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MEANINGFUL USE AND CERTIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY RULES UNVEILED

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Since passage of the American Recovery and Reinvestment Act of 2009 (ARRA), health care providers have been anxious to learn what "meaningful use of certified electronic health record (EHR) technology" means and how they can receive part of the estimated $27 billion in incentive payments made available under Medicare, Medicare Advantage, and Medicaid. On December 30, 2009, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) provided an initial answer. CMS released a proposed rule (the "Incentive Program Rule")[1] regarding the criteria that eligible professionals (EP), including non-hospital-based physicians,[2] and eligible hospitals (EHs) must meet to qualify for incentive payments, as well as calculation of those payments and penalties for failing to use EHRs. Concurrently, ONC put out an interim final rule (the "EHR Technology Rule") adopting initial standards, implementation specifications, and certification criteria for EHR technology.[3] The proposed rule and interim final rule were subsequently published in the Federal Register on January 13, 2010, and both include sixty-day comment periods. Although the rules answer many questions, physicians, hospitals, and their counsel will likely need more guidance before widespread adoption of EHRs occurs.

The Health Information Technology for Economic and Clinical Health Act (HITECH), which was part of ARRA, established incentives in the Medicare Fee-for-Service (FFS), Medicare Advantage (MA), and Medicaid programs for EPs and EHs to promote adoption and meaningful use of EHR technology that meets certification standards[4] adopted by ONC. The Medicare and Medicaid incentive programs are, however, separate, with different eligibility criteria and incentive payments.

I. Eligibility

CMS has defined an EP as a doctor of medicine or osteopathy, dentist or dental surgeon, podiatrist, optometrist, or chiropractor. Hospital-based physicians, however, are not eligible. The excluded providers include pathologists, anesthesiologists, emergency physicians and any other professional who furnishes at least 90% of his or her professional services in a hospital inpatient or outpatient setting, as determined from Medicare claim point-of-service codes. The only exception is for physicians practicing predominantly in a federally qualified health center (FQHC) or rural health clinic (RHC), who will be eligible for the Medicaid incentive.[5]

Hospitals qualify as EHs if they are "subsection (d) hospitals" that are paid under the hospital inpatient prospective payment system (IPPS).[6] In addition, EHs must be located in one of the 50 states or the District of Columbia.

The MA incentive payments are only available to hospitals and professionals who meet certain MA affiliation requirements. To qualify, EPs must provide at least twenty hours per week of patient care services and either be employed by a qualifying MA organization or an entity that receives at least 80% of its total Medicare revenue from the qualifying MA. Hospitals are eligible for MA incentive payments if they are under common corporate governance with a qualifying MA organization and at least two-thirds of the Medicare beneficiaries at the hospital are enrolled in MA.[7] In addition, the MA organization must pre-identify potential MA EHs in plan year 2011 and then affirmatively identify the MA EHs to CMS on, or before the end of, that federal fiscal year (September 30).[8] If more than one third of a MA-affiliated hospital's Medicare bed-days are reimbursed under the Medicare FFS, then the MA-affiliated hospital will not qualify for a MA incentive payment.[9] Instead, the MA organization will be eligible to receive payments under the FFS incentive program.[10]

EPs potentially eligible for the Medicaid incentive program include physicians, pediatricians, dentists, certified nurse midwives, nurse practitioners, and physician assistants operating at a FQHC or RHC. To qualify for the Medicaid incentive, EPs, except pediatricians, must attest that at least 30% of all their patient encounters in a continuous ninety-day period in the most recent calendar year were with Medicaid patients.[11] Pediatricians need only meet a patient-volume threshold of 20%.

Under the currently proposed rule, only acute care hospitals and children's hospitals may be EHs for the Medicaid incentive program.[12] An acute care hospital is defined as a health care facility (1) with an average length of stay of twenty-five days or fewer and (2) has a CMS

certification number that has the last four digits between 0001 and 0879.[13] Similar to EPs, an acute care hospital must also attest annually that at least 10% of its patient encounters involve Medicaid beneficiaries, as evidenced by any representative, continuous ninety-day period.[14] A children's hospital is defined to include those hospitals with a CMS certification number whose last four digits are in the 3300 to 3399 series.[15] Unlike an acute care hospital, children's hospitals do not have a Medicaid patient encounter test.

If an EP meets the Medicare FFS, MA and Medicaid eligibility criteria, the EP must elect between the incentive programs. Although CMS will allow an EP to change his or her election once during the EHR incentive program,[16] no EP may receive more than the maximum Medicaid incentive payments.[17] Unlike EPs, a Medicaid EH may also receive incentive payments from the FFS incentive program.[18]

II. Meaningful Use

The statute specifies three requirements for meaningful use: 1) use of certified technology in a meaningful manner; 2) electronic exchange of health information to improve quality of care; and 3) submission of information on clinical quality measures to the Secretary for Health and Human Services (the Secretary). CMS has proposed a phased approach to meaningful use of EHRs, with the definition advancing through three stages of increasingly robust criteria.

The initial, or Stage 1, proposed criteria focus on use of the computerized provider order entry (CPOE) functionalities and clinical decision support tools of EHRs to capture health data, track key clinical conditions, and coordinate care of those conditions, as well as electronic provision of information to patients and their families and ensuring privacy and security protections. Although CMS has proposed goals for the second and third stages, the Incentive Program Rule includes only the criteria for Stage 1 and future rules will cover the remaining stages. An EP or EH who seeks to qualify for the FFS or MA incentive must satisfy all of the Stage 1 meaningful use objectives25 for EPs and 23 for EHs. While many of the EP and EH objectives are the same, there are some variations accounting for differences between the outpatient and inpatient settings. To demonstrate that each objective has been met, EPs and EHs must report on a specified measure for each to CMS. These objectives and measures are summarized in Table 2 of the Incentive Program Rule.[19] Until CMS has the capacity to electronically accept data on the measures, EPs and EHs will demonstrate that they satisfy the meaningful use objectives through attestation.

The third element of meaningful use is reporting of quality data to the Secretary (or, for Medicaid, the states). The clinical quality measures captured on Tables 3 through 21 of the Incentive Program Rule[20] consist of process, experience and outcome measures of patient care, observations or treatment that relate to goals for effective, safe, efficient, patient-centered, equitable, and timely care.[21] In proposing the measures, CMS gave preference to measures selected for the Physician Quality Reporting Initiative (PQRI) and the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program, with the goal of aligning quality reporting requirements for meaningful use and the PQRI and RHQDAPU programs and, eventually, having EPs and EHs use EHRs to transmit all quality data to CMS.

Each EP seeking the incentive funds must report on the core measures inquiry regarding tobacco use, blood pressure measurement, and drugs to be avoided in the elderly and the measure set for his or her specialty group (found in Tables 5 through 19 of the Incentive Program Rule).[22] The quality measures for EHs covered in table 20 focus on emergency department throughput, ischemic stroke treatment, VTE prophylaxis and therapy, AMI treatment, readmission prevention, and preventable hospital-acquired infections. Because CMS does not anticipate having the capacity to electronically accept data on clinical quality measures in 2011, it proposes that, at least for the first year, EPs and EHs use an attestation methodology to submit summary information of the quality measures data captured, and calculated, by the EHR technology.

Although CMS has proposed that the Medicaid meaningful use standards and measures be the same as those in the Medicare incentive program, states will have some ability to require providers to demonstrate additional objectives.[23] To add objectives, though, states must first seek approval from CMS.

III. Incentive Payments

A. Medicare

To qualify for a FFS incentive payment, an EP or EH must be a meaningful user of EHR technology during the reporting period, which CMS has proposed as a continuous ninety-day period within the first payment year and the entire payment year for second and subsequent years. The reporting period may begin as early as the first day of the 2011 payment year and as late as the last day in the payment year that allows for the reporting period (ninety days) to be completed.

Following a phased approach, any EP who first adopts an EHR at any time between 2011 and 2014 will only need to satisfy the Stage 1 criteria during their first year of use to obtain the first year's Medicare FFS or MA incentive payment. Those EPs who first adopt and meaningfully use EHRs in 2011 or 2012 are eligible to receive Medicare FFS and MA incentive payments over a five-year period. A

qualifying EP may receive an incentive payment of 75% of Medicare allowable charges during the reporting year , up to a maximum of $18,000 in the first year of meaningful use and up to $44,000 over the term of the incentive program[25]. The annual payment limits decrease between 2011 and 2016, depending on the calendar year of the EP's first meaningful use. Payments will be made to the EP, or his or her employer, by the carriers or Medicare Administrative Contractors. Beginning in 2015, any EP who is not a meaningful user and has not been granted an exception for significant hardship will experience a 1% fee schedule reduction each year, up to a maximum 5% reduction.[26]

Eligible hospitals may receive Medicare incentive payments for only four consecutive federal fiscal years, but incentive payments are available as early as fiscal year 2011. Unlike the Medicare incentive payments for EPs, the EH incentives are not capped at any specific amount and are calculated using a complicated formula that multiplies an initial amount by the EH's "Medicare share" and a "transition factor." The initial amount includes a "base amount" of $2 million and a "discharge related amount" that provides an additional $200 for each of the 1,150th through 23,000th discharges in a cost-reporting period. The Medicare share takes into account the number of the EH's inpatient-bed-days for individuals enrolled in Part A or Part C, as well as the amount of charity care provided by the EH as compared to its total charges. The transition factor reduces the incentive payments over a four-year periodi.e., full payment in year one, three-fourths paid in year two, one-half paid in year three, and one-fourth the fourth year. If hospitals implement after 2013, then the transition factor will be less than 1 for the first year, and fiscal year 2015 is the last year in which EHs may begin participation and still receive an incentive. EHs who are not meaningful users of EHR technology beginning in 2015 and have not been granted an exception for significant hardship will received a reduced market basket update to the IPPS standardized amount, which will equate to one-quarter, one-half, and three-quarters reductions in 2015, 2016, and 2017, respectively.

For the MA-affiliated hospitals, EHR incentive payments may be made under either the FFS or MA incentive program. In both cases, the payment will be made to the MA organization and the payment methodology for the MA incentive program will be identical to the FFS incentive program.[27]

B. Medicaid

EPs and EHs will be eligible for Medicaid incentive payments if they are "engaged in efforts to adopt, implement, or upgrade certified EHR technology"without having achieved meaningful use in the first payment year.[28] EPs and EHs that qualify for an incentive payment in the first year without achieving meaningful use must achieve meaningful use in the second payment year.[29]

Unlike the Medicare incentive program's set payment schedule, the Medicaid incentive payment for EPs is calculated based on the "net average allowable costs" for purchase, implementation, operation, maintenance and use of EHR technology. An EP may receive up to $63,750 over the six-year period from 2011 to 2016.[30]

Medicaid incentive program EHs will be reimbursed by the State for up to 100% of the aggregate Medicaid hospital EHR incentive amount provided over a period of time between three and six years.[31] The actual Medicaid EHR incentive payment for an EH will be determined by multiplying the aggregate Medicaid hospital EHR incentive amount by the percentage of that EH's inpatient, non-charity care days for Medicaid beneficiaries, including Medicaid managed care patients.[32] Additionally, the Medicaid incentive payments will be limited to no more than 50% of the aggregate payment in any given year and no more than 90% of the aggregate incentive payment in any two year period.[33] Medicaid EHs may begin receiving year one payments as late as 2016 and the final year for any Medicaid incentive payment to an EH will be 2021.

IV. Certified EHR Technology

The coordinated efforts of CMS and ONC are most evident in the EHR Technology Rule, which links the certification criteria and standards for EHR technology to CMS's proposed meaningful use objectives. ONC utilized CMS's meaningful use matrix to structure its certification criteria, with the idea that any EHR component must support the achievement of meaningful use in an ambulatory setting (by EPs) or inpatient setting (by EHs).[34] The certification criteria[35] apply only to the capabilities of EHR technology and should not be confused with the performance requirements for EPs found in the Incentive Program Rule.

ONC has given EPs and EHs the option of using a complete EHR that includes all capabilities, or individual EHR technologies, referred to as EHR Modules, that, when integrated, will provide the necessary capabilities for meaningful use.[36] ONC believes that allowing EPs and EHs the option to combine component EHR technologies will permit market innovation; however, EPs and EHs that choose to combine separate EHR technologies will have the extra burden of ensuring that those technologies sufficiently integrate to achieve meaningful use.

ONC's initial set of standards encompass standardized nomenclature (the vocabulary standard),[37] content exchange standards (clinical summaries, prescriptions, etc.),[38] transfer protocols (the transport standard)[39] and privacy and security standards (HIPAA Security Rule as

a starting point).[40] ONC developed the standards as a floor for certification to allow for future innovation.

EHRs in ambulatory settings and inpatient settings have similar but somewhat different certification criteria that reflect the different requirements and capabilities of those practice settings.[41] For example, certified EHR technology for EPs (but not EHs) must be able to generate and transmit electronic prescriptions while certified EHR technology for EHs (but not EPs) must allow for the creation of patient discharge summaries on electronic media.[42]

ONC will propose, in a separate rulemaking, processes to establish the policies for the certification of health information technology and the process a certification organization will need to follow to become an authorized by the ONC to certify EHR technology.[43]

ENDNOTES

[1] Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg 1,844 (Jan. 13, 2010), [hereinafter the Incentive Program Rule].

[2] *See id.* at 1,904-07.

[3] Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2,014 (Jan. 13, 2010), [hereinafter the EHR Technology Rule].

[4] The definition of "eligible hospital" varies among the FFS, MA and Medicaid incentive programs. For example, only certain children 's hospitals and acute care hospitals are eligible for the Medicaid incentive payments and only those MA-affiliated hospitals that meet certain bed-use criteria are eligible for payments under the MA incentive program. *Id.* at 1,930-32, 1,922.

[5] *Id.* at 1,905, 1,930.

[6] Although Maryland hospitals are not paid under the IPPS, CMS has specifically stated that Maryland hospitals will meet the definition of "eligible hospital." *Id.* at 1,911.

[7] *Id.* at 1,922.

[8] *Id.* at 1,922.

[9] *Id.* at 1,922, 1,925.

[10] *Id.*

[11] *Id.* at 1,931. Table 26 provides a quick reference for volume threshold requirements for EP Medicaid incentive eligibility. *Id.* at 1,932.

[12] *Id.* at 1,930.

[13] *Id.* at 1,930. This would include the 11 cancer hospitals in the United States. *Id.*

[14] *Id.* at 1,931-32. Individual States may request CMS to approve an alternative methodology for determining Medicaid patient volume. *Id.*

[15] *Id.* at 1,931. CMS believes that there are only 78 eligible children's hospitals and is considering a broader rule that would include short-term hospitals, rehabilitation hospitals, and psychiatric hospitals that exclusively provide services to patients under the age of 21. *Id.*

[16] *Id.* at 1,907.

[17] *Id.* at 1,904.

[18]18 *Id.* at 1,938.

[19] *Id.* at 1,867-70.

[20] *Id.* at 1,874-1,900.

[21] Detailed technical specifications documents will be published on the CMS web site on or before April 1, 2010.

[22] *Id.* at 1,891-95.

[23] *Id.* at 1,851-52, 1,942-43.

[24] *Id.* at 1,907. MA EP incentive payments will only be calculated based on services provided to enrollees of MA plans and will not include any services by the EP reimbursed by Medicare FFS. *Id.* at 1,923.

[25] *Id.* at 1,908. Table 22 on page 1,908 provides concise information on the incentive payments by year. The incentive payment will be increased by 10 percent for EPs who predominantly furnish services in an area designated by the Secretary as a geographic health professional shortage area. *Id.* at 1,908-10. Tables 23 and 24 provide a quick reference for the funds available to Medicare EPs who predominantly serve an HPSA.

[26] *Id.* at 1,911.

[27] *Id.* at 1,925.

[28] *Id.* at 1,941-42.

[29] Table 32 displays the schedule for compliance with meaningful use under the Medicaid incentive program. *Id.* at 1,944.

[30] *Id.* at 1,935-36. Table 28 provides a summary the incentives available by calendar year of adoption, and Table 29 summarizes the maximum incentive payments. *Id.* at 1,936.

[31] *Id.* at 1,937.

[32] *Id.* at 1,937-38.

[33] *Id.* at 1,939.

[34] EHR Technology Rule, *supra* note 3, 75 Fed. Reg. at 2,024.

[35] *Id.* at 2,025-28.

[36] *Id.* at 2,022-23.

[37] *Id.* at 2,031. Table 2A provides a concise summary of the vocabulary and content exchange standards. *Id.* at 2,033-34.

[38] *Id.* at 2,031-32.

[39] *Id.* at 2,030-31.

[40] *Id.* at 2,034-35.

[41] *Id.* at 2,022.

[42] *See* Table 1, *id.* at 2,036 -27.

[43] *Id.* at 2,017.