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First View of Implementing Regulations Under the Medicare and Medicaid Health IT Programs

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The highly-anticipated proposed regulations for implementing Medicare and Medicaid health information technology (health IT) incentives are out. The incentive programs were created by the American Recovery and Reinvestment Act (ARRA, Pub. L. No. 111-5) in February 2009. ARRA also included authority and funding for other federal and state initiatives to promote the deployment and adoption of health IT and greater health data exchange for the purpose of establishing the information infrastructure necessary to support healthcare reform activities and improved care delivery.

Collectively, the health IT provisions of ARRA are referred to as the Health Information Technology for Economic and Clinical Health Act, or HITECH. The federal investment is unprecedented: for the Medicare and Medicaid programs, spending is anticipated to be more than $40 billion; for the other health IT programs in HITECH, Congress has provided $2 billion. This much money comes with strings attached.

On December 30, the Secretary of the Department of Health and Human Services (HHS) issued two of three coordinated rules – totaling nearly 700 pages – related to the adoption and "meaningful use" of certified electronic health records (EHRs).

The first, an interim final rule prepared by the Office of the National Coordinator for Health Information Technology (ONC), sets forth the initial standards, implementation specifications, and certification criteria for EHRs included in these federally-funded programs. The second, a proposed rule from the Centers for Medicare and Medicaid Services (CMS), covers the mechanics of implementing the Medicare and Medicaid EHR Incentive Programs. These two sets of regulations, along with a third that is still under

development, must be read together to achieve a full understanding of the Administration's initial implementation strategy.[2]

Nearly a year has passed since ARRA established the health IT incentive programs, with much speculation in the industry about how HHS will resolve the multitude of open issues presented by the requirements of the statutes in light of the complexity of the U.S. healthcare industry.

In a telephone briefing the day of release, HHS outlined the basics and rationale underlying the proposed regulations. First and foremost, this is part of a larger comprehensive effort to improve healthcare delivery. ONC and CMS staff stressed collaboration by agency staff to achieve consistency across the programs and maximize the positive impact on healthcare outcomes. Common definitions, methodologies, and timelines will enhance understanding by participating providers and ease the administrative burden for federal and state agencies. As much as possible, Medicare and Medicaid processes are aligned. In addition, the incentive programs are to be coordinated as much as possible with HHS's other health IT initiatives and with state and regional efforts to encourage greater, more effective, and secure health information exchange (HIE).

The most anticipated proposals are those that describe what HHS will require in connection with achieving and demonstrating the "meaningful use" of health IT by providers, as required by HITECH. It is in the CMS rule that we see the meat of the initial proposed meaningful use criteria. The rule proposes three stages to be phased in over the life of the incentive programs. Detailed criteria are proposed for stage 1, and proposed changes outlined for later stages, in order to elicit feedback from the public.

In the related interim final rule on standards and certification, ONC prescribes requirements regarding qualified technology, *i.e.*, what is qualified for certification and therefore eligible for an incentive.

Some important questions have been answered, others have solutions posed in the alternative, and yet others remain open. HHS staff stressed in its press release, each rule preamble, and on the telephone call that these implementing regulations will remain a work in progress over the years.

Many of the issues addressed in the current proposals, however, are foundational to decisions that must be made in the near future by healthcare executives regarding the capability of the technology that must be implemented, the types of use required of clinicians, and the outcomes to be measured. In many ways they will set a course that would be expensive (or even impossible) to change in the future. Thus, policy choices

made now will have deep and lasting effects that will determine the cost, scope, and effectiveness of the federal government's HITECH investment.

HHS therefore is attempting to balance the need to require as much as possible from health IT with both the challenges of broad deployment in a complex environment and the tasks involved in establishing and administering these programs at the federal and state levels. The requirements will become more rigorous over time, as required by HITECH, but HHS states its intention to balance the need for rigor with the ability of the technology to deliver and of providers to implement.

Reactions to the proposed rules are mixed. Perhaps that means HHS has made some choices that don't fall too far on either side of the balance. But the provider community generally has been reserved in their immediate response. And our conversations with teaching hospital representatives in particular reveal some of the particular challenges they still need to have addressed. Other large hospital systems and group practices will have similar concerns, such as the treatment of physicians working in hospital outpatient settings as "hospital-based" and the issue of calculating the payment over multiple facilities. These issues arise because of the challenge of defining national rules for a country of unique providers. There is no question that the level of comment on these proposals will be on a par with the interest and commentary we have seen since ARRA passed.

Comments are due 60 days from the date of formal publication (expected to be January 13, 2010).

This overview will provide an introduction to the proposed regulation and interim final rule just released. The first part provides a high-level overview of the Medicare and Medicaid EHR incentive programs and their requirements, along with a description of how the regulations treat several key issues that have been the subject of great debate as the rules were being developed. The second part summarizes the interim final rule that covers standards, certification criteria, and privacy and security. Because of the length and complexity of the proposals, this summary does not treat the issues comprehensively.

The *Medicare* EHR incentive program will provide incentive payments to (1) eligible professionals (EPs) for up to five years, and (2) eligible hospitals for up to four years if they demonstrate that they are meaningful users of certified EHRs.[3] Throughout this article, EPs and hospitals sometimes are referred to collectively as "providers." Incentive payment amounts are based generally on a percentage of reimbursement for EPs and on Medicare volume for hospitals, with statutory limits. Medicare incentive payments will be made to providers through Medicare contractors. After fiscal year/calendar year (FY/CY)

2015, Medicare providers who do not use certified EHR technology in a meaningful manner will see reductions in their reimbursement rates.

The *Medicaid* EHR incentive program will provide incentive payments to EPs and hospitals for efforts to adopt, implement, or upgrade certified EHR technology or for meaningful use in the first year, and for meaningful use for up to another five years. There will be a 100% federal funds match for state payments to EPs and hospitals as incentive to adopt, implement, and operate certified EHR technology. Medicaid incentive payment calculations are related to technology and implementation costs, with limits based on average costs as proposed in the regulation. There is no statutory starting date (in fact, states may elect to start incentive payments before the Medicare start date), and no penalty under federal law for failure to use qualifying technology. States will determine the process for making Medicaid incentive payments. ARRA also established a 90% federal match for state expenses for administration of the incentive payments and for promoting EHR adoption.

EPs may participate in either program, but not both. Eligible hospitals may participate in both programs if they qualify.

Congress has given HHS a lot of discretion in implementing HITECH. Because both programs will provide payments to EPs and hospitals that use "certified" and "qualified EHR technology" "in a meaningful manner," will require reporting on and documentation of that use, and will have some similarities in the manner of identifying eligible participants and calculating incentive payment amounts, CMS is proposing to define and establish methodologies for these and other aspects of the two programs in as much the same way as possible. The differences between the Medicare and Medicaid health IT incentive programs that exist as a result of fundamental differences in the programs themselves or because of the HITECH statutory requirements are then addressed in separate sections of the CMS proposed rule.

In addition, Congress charged HHS to develop a program for incentives to EPs and hospitals that can be considered affiliated with a Medicare Advantage plan, which the rule covers in another section.

THE PROPOSED RULE

Under Common Provisions below, we outline the CMS proposed regulation provisions that cover definitions and methodologies common to the Medicare Fee-for-Service (FFS), Medicare Advantage, and Medicaid EHR Incentive Programs. Thereafter, we break out and discuss the provisions covering elements specific to each program. In this latter group are found payment calculations by type of provider and other differing provisions.

Common Provisions

Eligible Professionals

A Medicare EP is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, who is legally authorized to practice under state law. A qualifying EP is one who demonstrates meaningful use for the EHR reporting period.

Hospital-based professionals who furnish substantially all of their services in a "hospital setting" are not eligible for incentive payments. CMS proposes that a hospital-based professional be defined as a professional who furnishes 90% or more of his/her allowed services in a hospital, including all hospital inpatient, outpatient, and emergency department settings. This is regardless of the billing arrangement or contractual arrangement between the parties.

A qualifying EP can receive Medicare EHR incentive payments for up to five years, with payments beginning as early as 2011.

Medicaid EPs are physicians, dentists, nurse practitioners, and certified nurse midwives. Physician assistants who practice predominantly in a Federally Qualified Health Center or Rural Health Clinic (FQHC/RHC) directed by a physician assistant also may qualify.

Medicaid EPs must meet patient volume thresholds annually, measured by a ratio of which the numerator is the total number of Medicaid (including Medicaid managed care) patient encounters (or, in the case of eligible professionals practicing predominately[4] at FQHCs and RHCs, needy individual[5] encounters) over any representative continuous 90-day period in the most recent calendar year and the denominator is all patient encounters over that same 90-day period.

For all EPs except pediatricians, the patient volume threshold is 30%; for pediatricians, it is 20%. Like Medicare, there is no provision for determining eligibility or making payments at the group practice level, including for FQHCs and RHCs. So each professional must meet the threshold requirement. CMS proposes to measure this as a minimum percentage of all patient encounters attributable to Medicaid over any continuous 90-day period within the most recent calendar year prior to reporting.

Medicaid EPs also must not be hospital-based. The proposed rule aligns the definition of hospital-based with the Medicare definition.

Under both programs, for the *first* year that an EP applies for and receives an incentive payment, CMS proposes that an EHR Reporting Period be 90 days for any continuous

period beginning and ending within the year. The first year may be no later than 2014 for Medicare and 2016 for Medicaid. For every year after the first payment year, CMS proposes that the EHR reporting period be the entire year. A payment year is a calendar year.

EPs who meet the eligibility requirements for both the Medicare and Medicaid incentive programs may participate in only one program and must designate the program in which they would like to participate. CMS proposes that, after the initial designation, EPs be allowed to change their program selection only once during payment years 2012 through 2014.

Hospitals

An eligible hospital for Medicare incentive payments is a "subsection (d) hospital" that is paid under the hospital inpatient prospective payment system or a critical access hospital (CAH). Hospitals must be located in one of the 50 states or the District of Columbia.

Eligible hospitals may qualify to receive incentive payments for up to four years beginning in FY 2011. FY 2015 is the last year for which an eligible hospital can begin receiving incentive payments for meaningful EHR use.

At page 206, the proposed rule states: "For purposes of this provision [Section 1886(n)], we will provide incentive payments to hospitals as they are distinguished by provider number in hospital cost reports. Incentive payments for eligible hospitals will be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider (also referred to as OSCAR number). Payments to eligible hospitals are made to each provider of record." No examples are provided to clarify this proposed treatment, so there is still a great deal of uncertainty on a key aspect of this program.

HITECH provided for CMS to develop the methodology for CAHs. The proposed methodology is included.

Under Medicaid, hospitals that may participate are acute care hospitals and children's hospitals.

An acute care hospital is defined as a primary healthcare facility in which the average length of patient stay is 25 days or fewer. Hospitals with an average length of stay of 25 days or fewer and a CMS Certification Number (CCN) that has the last four digits in the series 0001 – 0879 are eligible. This specification includes short-term general hospitals and the 11 cancer hospitals in the United States.

Acute care hospitals must have a minimum threshold of 10% Medicaid (including Medicaid managed care) patient volume, measured in any representative continuous 90-day period in the preceding calendar year.

A children's hospital is defined as a separately certified children's hospital, either freestanding or hospital-within-hospital, that has a CCN with the last 4 digits in the series 3300-3399 and predominately treats individuals less than 21 years of age.

A qualifying hospital is an eligible hospital that demonstrates meaningful use for the EHR reporting period during a payment year. A Payment Year is a federal fiscal year.

CMS proposes that, for the first year an eligible hospital demonstrates meaningful EHR use, an EHR Reporting Period equal any 90 continuous days beginning and ending within the year. For every year after the first payment year, CMS proposes that the EHR reporting period be the entire year.

Meaningful Use

Congress specified three requirements for meaningful use: (1) use of certified EHR technology in a meaningful manner (for example, electronic prescribing); (2) the certified EHR technology must be connected in a manner that provides for the electronic exchange of health information to improve the quality of care; and (3) in using certified EHR technology, the provider must submit to the Secretary of HHS information on clinical quality measures and such other measures selected by the Secretary.

With regard to use in a meaningful manner, CMS' proposed rule would phase in criteria for demonstrating meaningful use in three stages, each becoming more robust. Anticipated Stages 2 (for 2013) and 3 (for 2015) will be proposed in future rule making.

The proposed Stage 1 criteria for meaningful use focus on capturing health information in a coded format electronically, using that information to track key clinical conditions, communicating that information for care coordination purposes, and initiating the reporting of clinical quality measures and public health information.

For Stage 1, which begins in 2011, CMS proposes 25 objectives/measures for EPs and 23 objectives/measures for eligible hospitals that must be met to be deemed a meaningful EHR user. CMS does not propose to adopt the complete recommendations from the Health IT Policy Committee, the advisory committee established by ARRA that made recommendations to HHS in the summer of 2009. For the Stage 1 meaningful use criteria, see http://www.federalregister.gov/OFRUpload/OFRData/2009-31217_PI.pdf at page 103 *et seq*.

To qualify as a meaningful EHR user for 2011, CMS proposes that an EP or eligible hospital must demonstrate that they meet all of the Stage 1 objectives and their associated measures. Except as otherwise indicated, each objective must be satisfied by an individual EP as determined by unique National Provider Identifiers (NPIs) and an individual hospital as determined by unique CCNs.

Stage 2 would expand upon the 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 and research, and bi-directional communication with public health agencies. CMS may consider applying the criteria more broadly to both the inpatient and outpatient hospital settings.

Consistent with other provisions of Medicare and Medicaid, Stage 3 would 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.

"Meaningful use" also requires clinical quality reporting by providers. The rule contains extensive discussion regarding this requirement and how CMS proposes to coordinate reporting under this and other quality reporting initiatives. See pages 110 to 163 at the link above.

Documentation of Meaningful Use

Most requirements under the proposed rule will be met by attestation.

Medicare

Payments

With some exceptions, a qualifying EP will receive an incentive payment equal to 75% of Medicare Part B allowable charges for covered professional services furnished by the EP in a payment year, subject to maximum payment limits. In general, the maximum amount of total incentive payments that an EP can receive under the Medicare program is $44,000.

The qualifying EP can receive an annual incentive payment as high as $18,000 if the EP's first payment year is 2011 or 2012. Otherwise, the annual incentive payment limits in the first, second, third, fourth, and fifth years are $15,000, $12,000, $8,000, $4000, and $2,000 respectively. [6] The cap becomes less generous as use is delayed.

Calendar Year	**First CY in which the EP Receives an Incentive Payment**				
	2011	2012	2013	2014	2015 and subsequent years
2011	$18,000				
2012	$12,000	$18,000			
2013	$8,000	$12,000	$15,000		
2014	$4,000	$8,000	$12,000	$12,000	
2015	$2,000	$4,000	$8,000	$8,000	$0
2016		$2,000	$4,000	$4,000	$0
TOTAL	$44,000	$44,000	$39,000	$24,000	$0

An EP who predominantly furnishes services in a geographic Health Professional Shortage Area is eligible for a 10% increase in the maximum incentive payment amount.

Payments under Medicare will be made to individual professionals and disbursed through Medicare Administrative Contractors (MAC) or carriers to the Tax Identification Number provided by the qualifying EP. Provided they meet certain conditions, an EP can reassign the entire amount of his or her incentive payment to one employer or entity.

EPs who are not meaningful EHR users will be subject to lower payment updates for their covered professional services beginning in 2015.

Eligible hospitals can qualify to receive payments from both the Medicare and Medicaid EHR incentive programs.

The Medicare incentive payment for each eligible hospital will be calculated based on:

Incentive Payment Amount equals [Initial Amount] x [Medicare Share] x [Transition Factor]

o Initial Amount equals $2,000,000 + [$200 per discharge for the 1,150th – 23,000th discharge]

o Medicare Share equals *Medicare*/(*Total***Charges)*

Medicare equals [number of Inpatient Bed Days for Part A Beneficiaries] plus [number of Inpatient Bed Days for MA Beneficiaries]

Total equals [number of Total Inpatient Bed Days]

Charges equals [Total Charges minus Charges for Charity Care[7]] divided by [Total Charges]

Transaction Factor for Medicare FFS Eligible Hospitals

Fiscal Year	**Fiscal Year that Eligible Hospital First Receives the Incentive Payment**				
	2011	2012	2013	2014	2015
2011	1.00				
2012	0.75	1.00			
2013	0.50	0.75	1.00		
2014	0.25	0.50	0.75	0.75	
2015		0.25	0.50	0.50	0.50
2016			0.25	0.25	0.25

The annual payment update for inpatient hospital services for eligible hospitals that are not meaningful EHR users will be reduced beginning in FY 2015.

Medicare Advantage

Incentive payments will be made to qualifying Medicare Advantage (MA) organizations for the adoption and meaningful use of EHR technology by their affiliated EPs.

MA-Affiliated EPs are EPs who are employed or subcontracted by an MA organization and on average provide at least 20 hours of patient care services per week. For a subcontracted EP, at least 80% of his/her professional services are furnished to enrollees

of the MA organization. MA organizations will also be subject to payment adjustments if their affiliated EPs are not meaningful users of EHR technology beginning in 2015.

Incentive payments will be made to qualifying MA organizations for the adoption and meaningful use of EHR technology by their affiliated eligible hospitals. A MA-affiliated hospital is an eligible hospital that is under common corporate governance with the MA organization and serves individuals enrolled by the MA plan. With some exceptions, CMS proposes to make incentive payments to MA-affiliated hospitals under the Medicare FFS EHR program. MA organizations will be subject to payment reductions if their affiliated hospitals are not meaningful EHR users beginning in FY 2015.

Medicaid

Payments

Under Medicaid, payments to EPs are based in part on cost. In the rule, CMS proposes the specific maximum allowable cost amounts required by HITECH. They are set at levels that should allow professionals to use several sources of funding and still meet the requirement of the law that they pay directly a portion of the costs of acquisition and implementation.

EPs can receive up to $63,750 over the six year period; pediatricians with Medicaid patient volume between 20% and 29% of their total patient volume can receive two-thirds of the maximum amount. This includes first-year payments for most Medicaid programs for adopting, implementing, upgrading, or meaningfully using certified EHR technology in CY 2011.

Maximum Incentive Payments for Medicaid EPs Who Are Meaningful Users in the First Payment Year

Calendar Year	Medicaid EPs who begin meaningful use of certified EHR technology in--					
	2011	2012	2013	2014	2015	2016
2011	$21,250					
2012	$8,500	$21,250				
2013	$8,500	$8,500	$21,250			

2014	$8,500	$8,500	$8,500	$21,250		
2015	$8,500	$8,500	$8,500	$8,500	$21,250	
2016	$8,500	$8,500	$8,500	$8,500	$8,500	$21,250
2017		$8,500	$8,500	$8,500	$8,500	$8,500
2018			$8,500	$8,500	$8,500	$8,500
2019				$8,500	$8,500	$8,500
2020					$8,500	$8,500
2021						$8,500
TOTAL	$63,750	$63,750	$63,750	$63,750	$63,750	$63,750

The hospital payment calculation under the Medicaid incentive program is analogous to the Medicare payment calculation, substituting the Medicaid share for the Medicare share and including a growth factor. HITECH places some limits on the timing and amounts states can provide for incentive payments.

Unlike Medicare, there is no penalty for non-use of certified EHRs by Medicaid providers after a certain date.

State Activities

The proposed rule provides additional guidance to states regarding the administration of their Medicaid EHR incentive programs.

Promoting EHR Adoption

HITECH allows EPs to assign their incentive payments to their employers or to state-designated "entities that promote the adoption of certified EHR technology." The regulation's definition of such an entity requires the entity to enable oversight of the business, operational, and legal issues involved in the adoption and implementation of EHR and/or the exchange and use of electronic health information between participating providers, in a secure manner.

THE INTERIM FINAL RULE

The interim final regulations issued by ONC provide an initial framework for certified EHR technology and, in particular, establish the required capabilities and standards that such technology will need to include in order to support meaningful use Stage 1 (as described above) by eligible providers and eligible hospitals under the Medicare and Medicaid Incentive Programs.[8] As expected, the regulations are closely aligned to CMS' proposed meaningful use Stage 1 rules and, like those rules, are designed with an incremental approach for compliance. Below we provide an overview of the core components of the new rule, discuss its practicalities, and highlight some areas and issues that provide fertile ground for comment.

Overview

To absorb the implications of the ONC regulations, one must first understand the basic definitions set forth in the rule. The ONC standards follow much of the framework established by the HITECH Act; for example, the standards contain identical definitions of the main framework of the ONC interim final rule, including the core definition, "Qualified EHR." A Qualified EHR is one that (1) includes certain core requirements to identify the individual and provide medical history and (2) has the capacity to (i) provide clinical decision support, (ii) support physician order entry, (iii) capture and query information relevant to quality of care, and (iv) exchange and integration such information.[9] Only a Qualified EHR is eligible to become Certified EHR technology and therefore able to be submitted to CMS as the basis for an incentive payment. Certified EHR technology must (1) meet the requirements of the definition of a Qualified EHR and (2) have 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.[10]

Applicability

As a general matter, the regulations set forth standards, implementation specifications, and certification standards. These rules apply to "Complete EHRs" and "EHR Modules." A Complete EHR is one in which the technology has been developed to meet all applicable certification criteria adopted. An EHR module is one in which "any service, component, or combination thereof can meet the requirements of at least one certification criterion adopted."[11]

An interesting design component to the rule is the acknowledgement of the ability of Certified EHR technology to be either through a "Complete EHR" or by the compiling of several "EHR Modules" that together form an EHR capable of being certified as such. In

explaining the rationale for this approach, ONC states that an "innovative and competitive HIT marketplace needs to exist"[12] and even goes as far as to compare it to the establishment of a home theater, including a television, DVD player, and stereo system, each component purchased from a different manufacturer but still providing a comprehensive package.

Core Components

The standards and implementation specifications are divided into four main components, including (1) transport exchange, (2) content exchange, (3) vocabulary standards, and (4) privacy and security standards. The transport standards are the standards that are used to establish a common, predictable, secure communication protocol between systems. Remember, a main goal of the HITECH Act and the adoption of meaningful use is interoperability of the systems – just as in the Health Insurance Portability and Accountability Act (HIPAA) standard transactions rules, transport between these systems must be in a standard format to promote the widespread use and adoption of electronic health records.

The content exchange standards are the standards that are used to share clinical information such as clinical summaries and prescription information. The content standards have been adopted from a variety of sources and existing standards. The Health Level Seven (HL7) standards, for example, are utilized liberally by the content standards. HL7 is a not-for-profit organization that has been working through the issues related to electronic health records since 1987. HL7 is not the only organization consulted by ONC, but it is representative of many of the kinds of organizations consulted during the development of the interim final rule.

Vocabulary standards establish the standardized nomenclatures and codes sets used to describe clinical issues and procedure, medications, and allergies. The privacy and security standards establish new requirements that are in addition to existing HIPAA privacy and security requirements.

Staging

Each of the content and vocabulary standards and implementation specifications includes staged requirements. Just as in the proposed rule and the stages for meaningful use, the content and vocabulary standards have been outlined with the adopted standard for meeting Stage 1 of meaningful use and proposed or "candidate" standards for meeting Stage 2. There are several standards that do not currently have a standard until Stage 2, so testing and certification will not require implementation of certain standards, although design of an EHR clearly should be prepared with all standards in mind.

The rule also contains several "reserved" sections.[13] While reserved sections are not uncommon in the drafting of regulations, it is important to note that these appear to be designed to accommodate advances in technology. In the content and vocabulary standards, almost every requirement has a standard and an alternate standard; where no alternate appears, there is a spot reserved, signaling the changes that can be expected in the future.

Privacy and Security

As noted above, Certified EHR technology must meet the HIPAA requirements for protecting electronic health information, but the interim final rules add several requirements. First and foremost, there is a requirement that a Certified EHR must encrypt all electronic health information. In a discussion of this standard, ONC has acknowledged that while encryption is an "addressable" requirement in the HIPAA Security Rule, there is a strong interest in the encryption of electronic health information and by requiring encryption its use will become "more prevalent." [14]

The other privacy and security standards articulated include specific standards relative to the maintenance of an audit log to track when changes are made to an EHR, the use of a specified algorithm to verify information was not altered while in transit, and the specifications for cross-enterprise authentication to ensure the correct parties are sharing information.

Under the HITECH Act, a new HIPAA requirement for disclosure accounting was articulated. EHRs must be capable of recording and accounting for all disclosures, including disclosures made for treatment, payment, and healthcare operations, categories previously exempt from the accounting requirements. The effective date for this requirement is January 1, 2011, for any HIPAA covered entity with an electronic health record after January 1, 2009.[15] In addition to tracking each time information is viewed or disclosed in a system, the system must be capable of tracking the "description of the disclosure."[16] A discussion of this requirement is among the most interesting in the preamble. While noting that this requirement is an established standard, there is essentially no guidance for what a description might include when documented. Clearly the more difficult disclosures to describe will be those that fall under "health care operations," however one should not assume that those that fall under "treatment" or "payment" are as simple as they may initially seem.

It appears that no guidance is provided "because the Secretary has not yet weighed the interests of individuals with the administrative burden associated with accounting for such disclosures to determine what information shall be collected."[17] This wording raises several red flags and begs the question of whether there will ever be more guidance on

this standard provided by regulators or whether a de facto standard will be established. The possible ways in which this might be interpreted are wide-ranging, and this is an area in which one might anticipate comments.

Requests for Public Comment

In several areas of the regulations, ONC specifically asks the public for comments. Toward the end of the preamble, ONC requested comments in three areas.[18] ONC expressed interest in comments on whether "specific certification criteria could be adopted to further promote the capabilities Certified EHR Technology should provide" with respect to (1) meeting the accessibility needs of individuals with disabilities and (2) the prevention and detection of fraud, waste, and abuse. [19] The final request for comments in this section of the preamble requested feedback on the "candidate standards" proposed for meeting Stages 2 and 3 of meaningful use requirements. The request for comment was narrowed to feedback on the "Implementation feasibility, maturity and prevalence in the industry."[20]

The ONC regulations will be in effect 30 days from their publication in the *Federal Register*, currently anticipated to be January 13, 2010. Comments should be submitted no later than 60 days from publication.

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[2] The third rule will be a proposed rule from ONC regarding the process for certification of EHR technology.

[3] "Certified EHRs" and "certified EHR technology" are defined in the interim final rule.

[4] CMS proposes "practices predominantly" to mean when the clinical location for over 50% of his or her total patient encounters over a period of six months occurs at an FQHC or RHC. Such professionals are not subject to the hospital-based exclusion.

[5] "Needy individuals" means individuals meeting any of the following three criteria: (1) they are receiving medical assistance from Medicaid or the Children's Health Insurance Program (CHIP); (2) they are furnished uncompensated care by the provider; or (3) they are furnished services at either no cost or reduced cost based on a sliding scale determined by the individual's ability to pay.

[6] This chart reflects no adjustment for Health Professional Shortage Areas. There are adjustments made for EPs who adopt after 2011 – the cap becomes less generous –

which are reflected in the chart. The three charts herein are directly from CMS publications.

[7] If data on charity care are not available, then the Secretary will use data on uncompensated care as a proxy. If the proxy data are also not available, then "*Charges*" will be equal to 1.

[8] This article does not address the historical evolution of the interim final rule, discussion of which is set forth in the background section of the rule. It is noteworthy, however, that the regulations are based, in part, on standards and implementation specifications established by ONC prior to the enactment of the HITECH Act. *See* U.S. Dep't of Health & Human Servs., Office of the Nat'l Coordinator, Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology 23 (Interim Final Rule, Dec. 30, 2009) (hereinafter Interim Final Rule). Moreover, the regulations do not follow any of the previously recognized certification criteria, opting to adopt other certification criteria that would allow the regulations to be aligned with the proposed definition of meaningful use Stage 1. *See id.* at 24.

[9] 42 C.F.R. 170.102

[10] *Id.*

[11] 45 C.F.R. 170.102

[12] Interim Final Rule, page 40.

[13] 45 C.F.R. 170.205 and 45 C.F.R. 170. 299

[14] Interim Final Rule page 83.

[15] HITECH Act section 13405(c)(4), Interim Final Rule page 90.

[16] 45 C.F.R. 170.210(e).

[17] Interim Final Rule page 91.

[18] Interim Final Rule page 93.

[19] *Id.*

[20] Interim Final Rule page 94 of 136.