HCCA

HEALTH CARE COMPLIANCE ASSOCIATION

COMPLIANCE TODAY

Volume Thirteen
Number One
January 2011
Published Monthly

Meet

Paul J. McNulty

Partner, Baker & McKenzie, LLP, former Deputy Attorney General of the United States

PAGE 14

Feature Focus:

2011 OIG Work Plan: Projects reflect shifting regulatory environment

Part 1 – PAGE 20

INSIDE PAGES PRINTED ON 100% RECYCLED PAPER

SEE PAGE 19

Achieving "meaningful use" compliance in the Medicare FFS incentive program

By Janice A. Anderson, JD, BSN and Rebecca L. Frigy, JD, MPH

Editor's note: Janice A. Anderson, Shareholder in the Chicago offices of Polsinelli Shughart PC, has over 25 years' experience focusing on health regulatory and compliance issues and over 30 years' experience working in the health care industry. She may be contacted by e-mail at janderson@polisnelli.com or by telephone at 312/873-3623.

Rebecca L. Frigy is an attorney in the St. Louis offices of Polsinelli Shughart PC. She may be contacted by e-mail at rfrigy@polsinelli.com or by telephone at 314/889-7013.

The American Recovery and Reinvestment Act (ARRA), passed in February of 2009 with the Health Information Technology for Economic and Clinical Health Act (HITECH), established several incentive programs focused on promoting the adoption of electronic health record (EHR) technology: a Medicare Fee-For-Service (FFS) incentive program, a Medicare Advantage (MA) incentive program, and a Medicaid incentive program. (A discussion of the MA and Medicaid incentive programs will be included in future issues.) Although the three programs are separate and distinct, they have many common elements, particularly related to demonstrating and achieving meaningful use. Through these incentive programs, the government anticipates it will make over $20 billion in incentives available to providers who "meaningfully use" certified EHR technology. The incentive programs conceptualized by HITECH will be implemented through several rounds of rulemaking by the Centers for Medicare and Medicaid Services (CMS). The regulations promulgated so far, and those that will be promulgated in the future, set forth the standards that a provider must meet to achieve "meaningful use," the details regarding how incentive payments will be calculated and made, and certain certification criteria that the EHRs used by providers must meet. The Office of the National Coordinator for Health Information Technology (ONCHIT) is the government body charged with establishing the certification criteria for EHRs and health information technology (HIT). Providers must use EHRs that meet such certification criteria to achieve meaningful use; however, merely meeting the certification criteria alone is not enough to qualify as a meaningful user of EHR technology.

Two sets of final regulations related to meaningful use were simultaneously released on July 13, 2010 by CMS and by ONCHIT. The Final Rule from CMS sets forth the criteria required to achieve meaningful use by eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) in the first stage of the incentive programs; the relevant time lines for each incentive program; and the amount of incentive payments that a provider may be eligible for in each program. The details related to the Medicare Fee for Service (FFS) incentive program and a discussion of potential legal pitfalls of the incentive programs are summarized in this article.

The Final Rule creates incentives under the Medicare FFS program (as well as MA and Medicaid programs) for EPs, EHs, and CAHs to adopt and demonstrate meaningful use of certified EHR technology starting in 2011. The first payment year for EPs is any calendar year (CY) beginning with CY 2011; and for EHs and CAHs, it is any fiscal year (FY) beginning in federal FY 2011, which began October 1, 2010. This means that EHs and CAHs may begin qualifying for incentives for payment year 2011 as early as October 1, 2010. Although it is not clear in the regulations, it appears that this does not mean that EHs and CAHs must qualify for incentive payments on October 1, 2010, but rather must qualify for the incentive payments (by meeting all of the meaningful use requirements for a period of 90 days) during federal fiscal year 2011. The Final Rule also includes payment adjustments (penalties) under the Medicare FFS and MA programs for EPs, EHs, and CAHs that fail to adopt and demonstrate meaningful use after 2015.

Medicare incentive payments to eligible professionals

Medicare EPs who may qualify for the incentive by demonstrating meaningful use are doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, or chiropractors who are legally authorized to practice under state law. Under The Final Rule, hospital-based EPs are not eligible to

receive the Medicare incentive payments. By definition, hospital-based EPs furnish 90% or more of their allowed services in hospital inpatient or emergency department settings, including all settings that meet the definition of the main provider, department of a provider, or having a provider-based status.

Under the Medicare FFS incentive program:

- Qualifying EPs are entitled to receive incentives for up to five years, with payments beginning as early as CY 2011.
- No incentives will be paid after CY 2016.
- Incentive payments will be equal to 75% of the Medicare allowable charges for covered professional services furnished by the EP in a payment year, subject to the incentive payment maximums.
- The aggregate maximum amount of total incentive payments that an EP can receive under the Medicare FFS incentive program is $44,000.
- If the EP "predominantly furnishes" professional services (i.e., more than 50%) in a Health Professional Shortage Area (HPSA), the maximum annual incentive amounts are increased by 10%.
- EPs who become meaningful users after CY 2014 will not be eligible to receive incentive payments.

Table 1 shows the maximum incentive payment amounts available each year to EPs in a non-HPSA under the Medicare FFS incentive program.

Table 1

Meaningful Use Established	EP Medicare Incentive Payment						
	2011	2012	2013	2014	2015	2016	Total
2011	$18,000	$12,000	$8,000	$4,000	$2,000	0	$44,000
2012		$18,000	$12,000	$8,000	$4,000	$2,000	$44,000
2013			$18,000	$12,000	$8,000	$4,000	$39,000
2014				$12,000	$8,000	$4,000	$24,000
2015					0	0	0

Beginning in CY 2015, if an EP has not established meaningful use, the Medicare physician fee schedule amount for covered professional services furnished by the EP during the year will be reduced by applying a sliding scale percentage reduction to the fee schedule amount that would otherwise apply. For 2015, an EP who does not meet the meaningful use requirements would receive:

- only 99% of the Medicare fee schedule amount (or if the EP is also not a successful e-prescriber, 98%),
- only 98% for 2016, and
- only 97% for 2017 and beyond.

Under the Medicare Improvements for Patients and Providers Act (MIPPA), with respect to covered professional services furnished by an EP during 2012 or any subsequent year, if the EP is not a successful e-prescriber for the year, the fee schedule amount for such services will be reduced by 1% for 2012; 1.5% for 2013; and 2% for 2014 and each subsequent year. The HITECH Act and The Final Rule do not have any effect on MIPPA; and therefore, these reductions will begin in 2012 as legislated. However, neither MIPPA, nor the HITECH Act and The Final Rule provide that there will be a reduction in the reimbursement amounts that the EP would otherwise have been entitled to receive. Therefore, CY 2015 is the only year in which an EP would face an additional 1% decrease if such EP was not a successful e-prescriber, because in subsequent years, the meaningful use reductions would be equal to or greater than a 2% fee reduction.

Incentive payments under the Medicare FFS incentive program will be made to qualifying EPs in a single, consolidated annual payment through Medicare Administrative Contractors (MAC) or Carriers. Incentive payments will be made on a rolling basis as soon as the MAC ascertains that an EP successfully demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year and a full calendar year for subsequent years). The incentive payments will be made to the Tax Identification Number (TIN) provided by the EP. For EPs associated with more than one practice, CMS requires that the EP select only one TIN to receive applicable EHR incentive payments. EPs are allowed to reassign incentive payments to an employer or an entity with which they have a valid employment agreement or contract providing for such reassignment.

Unlike EHs, which may participate in both the Medicare FFS and the Medicaid incentive programs, EPs may participate in only one program. CMS has proposed to allow each EP to designate its program of choice and to allow the EP to change its designation one time before 2014.

Incentive payments to eligible hospitals

An EH is a hospital paid under the hospital Inpatient Prospective Payment System (IPPS) that is located in one of the 50 states or the District of Columbia. Eligible hospitals do not include psychiatric, rehabilitation, long-term care, children's hospitals, or cancer hospitals, which are excluded from the IPPS. Qualifying CAHs include all certified critical access hospitals.

Under the Medicare FFS incentive program:

- A qualifying EH or CAH may receive incentive payments for up to four years, beginning FY 2011.
- FY 2015 is the last year for which an EH or CAH can begin receiving incentive payments for meaningful use.

Continued on page 32

 ...continued from page 31

- An EH or CAH can qualify to receive payments from both the Medicare and Medicaid EHR incentive programs.
- Incentive payments for EHs and CAHs are calculated based on the provider number used for cost reporting purposes, which is the CMS Certification Number (CCN) of the main provider (also referred to as OSCAR number).

In determining incentive payment amounts, the EH's incentive payment will be based on the hospital's Medicare Part A and MA inpatient bed days, total inpatient bed days, and charges for charity care. In contrast, CAHs can receive incentive payments for the reasonable costs incurred for the purchase of depreciable assets such as computers, hardware, and software necessary to administer certified EHR technology, excluding all depreciation and interest expenses associated with acquisition. The incentive payments received by a CAH will be equal to the product of the CAH's reasonable costs incurred for the purchase of certified EHR technology and its Medicare share percentage. (The Medicare share percentage of a CAH equals the lesser of (1) 100%; or (2) the sum of the Medicare share fraction for the CAH and 20 percentage points.)

CMS will determine incentive payments at the time of settling the 12-month Cost Report for the EH's fiscal year after the beginning of the payment year. The data used will be based on the hospital discharge and other data from that Cost Report period, once the hospital has qualified for meaningful use. Fiscal Intermediaries (FIs) and MACs will calculate incentive payments for qualifying EHs and CAHs, and will disburse such payments on an interim basis, once the EH or CAH has demonstrated meaningful use for the EHR reporting period.

Like EPs, EHs and CAHs that do not meet the meaningful use requirements by FY 2015 and beyond will be subject to penalties in the form of reductions in reimbursement. EHs that do not meet the meaningful use requirements will incur 25%, 50%, and 75% reductions of their market basket updates in FY 2015, FY 2016, and FY 2017 and subsequent years, respectively. CAH reimbursement for those CAHs that fail to meet the meaningful use requirements by 2015 will be reduced from 101% of its reasonable costs to 100.66%, 100.33%, and 100% in the cost reporting periods beginning in FY 2015, 2016, and 2017 and beyond, respectively.

CMS will also conduct selected compliance reviews of EPs, EHs, and qualified CAHs that register for the incentive programs and are recipients of incentive payments for the meaningful use of certified EHR technology.

- uses certified EHR technology to submit information to the Secretary of CMS on specified clinical quality measures and other measures.

The meaningful use criteria will be rolled out by CMS in three "stages" and it is anticipated that each of the stages will build on the criteria in the prior stage. The Final Rule includes the criteria for Stage 1 only, and CMS has not yet proposed criteria for Stages 2 and 3. CMS expects to update the meaningful use criteria on a biennial basis, with the Stage 2 criteria being released by the end of 2011 and the Stage 3 criteria being released by the end of 2013. Depending on the payment year in which an EP, EH, or CAH establishes meaningful use, the provider will have to meet the relevant criteria. Table 2 outlines how CMS anticipates applying the stages of meaningful use criteria in the first years of the program.

Table 2

First Payment Year	Criteria Required by Payment Year				
	2011	2012	2013	2014	2015
2011	Stage 1	Stage 1	Stage 2	Stage 2	TBD
2012		Stage 1	Stage 1	Stage 2	TBD
2013			Stage 1	Stage 1	TBD
2014				Stage 1	TBD

Criteria and incentive timeline for achieving meaningful use

An EP or EH is considered a "meaningful user" of EHR technology and will receive the incentive payments described above, if, during the specified reporting period, it:

- demonstrates use of certified EHR technology in a meaningful manner;
- demonstrates that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information in order to improve the quality of health care, such as promoting care coordination; and

Under the Final Rule, EPs, EHs, and CAHs seeking to achieve Stage 1 meaningful use must be able to meet 14 required criteria objectives for EHs/CAHs and 15 required criteria objectives for EPs, and 5 of 10 optional criteria objectives with their associated measures which are found on a "menu" of 10 optional criteria objectives. The required criteria objectives that an EP, EH, or CAH must meet include:

- Use computerized prescriber order entry (CPOE) for medication orders directly entered by any licensed health care professional;

- Implement drug-drug and drug-allergy interaction checks;
- Generate and transmit permissible prescriptions electronically (EPs only);
- Record certain demographics, including gender, preferred language, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality in the EH or CAH;
- Maintain an up-to-date problem list of current and active diagnoses;
- Maintain an active medication list;
- Maintain an active medication allergy list;
- Record and chart changes in vital signs including height, weight, and blood pressure; calculate and display BMI; and plot and display growth charts including BMI for patients 2–20 years old;
- Record smoking status for patients age 13 years or older;
- Implement one clinical decision support rule related to a high priority condition with the ability to track compliance with that rule;
- Report quality measures to CMS or the states;
- Provide patients with an electronic copy of their health information, including diagnostic test results, a problem list, medication lists, medication allergies, and discharge summaries and procedures upon request (EHs/CAHs only);
- Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request (EHs/CAHs only);
- Provide clinical summaries for patients for each office visit;
- Able to exchange key clinical information among providers of care and patient-authorized entities electronically; and
- Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

EPs/EHs/CAHs also must meet five of the menu set of criteria objectives, including:

- Implement drug-formulary checks;
- Record advanced directives for patients age 65 years or older (EHs/CAHs only);
- Incorporate clinical lab test results into certified EHR technology as structured data;
- Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and research or outreach;
- Send reminders to patients per patient preference for preventive/follow-up care (EPs only);
- Provide patients with timely electronic access to their health information within four business days of the information being available to the EP (EPs only);
- Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient, if appropriate;
- Perform medication reconciliation upon receiving a patient from another setting or provider of care;
- Provide a summary-of-care record for each transition of care or referral if transitioning or referring a patient to another setting or provider of care;
- Able to submit electronic data to immunization registries or immunization information systems and actual submissions in accordance with applicable law and practice;
- Able to report electronic data on reportable lab results to public health agencies (as required by state or local law) and make actual submission in accordance with applicable law and practice (EHs/CAHs only); and
- Able to submit electronic syndromic surveillance data to public health agencies and make actual submission in accordance with applicable law and practice. (Note: The criteria right now is the ability to make these submissions – there are questions related to whether or not the immunization registries and public health agencies all have the ability to receive this type of data electronically right now, and the EP/EH/CAH should not be penalized.)

One of the requirements that must be met in order to achieve "meaningful use" is that the EP, EH, or CAH must use certified EHR technology to submit information to the Secretary of CMS on specified clinical quality measures and other measures. Under The Final Rule, EPs are required to report data on three core quality measures in CY 2011 and 2012: blood-pressure level, tobacco use status, and adult weight screening and follow-up. Some alternate quality measures (to which the above quality measures do not apply) are: weight assessment and counseling for children, influenza immunization, and childhood immunization status.

Notably, to meet the meaningful use requirements, EPs need only report the required clinical quality measures; they need not satisfy a minimum value for any of the clinical quality measures. Additionally, EPs must also choose three other measures (from a list of 38) that it is able to incorporate into its EHRs. Similarly, by payment year 2011-2012, EHs and CAHs will be required to report on each of 15 clinical quality measures that are included in the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU). Again, for EHs and CAHs, the report must only be made and a minimum value need not be satisfied. The 15 RHQDAPU measures are:

- Admitted patients' median time from emergency department (ED) arrival to ED departure;
- Admission decision time to ED departure time for admitted patients;

Continued on page 34

Achieving "meaningful use" compliance in the Medicare FFS incentive program *...continued from page 33*

- Ischemic stroke patients prescribed antithrombotic therapy at hospital discharge;
- Ischemic stroke – anticoagulation for atrial-fib/flutter;
- Ischemic stroke – thrombolytic therapy for patients arriving within 2 hours of symptom onset;
- Ischemic or hemorrhagic stroke – antithrombotic therapy by Day 2;
- Ischemic stroke – discharge on statins;
- Ischemic or hemorrhagic stroke – stroke education;
- Ischemic or hemorrhagic stroke – rehabilitation assessment;
- Venous thrombo embolism (VTE) prophylaxis within 24 hours of arrival;
- Intensive Care Unit VTE prophylaxis;
- VTE anticoagulation overlap therapy;
- VTE platelet monitoring on unfractionated heparin;
- VTE discharge instructions; and
- Incidence of potentially preventable VTE.

To receive incentive payments in payment year 2011, a provider may use an attestation method to submit summary information to CMS relating to each quality measure, rather than submitting such information electronically. However, starting in payment year 2012, in addition to meeting requirements for meaningful use, Medicare EPs, EHs, and CAHs will be required to electronically submit clinical quality measure results (numerators, denominators, exclusions) as calculated by certified EHR technology.

In the first payment year only, a provider need only satisfy the Stage 1 criteria for any continuous 90-day period during the payment year in order to qualify for an incentive payment. After the initial payment year, however, the provider must meet all of the Stage 1 criteria for the entire payment year. This gives providers some leeway in getting EHR technology up and running in FY 2010. However, providers should consider attempting to meet more than the minimum Stage 1 meaningful use criteria from the outset, as CMS has indicated that all Stage 1 criteria objectives, including all "menu" set objectives, will likely be a required in later stages.

Use of certified EHR technology

As described above, in order to achieve meaningful use of EHRs, a provider must use certified EHR technology. In conjunction with the release of The Final Rule, ONCHIT released the Certification Criteria Final Rule, which details the standards, implementation specifications, and certification criteria for EHR technology required for Stage 1 of the incentive programs (Certification Criteria).

The Certification Criteria represent the floor of the EHR technology's capabilities required for the incentive programs; the minimum requirements that EHR technology must meet in order to achieve certification. It is not, however, intended to act as a limit on the use of additional functionality or capabilities of EHR technology generally.

Additionally, it is important to note that the Certification Criteria Final Rule is not intended to specify the conditions under which adopted Certification Criteria must be used. Instead, it specifies the minimum functionality an EHR must demonstrate to attain certification. Certifiable EHR technology need only be capable of demonstrating the ability to comply with the Certification Criteria.

ONCHIT contemplates an evolving list of standards for continued certification going forward. Alterations and updates for subsequent stages (Stages 2 and 3) will be released on a biennial basis with intermediate "Optional Criteria" in the years between (which are expected to foreshadow coming changes in each biennial release). On the horizon, then, will be a series of optional criteria needed for certification preceding each new mandatory stage. This phased-in approach is designed to provide a vehicle for ongoing dialog with ONCHIT and providers, vendors, and the health care community-at-large on the topic of the meaningful use of Certified EHR Technology.

Potential legal pitfalls

As discussed above, it is estimated that CMS will make more than $20 billion in incentive payments to providers that meaningfully use certified EHR technology. Generally, where so much money is available from the government for a specified legitimate purpose, the stage is also set for individuals to inappropriately and fraudulently take advantage of the incentive programs. The three EHR meaningful use incentive programs will likely be no different than any other government program, and fraud is just one of several potential legal pitfalls.

Due to the expected large number of applicants for EHR incentives under the three incentive programs, it seems unlikely that CMS will be able to verify every applicant's assertion of meaningful use compliance. CMS may utilize its existing systems, such as the Provider Enrollment, Chain and Ownership System (PECOS) and National Plan and Provider Enumeration System (NPPES), to verify that applicants fall within a group that is eligible for the incentives in the first place; however, there are no corresponding mechanisms to check whether a provider has achieved compliance with the minimum necessary meaningful use measures. CMS will likely rely on random compliance audits and other verification methods of sampling applicants' compliance with the meaningful use criteria, such as expanding the Recover Audit Contractor (RAC) audits to include meaningful use compliance. This approach leaves it up to each applicant organization to hold itself to the appropriate level of internal oversight when determining compliance, and it is likely that a failure to do so could result in liability and penalties under the False Claims Act.

Additionally, one of the requirements to achieve meaningful use is for the provider to report certain clinical quality indicators to CMS. The Final Rule, however, does not require that a provider meet a minimum level of clinical quality measures. Nonetheless, the use of such clinical quality indicators by CMS to determine whether medical services were appropriately rendered is likely not far off, as CMS will implement Value Based Purchasing in FY 2013.[1] This quality reporting requirement may result in allegations of False Claims Act liability if the quality metrics are not accurate, the services are not rendered, or possibly even if the services rendered are below the standard of care.

Finally, the incentive programs should act as a motivating factor for providers to invest in and adopt the use of EHR technology, particularly given the reduction in Medicare fee schedule payments to providers who do not meet the meaningful use criteria by 2015. Because of this, many EPs will search for sources of funding to help adopt the use of EHR technology. One source of this funding may be the donation of EHR technology by hospitals with which the EP is affiliated. This practice is acceptable under both the Anti-kickback Statute and the Stark Law as long as each donation fits within the applicable EHR donation safe harbor and exception, respectively. Prior to a hospital donating EHR technology to an EP, however, legal counsel should review and approve the arrangement to help ensure that the donation meets all of the requirements of the applicable safe harbor and exception. ■

1 Patient Protection and Affordability Care Act § 3001.

Tankersley named Shareholder

HCCA member Regan E. Tankersley has recently been named a Shareholder at Hall, Render, Killian, Heath & Lyman, a national health law firm with offices in Indiana, Kentucky, Michigan and Wisconsin.