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Electronic health record incentive program

The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator rolled out the final rule on the Electronic Health Record Incentive Program on Tuesday, July 13th, 2010.

During the briefing on the final rule, David Blumenthal, MD, the National Coordinator for Health Information Technology (HIT), and Tony Trenkle of CMS summarized the revisions that were made to the rule in an effort to address the numerous concerns of the health care community. CMS received more than 2000 comments on the proposed rule.

The final rule eliminates the “all-or-nothing” criteria in which eligible professionals were expected to meet 25 objectives. Physician associations urged CMS in comments to scale back the criteria because the all-or-nothing approach would be too difficult to achieve, particularly for small practices. The HIT Policy Committee also recommended flexibility in meeting the meaningful use criteria.

For Stage 1, the final rule divides the objectives into a “core” group of 15 required objectives and a “menu set” of 10 procedures from which physicians can choose five and defer the rest. According to CMS, the “two track” approach ensures that the most basic elements of meaningful electronic health record (EHR) use will be met by all providers qualifying for incentive payments while at the same time allowing latitude in other areas to reflect providers’ varying needs and their individual paths to full EHR use.

The core set of requirements includes: (1) Record patient demographics, (2) record vital signs and chart changes, (3) maintain an up-to-date problem list of diagnoses, (4) maintain active medication list, (5) maintain active medication allergy list, (6) record smoking status for patients 13 or older, (7) provide patients with clinical summaries for each office visit, (8) provide patients with electronic copy of health information upon request, (9) generate and transmit permissible prescriptions electronically, (10) computerized physician order entry for medication orders, (11) implement drug-drug and drug-allergy interaction checks, (12) implement capability to electronically exchange key clinical information among providers and patient-authorized entities, (13) implement one clinical decision support rule and ability to track compliance with the rule, (14) implement systems to protect privacy and security of patient data in the EHR, and (15) report clinical quality measures to CMS or states.

Physicians will be required to implement one clinical decision support rule and check compliance with that rule. The proposed rule called for implementing five clinical decision support rules. Also, administrative simplification criteria have been postponed to Stage 2.

In addition, CMS has scaled back the quality reporting requirements. Physicians will have to report data on the following three core quality measures in 2011 and 2012: blood pressure level, tobacco status, and adult weight screening and follow-up; or alternatives if these do not apply. Physicians must choose three other measures from lists of metrics that are ready for incorporation into EHRs.

Blumenthal said that although CMS has scaled back some of the requirements, the overall structure has not changed. The incentive program will be implemented in three stages. As for the timeline, the final rule aligns Medicare and Medicaid program start dates, and key steps in the implementation timeline include:

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- The Office of the National Coordinator for Health Information Technology (ONC) began accepting applications from entities that seek approval as an ONC-Authorized Testing and Certification Body (ONC-ATCB) on July 1, 2010.
- ONC projects that certified EHR software will be available for purchase by hospitals and eligible professionals (EP) by Fall 2010
- Registration by both EPs and eligible hospitals with CMS for the EHR incentive program will begin in January 2011. Registration for both the Medicare and Medicaid incentive programs will occur at one virtual location, managed by CMS.
- For the Medicare program, attestations may be made starting in April 2011 for both EPs and eligible hospitals.
- Medicare EHR incentive payments will begin in mid-May 2011.
- States will be initiating their incentive programs on a rolling basis, subject to CMS approval of the State Medicaid HIT plan, which details how each state will implement and oversee its incentive program.

The EHR incentive program is one part in the electronic transformation of the health care system. The ONC also released the final rule on the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology. On June 24, 2010, the ONC published a final rule to establish a temporary certification program for HIT, and on July 28, 2010, the Office of Civil Rights announced a proposed rule on privacy, security, and enforcement protections under the Health Insurance Portability and Accountability Act.

CMS releases proposed GME changes mandated by health reform law

CMS released a rule July 2, 2010, proposing changes to the Medicare graduate medical education (GME) regulations. The GME provisions are part of a lengthy proposal on policy and payment changes for hospital outpatient departments and ambulatory surgical centers.

Mandated by the Affordable Care Act of 2010 (ACA), these changes would:

- Create a resident redistribution pool whereby 65% of unused residency slots are distributed to hospitals based on an application process. Hospitals receiving the positions must maintain their current number of primary care residents at the average number of those residents over the last three cost reporting years while maintaining no less than 75% of the new slots in primary care or general surgery programs. Priorities would be accorded to hospitals located in states with the lowest resident-to-population ratios, with the highest ratios of population in health professions shortage areas to total population or in rural

areas. This reallocation process would be effective beginning July 1, 2011.

- Modify current requirements for counting residents training in nonprovider (nonhospital) settings. In accordance with the proposal, for direct graduate medical education (DGME) purposes, a hospital could count all the time that residents spend in training regardless of setting if it pays resident stipends and benefits for the time spent in that setting. For indirect medical education (IME) purposes, the hospital could count all time residents spend in patient care activities in a nonhospital setting if it pays stipends and benefits for the time spent there. This provision would be effective for cost reporting periods beginning on or after July 1, 2010, for DGME purposes and for discharges occurring on or after July 1, 2010, for IME purposes.
- Clarifies that, for DGME purposes, a hospital can count all time residents spend in nonpatient care as didactic activities in a nonhospital setting primarily engaged in furnishing patient care. It cannot count time the residents spend in research that is not associated with treatment or diagnosis of a particular patient. This provision would be effective for cost reporting periods beginning on or after July 1, 2009. For IME purposes, the hospital could count all the time residents spend in nonpatient care as didactic activities in the hospital or a provider-based outpatient department, but could not count time spent in research. This provision is since policy is effective starting now going back to that period. For both DGME and IME purposes, hospitals could count all the time residents spend on vacation, sick leave, or other approved leave that does not prolong training time.
- Proposes a process for redistributing resident positions from a hospital that closes on or after two years before the ACA's enactment, with priority given to hospitals in the same or a contiguous area.

Food and Drug Administration's REMS meeting

On July 27-28, 2010, the Food and Drug Administration (FDA) held a public meeting to obtain feedback on issues and challenges associated with development of risk evaluation and mitigation strategies (REMS) for drugs and biological products. The FDA has been implementing the REMS process for more than two years. Since implementation, stakeholders have raised concerns with the agency and the impact of REMS on the health care system and its impact on affected stakeholders, which include prescribers, pharmacists, distributors, and patients.

Major themes include:

- Practicing physicians are excluded from the REMS development process. Future development and design of REMS must include discussion and input from physicians and na-

tional medical societies. A REMS stakeholder advisory committee should be formed to include input from health care providers in the REMS development process. REMS requirements need to be more transparent to all stakeholders.

- REMS should not create or impose additional barriers on patient access to care, particularly in rural and

medically underserved areas. REMS need to be evaluated for their impact on access to care.

- One factor that may affect patient access would be mandatory education for prescribers. If an educational component is determined for REMS, it needs to be developed in conjunction with national medical societies.