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ABOUT THE ACC

Cardiologists, the PINNACLE Registry, and the "Meaningful Use" of Electronic Health Records

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On July 9, 2010, the Secretary of the Department of Health and Human Services approved the final rule for "meaningful use" of electronic health records (EHRs) (1). This rule is important to cardiologists because it specifies the conditions under which physicians may qualify for the federal incentive funding (≤$44,000 per physician under Medicare or ≤$63,750 per physician under Medicaid) for the adoption and use of EHRs. These incentives are authorized under the American Recovery and Reinvestment Act of 2009 (2). In particular, title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act contain the language for these incentives and are known collectively as the Health Information Technology for Economic and Clinical Health (HITECH) Act.

The HITECH Act requires that participating providers meet the following 3 requirements: 1) use of certified EHR technology in a meaningful manner; 2) use of certified EHR technology that is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care; and 3) use of certified EHR technology to submit clinical quality measures to the Centers for Medicare & Medicaid Services (CMS).

The initial proposal from CMS was published on December 30, 2009. The requirements were so onerous that there was skepticism whether physicians and hospitals, other than those who had already made significant investments in health information technology, would be able to qualify at all. Following a vigorous round of more than 2,000 public responses and comments, the final rule incorporated many of the suggested modifications, and the requirements appeared to be much more achievable for the average provider (3). A complementary and equally important rule describing the standards and certification criteria for health information technology was published by the Office of the National Coordinator for Health Information Technology on July 28, 2010 (4).

It is important to note that HITECH does not give incentives to Medicare providers merely for the adoption and use of EHRs. Eligible providers (physicians and others) and hospitals must show significant improvement in health care processes and outcomes through their use of EHRs. "Significant improvement" is as yet undefined, but the concept is clear, and the term "meaningful use" has crystallized into a functional concept with the publication of the final rule.

What does the final rule require for meaningful use of EHRs, and how should interested cardiologists proceed? To qualify for incentives in 2011 and 2012, cardiologists must be sure that their EHR use conforms to 2 sets of objectives. The first set, known as the "core set," consists of 15 objectives that are expected of all eligible providers. The

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Table 1 Electronic Health Record Meaningful Use Objectives, 2010

Core set
Record patient demographics
Record vital signs and measurements
Record problem list
Record medication list
Record medication allergy list
Record smoking status
Provide clinical summaries for patients for each office visit
Provide health information summary for patients on request
Generate prescriptions electronically
Provide computer provider order entry for medication orders
Provide drug–drug interaction and drug–allergy checks
Exchange clinical information electronically among providers and patient-authorized entities
Incorporate 1 clinical decision support rule
Incorporate a system for privacy and patient data security
Report clinical quality measures to CMS
Menu set
Interact with drug formulary
Incorporate clinical laboratory test results as structured data
Generate patient condition-specific lists
Identify patient-specific education resources
Provide medication reconciliation between points of health care
Generate summary of care record for transferred patients
Submit immunization data to immunization registries
Submit surveillance data to public health agencies
Provide reminders to patients for preventive and follow-up care
Provide patients with electronic access to their health information

second set, the "menu set," includes 10 additional objectives. Providers must demonstrate compliance with any 5 of the menu set of objectives to qualify for incentive payments. In succeeding years, all 10 objectives (and perhaps more) will likely have to be met to qualify for subsequent annual portions of incentive payments. Table 1 summarizes these 25 meaningful use objectives. The final rule also provides the details of specific measures that will determine compliance with each objective.

A perusal of the final rule objectives results in the judgment that most are what one would consider standard and expected fare. There are 3, however, that are somewhat radical departures from the status quo and therefore deserve closer consideration. They are: 1) electronic clinical information exchange among providers and patient-authorized entities; 2) clinical decision support (CDS) rules; and 3) clinical quality measures report to the CMS.

Electronic Clinical Information Exchange

This objective is defined in the final rule as the "capability to exchange key clinical information (e.g., problem list, medication list, medication allergies, and diagnostic test results) among providers of care and patient-authorized entities electronically." The term "key clinical information" is defined as "all data needed to diagnose and treat disease, such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests."

The final rule defines "patient-authorized entities" as "any individual or organization to which the patient has granted access to their clinical information." Examples are listed and include insurance companies, entities facilitating health information exchange among providers, and personal health record vendors identified by the patient.

The measure of this objective in 2011 is for the physician to attest to the performance of at least 1 test of the EHR's capacity to electronically exchange information.

The significance of this objective is that it will be an incentive to EHR vendors to work together to provide interoperability among platforms. Historically, EHR vendors have attempted to maintain health information within their corporate proprietary software platform and only allow limited electronic interfaces to be built at great expense. Thus, the absence of interoperability has been a major drawback in the adoption of EHRs, and until now, it has never been to the economic benefit of EHR vendors to allow communication between products. With the electronic exchange of clinical information designated as a meaningful use objective, the terms are reversed. It will now be economically disadvantageous to EHR vendors if their products cannot exchange information seamlessly with other information technology systems. Interoperability will become a competitive advantage, and this should work to the benefit of patients and physicians.

CDS Rules

The final rule lists this objective as the implementation of "one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule." This will be challenging for many EHR vendors who rely primarily on International Classification of Diseases-9th revision, billing codes and not on clinical data sets such as the Systematized Nomenclature of Medicine–Clinical Terms (SNOMED–CT; 5) to build problem lists. The expanded use of SNOMED CT will allow a greater degree of clinical granularity to be built into problem lists to support CDS rules.

The 2011 measurement of this objective is the documentation of the implementation of 1 CDS rule.

The importance with which the Department of Health and Human Services holds this objective is reflected in the proposed rule that initially required 5 CDS rules. Public comment describing the complexity of this requirement led to the reduction of the requirement to 1 CDS rule for 2011. This requirement will likely grow in subse-

quent years. The American College of Cardiology's (ACC's) Appropriate Use Criteria are ideal solutions to this requirement for practicing cardiologists. For example, the appropriate use criteria for cardiac nuclear imaging can be recast as an embedded algorithm that will inform cardiologists at the point of care when the test meets ACC recommended indications (6). Plans are underway to facilitate the incorporation of these criteria into EHRs.

Clinical Quality Measure Report to CMS

The final rule simply states this objective as "Report ambulatory quality measure to CMS." The measurement of this rule differs in the first 2 years of implementation. In 2011, the physician will provide aggregate-level data for the numerator, denominator, and exclusions by attestation. In 2012, the physician will likely be required to electronically submit the data to CMS.

The final rule specifies 44 ambulatory quality measures that can be reported to CMS across a range of disease states. However, a substantial minority (11 of 44) are relevant to cardiovascular practice, including ischemic vascular diseases, hypertension, and heart failure. Thirty of the quality measures have been implemented through CMS's Physician Quality Reporting Initiative (7). All of the cardiovascular disease–associated ambulatory quality measures listed in the final rule are incorporated in the set of performance measures collected in the National Cardiovascular Data Registry (NCDR) and the ACC's PINNACLE (Practice INNovation And CLinical Excellence) Registry (8). In 3 instances (blood pressure control for ischemic vascular disease and hypertension and lipid control for ischemic vascular disease), the cardiovascular quality measures were outcomes measures; however, for the most part, process measures were selected as the cardiovascular ambulatory quality measures listed in the final rule. Process measurements have dominated quality programs to date because of their relative ease of measurement (9); however, it is likely that, as the use of EHRs expands, more outcomes measurements will be added in future iterations of meaningful use.

Implications for the Practice of Cardiovascular Medicine

Overall, we welcome the final rule and its intention to usher medical information management into the 21st century. Our profession's vast file rooms of paper records are no longer just quaint, they are dangerously anachronistic. We also applaud the fact that the government declined the temptation to pile one more unfunded mandate on American medicine's already overburdened back. Although the $44,000 per provider incentive is unlikely to cover the entire cost of the electronic migration, when combined with newfound competition among EHR vendors, we believe it will help overcome much of the inertia for adopting health information technology that our profession has faced in the past.

"Meaningful use" marks a sea change in how the individual physician will practice medicine in the future. It also challenges the large institutions within medicine to adopt innovative information technology with the same speed and appetite that has been characteristic of general industry for the last 2 decades. For the last 10 years, the ACC has worked diligently to prepare the field of evidenced-based medicine within a wired world. Guidelines were written (so many, in fact, that few physicians could be reasonably expected to master their evidence tables without information technology support), performance measures were specified, algorithms were constructed, and large inpatient and outpatient clinical databases were launched. But to date, just gathering the information necessary to make the system of evidence-based medicine work was a Herculean task—often centered on manual data collection. As a result, the ACC's proudest metric of success for the NCDR was the number of records it contained, not the impact it made. In the foothills of the 21st century, that is no longer enough. The ACC continues to work on novel methods to render collected data more actionable as a means of improving the quality of health care.

In the medium term, we believe that "meaningful use" will make clinical data—once rare and valuable—a commodity. Every physician, hospital, and EHR will have it. Leaders of the quality movement, including the ACC, will no longer be judged by the quantity, or even the quality, of their data but how it is used to advance the interests of patients and their physicians. We believe the ACC is already making much progress in this direction, as evidenced by the degree to which our ongoing efforts align with the most forward-looking requirements of "meaningful use." The NCDR, including the ambulatory PINNACLE Registry, is actively capturing data from EHRs and providing institution- and physician-level feedback on guideline adherence. PINNACLE Registry participation, currently offered at no charge to ACC members, allows for automatic collection of data required to calculate 26 performance measures relating to coronary artery disease, heart failure, atrial fibrillation, hypertension, and cardiac rehabilitation. As of December 31, 2010, 64 geographically diverse practices are participating in PINNACLE and are receiving quarterly performance reports. All of these practices have made invaluable contributions to the developmental stages of PINNACLE.

With the deployment of systems–integrator technology, PINNACLE (Practical Innovation and Clinical Experience) data capture is seamlessly woven into the daily workflow of practicing cardiologists—an essential characteristic for widespread participation in this registry. These same data are being submitted to CMS for Physician Quality Reporting Initiative and will likely help qualify eligible providers for meaningful use payments in the coming years. When and if EHR vendors incorporate PINNACLE data collection templates into their software, the need for an external systems–integrator solution will likely diminish. Integrated, electronic appropriate use criteria tools for imaging and revascularization are being piloted around the country, and the Hospital-to-Home Program is a champion for improving the continuity of care—including the continuity of medical information—across the inpatient–outpatient divide. Although PINNACLE functions in the outpatient realm, the entire spectrum of NCDR registries will assist both practitioners and hospitals in meeting meaningful use criteria.

The ACC is also partnering with others to enable the risk prediction models developed within its registries to be executed with patient-specific data and deployed at the time of medical decision making to support safer and more cost-effective care and to improve doctor–patient communication (10). Finally, the ACC is using these data to drive a whole new generation of continuing medical education that combines traditional didactic methods with the rigorous techniques for measuring performance improvement.

As medicine joins the rest of the United States in the information age, let us not be content with mere "meaningful use." Let us instead live up to this unique moment in history and strive for something closer to "maximum benefit" on behalf of our patients and society at large.

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