For eligible hospitals[5] and physicians treating Medicare patients, there will be an add-on payment to Medicare reimbursement if it is demonstrated that the provider is ''a meaningful EHR user''. Such incentive payments will be calculated as a percentage add-on to the fee schedule amounts paid for covered services in the case of physicians, up to a cap, and as an add-on payment to reimbursement for inpatient care by hospitals, taking into account Medicare share, charity care, and number of discharges. These incentive payments from the CMS may start as early as 2011.

Eligible providers who do not demonstrate that they are ''meaningful EHR users'' by the reporting years established for 2015 and beyond[6] will be subject to a reduction in their Medicare reimbursement, phased in over three years.

Medicaid

HITECH also established an incentive program to be administered by the states through their Medicaid programs. Unlike Medicare, payments may be made for acquisition in the first year, prior to demonstration of use. The timeframes for starting incentive payments under Medicaid are longer—the first payment year may be as far out as 2016 and run up to six years.

In addition, more types of providers are eligible for the incentives. Eligible professionals include non-hospital physicians, dentists, certified nurse midwives, nurse practitioners, and physician assistants in certain FQHCs. All except pediatricians must have 30 percent Medicaid patient volume in order to be eligible, unless they are practicing in an FQHC, where the threshold is 30 percent ''needy'' patients. For pediatricians, the threshold is 20 percent Medicaid patient volume.

Eligible hospitals include acute-care hospitals with at least 10 percent Medicaid patient volume and all children's hospitals. Eligibility does not appear to be limited to ''subsection (d) hospitals'', so this could be an option for any acute-care hospitals not currently eligible under the Medicare incentives program.

Hospitals may participate in both the Medicare and Medicaid programs; individual clinicians must choose one program or the other.

The Medicaid incentives are tied in part to cost. States will get federal funds to provide payments to eligible professionals of up to 85 percent of the provider's ''net average allowable costs'' of health information technology, up to a cap, if such providers demonstrate meaningful use.

For hospitals, the payment calculation is more complex and involves a determination by the state and CMS of the ''overall hospital EHR amount'' calculated for each hospital (which can be based on submitted cost information) and the Medicaid share of the hospital's inpatient bed days.

Another difference from Medicare is that the statute does not impose a penalty for non-use. However, states are not prohibited from requiring the use of technology by Medicaid providers.

There are a number of other requirements and limitations on state administration of their Medicaid health IT incentive programs; states are awaiting guidance from CMS on all of these issues so they can move forward. In addition, it is important to note that while there is a ''meaningful use'' requirement in Medicaid similar to that in Medicare, states may include additional criteria as long as they are not inconsistent with Medicare. For all of these reasons there is a great deal of uncertainty for providers who want to participate in Medicaid incentives.

Other Funding Available under HITECH

In addition to the incentive programs described above, new Section 3011 of the Public Health Service Act (PHSA) gives HHS the authority, through its offices, divisions, or agencies, to use funds under HITECH to ''support . . . (2) Development and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under'' the Medicare or Medicaid incentive programs.[7] The scope of and requirements for such funding, if any, will be included in regulations issued by the Office of the National Coordinator for Health IT (ONC) or one of the other agencies within HHS.[8]

Finally, HITECH requires HHS to provide funding to states to make grants and loans to providers for health IT adoption. This will be in addition to the Medicaid in-

[3] Other funding will be available to providers and health information exchanges through grants to states from the HHS Office of the National Coordinator for Health Information Technology (ONC). It is expected that the policies and criteria adopted through the process described here will be incorporated into those programs.

[4] For more details about the two programs, please see 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 and *healthit.hhs.gov*.

[5] Subsection (d) and critical access hospitals.

[6] Under HITECH, HHS will establish a ''reporting year'' related to each ''payment year''. For example, HHS could require providers to report use in 2010 for payment in 2011 (though it is highly unlikely). This concept gives HHS some flexibility when phasing in use requirements.

[7] HITECH Section 13301.

[8] See http://edocket.access.gpo.gov/2009/pdf/E9-19709.pdf.

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centives program. At this point we have little guidance from ONC on how that program will be operated.[9]

Outstanding Issues Being Addressed by Regulations

There are multiple goals for federal health IT funding, none of which is simply to automate existing health care practice—having an EHR or EMR in every hospital and physician office is not the primary purpose of HITECH. Instead, a review of the purposes of HITECH reveals Congress's strong desire to *change* (read *improve*) the existing health care delivery system.[10] For health IT to have the necessary impact on health care quality and cost, the technology must be capable of certain functions and it must be employed in a manner that supports improvements in care delivery and decision-making, evidence-based medicine, chronic care management, and preventive medicine.

Therefore, Congress made clear that in order to collect incentive payments providers must *use* (not necessarily buy) technology with certain capabilities[11] and such use must be ''in a meaningful manner''.[12] It did not want to specify particular technology and processes, however. While standards are being developed for privacy, security and interoperability, the requirements are to be technology neutral in order not to stifle innovation.[13]

Technology

Because of this, the definition of ''qualified electronic health record'' merits attention. Congress wants to promote the effective use of technology with certain capabilities, but research and experience show that most current widely available health IT systems do not generally support those capabilities.[14] Here, the rules that HHS is writing related to implementing the technology definition in HITECH[15] become important.

How should HHS deal with the obvious competing considerations? If the definition is interpreted to mean more capable technology than currently-deployed commercial electronic health record systems, the incentive programs can be a driver for the development and deployment of technology with the necessary sophistication to support real changes in health care delivery. There is widespread support for this approach among policymakers, including some in the Administration. But such an approach makes qualifying for incentives much harder, more expensive, and more uncertain for providers.

On the other hand, the definition could be interpreted in a way that covers most currently used systems. Providers will more easily qualify and the technology will be less expensive. More money will move out more quickly. In that case, though, advances in technology may be delayed or never developed—and sought-after health care quality improvements and cost reductions

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[9] The announcement for state funding of provider grants and loans is not expected soon. Although ONC recently released funding announcements for regional technical assistance centers and the state health information exchange initiatives, we understand that the next funding announcement is likely to be for workforce programs.

[10] Congress laid out a number of goals for the creation of the National Coordinator's Office and federal investment in health IT:

(b) Purpose.—The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

(4) provides appropriate information to help guide medical decisions at the time and place of care;

(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

(8) facilitates health and clinical research and health care quality;

(9) promotes early detection, prevention, and management of chronic diseases;

(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

(11) improves efforts to reduce health disparities. New PHSA Section 3001.

[11] HITECH: SEC. 3000. DEFINITIONS.

In this title:

''(1) CERTIFIED EHR TECHNOLOGY.—The term 'certified EHR technology' means *a qualified electronic health record that is certified* pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

. . .

(13) QUALIFIED ELECTRONIC HEALTH RECORD.—The term 'qualified electronic health record' means an electronic record of health-related information on an individual that—

(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

(B) 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.

[12] See, for example, the provision applicable to ''eligible professionals'' is at HITECH Section 4101 which added new SSA Section 1848(o), set out at footnote 17.

[13] This was confirmed in a number of conversations with lawmakers and staff as HITECH was being developed. Clearly, Congress wants to fund health IT as a tool for providers, but there is no requirement that all providers buy expensive systems. It is the use for the benefit of the patient that is key, and the technology can be leased or accessed through the web or in some other manner that makes the capabilities available to the clinician.

[14] See, *e.g.*, William W. Stead and Herbert S. Lin, editors; Committee on Engaging the Computer Science Research Community in Health Care Informatics; National Research Council, *Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions*, Jan. 9, 2009, http://www.nap.edu/catalog/12572.html, accessed April 27, 2009.

[15] See footnote 11.

will not be realized. This has to be a consideration for HHS, as the Administration has argued that health IT will yield great savings in the out-years as a justification for the current spending. Those industry leaders and policymakers who would like simply to get the money out fast face a strong counter-argument in this.

Given that context, what is required is first and foremost a record ''on an individual''. That record must have the capacity to perform certain functions required by the statute, but the functions are described in broad terms without much specificity. HHS will have to provide the details related to each element of the definition. What is meant by each of the terms ''clinical decision support'', ''physician order entry'', ''capture and query information relevant to health care quality'', and ''exchange electronic health information with . . . integrate such information from'' must be clarified.

HHS has not created a workgroup to address specifically the technology definition. The issues just described therefore will not be addressed in so straightforward a manner. Instead, the health care and IT industries will have to watch the recommendations of the HHS advisory groups working on health information exchange issues, adoption timelines, technology standards and certification process recommendations, as well as meaningful use criteria, to ascertain where they believe the bar should be set and what capabilities should be required from existing and new information systems.

Even after those recommendations are made, it will still be up to ONC and CMS to write the definitive regulations, with timelines for bringing those capabilities online. In this process, the policy arguments set out above come into play. Therefore, it is very hard to predict the content of regulations on the technology requirements at this time.

Certification

Once the criteria for the technology and other statutory requirements are established, Congress requires that the technology be certified as meeting standards specifically adopted for: privacy and security and use of limited data sets; nationwide exchange of data; utilization of an electronic record by every person in the U.S. by 2014; technology for accounting of disclosures; quality, care coordination, continuity of care, and population health; technology to make data unreadable and unusable (for security purposes); and collection of demographic data.[16]

One of the workgroups advising ONC has recommended changes in the existing process for EHR certification. As part of this, there has been debate about whether one or more entities should be able to certify under the new law, and whether there might be different levels of certification—one handling the certification requirements under HITECH, which are less extensive than commercial certification, and others to meet market demand.

The industry also has been seeking a way for the certification organization(s) to come on line sooner rather than later. However, in a media call on Aug. 20, in response to a question on the timing of decisions about the certification process, National Coordinator for Health IT Dr. David Blumenthal indicated that rulemaking is required to establish the process and ''it will be difficult to have that done by October.'' In the interim, the certification workgroup has proposed a transition plan with a provision for ''gap criteria,'' but how that might work still is being discussed.

Thus, the HITECH certification requirements themselves are also a source of market uncertainty at this point.

Use ''in a Meaningful Manner''

In the last six to eight months, many pages have been written about how HHS should define ''meaningful use'', or use ''in a meaningful manner'', but little has been decided yet.

Not surprisingly, a regular industry has formed around the development of meaningful use criteria and though a thorough review of all of the issues is beyond the scope of this discussion, the complex process that will lead to defining regulations needs to be understood.

The statutory criteria for being a ''meaningful EHR user'' under Medicare are quite skeletal, and essentially require only the following: (1) demonstration that the provider uses a certified EHR in a ''meaningful manner''; (2) demonstration that the technology is connected to provide for data exchange; and (3) submission of clinical quality measures.[17] Parallel requirements will govern Medicaid programs and state grants or loans to providers to invest in health IT.

The lack of detail in the statute elevates the importance of HHS's work to implement the meaningful use requirement. The degree of discretion given to HHS in this regard is intentional.[18] The task is enormous. The scope of proposed health care reforms remains unde-

[16] HITECH Section 13101, which added PHSA 3002(b)(2).

[17] HITECH Section 4101 added to new SSA Section 1848(o) (emphasis added):

''(2) *MEANINGFUL EHR USER*.—

''(A) IN GENERAL.—For purposes of paragraph (1), an eligible professional shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (a)(7), for an EHR reporting period under such subsection for a year) *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 during such period 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, in accordance with subparagraph (C)(i), 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.—Subject to subparagraph (B)(ii) and using such certified EHR technology, 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 under subparagraph (B)(i).

[18] Conversations with congressional staff while HITECH was being drafted confirmed their understanding of the scope and complexity of the issues that need to be resolved in an open process with stakeholder participation. Moreover, implementation through rulemaking provides more flexibility as technology is being developed to meet evolving delivery system improvements.

  HCPR ISSN 1068-1213

termined, yet potential significant changes must be taken into account when establishing capability and use criteria. If not now, there must be the capacity to do so in the future. In addition, the health IT industry continues to evolve, and a balance must be struck among the critical need for resources, reducing barriers to adoption, driving innovation, and assuring the greatest positive impact on improved care quality and cost-effectiveness. There is a lot at stake.

The official process for making these policy decisions about meaningful use and other implementation issues is set out in HITECH. HITECH established a policy body, the Health IT Policy Committee (the Policy Committee), and a standards body, the Heath IT Standards Committee. Both committees have divided work among workgroups, which have been coordinated by ONC.[19] The Health IT Standards Committee and the work groups propose recommendations to the Policy Committee, which then may adopt them and make the recommendations to ONC. ONC then reports directly to the Secretary of HHS.

Accordingly, HHS, through these committees, workgroups, and the National Committee on Vital and Health Statistics (NCVHS)[20], conducted a hearing in April and is developing recommendations specifically for the ''meaningful use'' of technology. Since HITECH was passed, HHS and its agencies and divisions have also received regular comments and recommendations from stakeholders and will continue to do so.

In July, based on recommendations from its workgroups, the Policy Committee adopted a vision and goals for ''meaningful use'' criteria and a nine-page matrix of recommended measures.[21] It is the first specific and significant set of detailed recommendations adopted under the official process related to the meaningful use criteria under HITECH.

The measures are mapped to stated priorities and goals. The priorities are:

- Improve quality, safety, efficiency, and reduce health disparities;
- Engage patients and families;
- Improve care coordination;
- Improve population and public health; and
- Ensure adequate privacy and security protections for personal health information.

These priorities reflect the desire to link meaningful use to the overall goals of HITECH. Yet—are the related objectives and their measures appropriate to the priorities? In other words, do they work? The answer is unclear.

The recommended measures are phased in and increasingly rigorous over time. There are three steps: 2011 Objectives, 2013 Objectives, and 2015 Objectives. In the Policy Committee recommendations, measures related to each of the objectives and goals are set out by ''eligible providers'' and ''hospitals''.

This is a sampling of the meaningful use measures proposed for 2011, where ''[EP]'' means ''eligible providers'' and ''[IP]'' means ''inpatient'':

- Report quality measures to CMS including:
  - -Percentage of diabetics with A1c under control [EP],
  - -Percentage of hypertensive patients with BP under control [EP], and
  - -Percentage of patients with LDL under control [EP];
- Percentage of smokers offered smoking cessation counseling [EP, IP];
- Percentage of orders (for medications, lab tests, procedures, radiology, and referrals) entered directly by physicians through CPOE;
- Use of high-risk medications (Re: Beers criteria) in the elderly;
- Report 30-day re-admission rate [IP];
- Percentage of encounters where med reconciliation was performed [EP, IP];
- Implemented ability to exchange health information with external clinical entity (specifically labs, care summary and medication lists) [EP, IP]; and
- Percentage of transitions in care for which summary care record is shared (electronic, paper, e-fax) [EP, IP].

The matrix is extensive and has been the subject of considerable public comment. The level of detail in the proposed measures (and their related goals and objectives) is valuable in that it provides a proposal to which stakeholders can react with specificity.

For example, the issue of coordinating new requirements with other mandates, such as transition to the next version of Health Insurance Portability and Accountability Act (HIPAA) electronic transactions standards in 2012 and ICD-10 in 2013, still needs to be addressed. All of these changes will consume significant time and resources for providers; complying with ill-timed new meaningful use requirements could greatly exacerbate the burden.

From stakeholder responses to the recommendations, we might conclude that the answer to the question of whether the measures will accomplish the goals might well be ''no.'' Comments from stakeholder groups like the American Hospital Association (AHA) and the American Medical Association (AMA) in response to the overall set of recommendations reflect the complexity of this process and the scope of the issues that still need to be resolved. Many organizations have submitted comments and the examples below from the AHA and AMA are singled out for no other reason than that they demonstrate the scope of stakeholder thinking and level of input into the process of establishing meaningful use criteria.

The depth of concerns with the proposed criteria raised by hospitals is demonstrated by some of their comments. In comments dated June 26, 2009[22], the AHA wrote that the proposed sequence of adoption is overly aggressive, even unrealistic, for most hospitals and urged that initial requirements be set at an achiev-

[19] See, e.g., the Health IT Policy Committee and Health IT Standards Committee web pages, reached by links on http://healthit.hhs.gov/portal/server.pt.

[20] Under the statute, HHS is directed to work with agencies and organizations with existing knowledge and experience on these issues. NCVHS is a public advisory committee to the Secretary of HHS with such knowledge. See http://www.ncvhs.hhs.gov/. NCVHS conducted the public hearing on April 28-29, 2009. The reports from that hearing are on the committee's website.

[21] The documents are at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=35&mode=2&in_hi_userid=11113&cached=true, the Committee webpage; scroll down to the 7/16/2009 meeting documents.

[22] http://www.aha.org/aha/letter/2009/090626-cl-hit-meaningful-use.pdf.

able level. More importantly, AHA recommended six additional functions for EHRs be added to the 2011 requirements so that they can be well established by the time CPOE and high thresholds of EHR use are required. They are: nursing documentation and assessments; electronic access by pharmacists to formularies; medication bar coding; implementing drug-drug, drug-allergy, and drug-formulary checks; maintaining active medication lists; and maintaining active medication allergy lists. The AHA and other hospital groups also raised other very significant concerns that HHS may want to address before regulations are finalized.

Physicians also have issues with the timing and order of criteria implementation, according to the AMA.[23] It begins with the general comment that the definition of meaningful use should be realistic and scalable to accommodate practices with varying IT adoption levels and different capabilities. In addition, criteria for specialties have not been developed, and many physicians might face clinical quality measure requirements that are not applicable to their practice, or core EHR functionality requirements (such as e-prescribing) they do not use and should not have to acquire. The AMA recommends that an outreach plan be established and that information on requirements for demonstrating meaningful use and certification be readily, regularly communicated to physicians and other health care partners well in advance of the 2011 incentive payment start date. This and technical assistance should be available before the requirements become effective.

The AMA developed an extensive list of recommended initial requirements for 2011, designed as a ''pathway'', which it argues should be required only if certain preliminary criteria have been met, such as initial interoperability standards being successfully developed, tested, and adopted. An additional prerequisite is that ''health care partners [be] capable of exchanging the requisite data and that data [be] presented in a way that is understandable to the physician (i.e., a pharmacy benefit manager (PBM) is capable of sharing complete medication history with physicians for their patients and formulary data shared by PBMs can be accepted by EHRs to help physicians select appropriate drug)''. It argues that a physician's ability to comply with meaningful use requirements is dependent on many factors beyond his or her control and that these factors are not taken into consideration in the recommendations.

The comments of AHA, AMA and other stakeholder groups demonstrate that the Policy Committee's recommendations should not be considered the final word on meaningful use criteria. They are strong voices, and many hope that in response HHS will moderate the requirements in the proposed rule. But many policymakers believe this is the best opportunity to promote effective health information systems to achieve health care reforms and could resist diluting the requirements. Either way, it is very likely that a number of changes will be made by the time final regulations are issued.

Though ONC has taken the lead on developing meaningful use criteria recommendations through its Policy Committee, CMS will develop the regulations governing meaningful use under Medicare and will provide guidance to states for the Medicaid program. CMS is participating in the ONC process. ONC and CMS are collaborating in unprecedented ways and there should be consistency in their approaches. It is expected that while CMS will not follow the Policy Committee recommendations completely, they will take them into account.

Clearly, while there are numerous specific recommendations adopted by the Policy Committee, there are still too many outstanding issues around the definition of ''meaningful use'' and too many steps left in the rulemaking process to have any certainty at this point about what capabilities and processes will be sufficient to qualify for incentives.

Demonstration of Meaningful Use

An eligible professional or hospital purchasing certified EHR technology and using it in a meaningful manner also must ''demonstrate'' such use and information exchange in a manner established by HHS. HITECH provides, in the case of physicians:

> (C) DEMONSTRATION OF MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY AND INFORMATION EXCHANGE.—
>
> (i) IN GENERAL.—A professional may satisfy the demonstration requirement of clauses (i) [use of certified EHR technology in a meaningful manner] and (ii) [connected for electronic information exchange] of subparagraph (A) through means specified by the Secretary, which may include—
>
> (I) an attestation;
>
> (II) the submission of claims with appropriate coding (such as a code indicating that a patient encounter was documented using certified EHR technology);
>
> (III) a survey response;
>
> (IV) reporting under subparagraph (A)(iii) [electronic reporting of clinical quality measures]; and
>
> (V) other means specified by the Secretary.
>
> (ii) USE OF PART D DATA.—Notwithstanding sections 1860D-15(d)(2)(B) and 1860D-15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D-15 that are necessary for purposes of subparagraph (A).[24]

A similar provision applies to hospitals.[25]

This aspect of the incentive program presents its own challenges. The documentation requirements must be rigorous to assure the necessary accountability. CMS will have to determine an appropriate methodology, but CMS must also have the capability to handle submissions from providers.[26] In this regard, note a comment made on Aug. 14 by a CMS official that no compliance process (electronic) will be developed that CMS cannot

[23] http://www.ama-assn.org/ama1/pub/upload/mm/472/meaningful-use-attachment.pdf, also available through the AMA HITECH website, http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/health-information-technology/hit-resources-activities.shtml.

[24] PHSA Section 4101(a), which added SSA 1848(o)(2)(C).

[25] PHSA Section 4102(a), which added SSA 1886(n)(3)(C).

[26] HITECH provides: ''(ii) LIMITATION.—The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) [electronic reporting of clinical quality measures] unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.'' SSA Sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii).

  HCPR ISSN 1068-1213

accept. Therefore, the aging infrastructure at CMS will have an impact on timelines for demonstrating meaningful use.

Finally, establishing the requirements for demonstrating meaningful use and information exchange may also await final decisions on the other requirements: certified EHR technology and meaningful use criteria.

Conclusion

Clearly, there are extensive and significant implementation issues that await resolution just around the meaningful use requirement of the new health IT incentive programs. In addition, CMS will have to make final decisions and prepare regulations about other major outstanding issues, such as how to establish and administer program requirements, reporting methodologies, and payments for large group practices, Medicare Advantage providers, and integrated health systems with multiple Medicare provider numbers.

The outstanding issues bear directly on most of providers' business decisions about health IT. The incentive formulas in HITECH can provide a rough estimate, perhaps, of what a provider might expect from the new federal incentives program, at least under Medicare, but other decisions yet to be made will have significant implications for the costs of and benefits from participating in the incentives programs.