

## CMS and ONC Issue Final Rules about “Meaningful Use”

Under the Health Information Technology for Economic and Clinical Health (HITECH) provisions of the American Recovery and Reinvestment Act of 2009 (ARRA), eligible healthcare professionals (EP), eligible hospitals (EH), and critical access hospitals (CAH) may qualify for Medicare and Medicaid incentive payments upon the implementation and demonstration of “meaningful use” of certified electronic health record (EHR) technology.<sup>1</sup> Through HITECH, the federal government will make available incentive payments totaling up to \$27 billion over 10 years, or as much as \$44,000 through Medicare and \$63,750 through Medicaid per clinician.<sup>2</sup> The legislation links payments to the achievement of advances in healthcare clinical and quality processes and outcomes.<sup>3</sup>

On July 13, 2010, the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator of Health Information Technology (ONC) released the Final Rules for meaningful use enumerating: (1) the criteria for eligible hospitals and providers to *meaningfully use* health information technology (CMS); and, (2) the certification criteria and standards for EHR technology (ONC).<sup>4</sup> Together, these two rules establish the criteria and technical standards providers must meet to achieve meaningful use of EHR technology and qualify for incentive payments.<sup>5</sup>

The HITECH Act seeks to improve the health of Americans and the performance of the US healthcare system by incentivizing the “*meaningful use*” of EHR’s to achieve the following five healthcare quality and efficiency goals: (1) improve the quality, safety, and efficiency of care while reducing disparities; (2) engage patients and families in their care; (3) to promote public and population health; (4) improve care coordination; and, (5) promote the privacy and security of EHRs.<sup>6</sup>

Pursuant to the HITECH Act, an EP or EH/CAH is considered a meaningful user of EHR if, during the specified reporting period, they:

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

- (3) Use certified EHR technology to submit information to the Secretary of CMS on specified clinical quality measures and other measures.<sup>7</sup>

### *CMS Final Rule- Meaningful Use Criteria*

The Final Rule specifies the criteria and objectives that EP and EH/CAH must achieve in 2011 and 2012 to demonstrate “*meaningful use*” and qualify for incentive payments. The proposed rule, published on January 16, 2010, contained an original requirement for providers to meet 25 specific criteria (23 for hospitals), and received substantial criticism regarding its rigid, “*all-or-nothing*” approach.<sup>8</sup> This proposed rule garnered more than 2,000 responses, many of which suggested that the rule would negatively impact provider participation.<sup>9</sup>

Accordingly, CMS’s Final Rule regarding meaningful use contains several changes to the proposed rule, aimed at making the criteria more readily attainable, while maintaining the overall goals of the HITECH Act and the original implementation timeline. The Final Rule divides the objectives into a “*core*” group of mandatory objectives and a “*menu*” of additional procedures from which providers can choose.<sup>10</sup> By utilizing this “*two track*” approach, CMS hopes to ensure that the most basic elements of meaningful use will be met by all providers who qualify for incentive payments, while allowing flexibility in other areas to account for providers’ diverse needs and individual paths to full EHR usage.<sup>11</sup> The Final Rule addresses the requirements of Stage 1 (2011-2012) of the multi-year incentive program, and the rules addressing Stages 2 and 3 will be released in subsequent years.<sup>12</sup>

As indicated above, the Final Rule includes the core criteria that EPs are required to meet in order to qualify for incentive payments, as well as the EP’s choices in a menu of additional criteria.<sup>13</sup> The Final Rule reduces the clinical criteria measures from the proposed 25 mandatory objectives and associated measures, and replaces them with a lower number of “*core set of objectives with associated measures and a menu set of objectives with associated measures*” from which clinicians can choose. The Final Rule requires that EPs meet 20 total measures; 15 core mandatory measures and an additional five (5) measures from a menu of ten (10) options. The menu options include choices such as

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capacities to perform drug-formulary checks, providing reminders to patients for needed care, identifying and providing patient-specific health education resources, and incorporating clinical laboratory results into EHRs.<sup>14</sup>

CMS also reduced the proposed 23 required measures for EHs/CAHs to 14 core measures plus five (5) from a menu of ten (10) options. Additionally, CMS lowered the rule's proposed 44 required clinical quality measures to six (6) quality measures for EPs and 15 quality measures for both EHs and CAHs.<sup>15</sup>

In Stage 1, the criteria for meaningful use focuses on: "(1) electronically capturing health information in a coding format; (2) using that information to track key clinical conditions; (3) communicating that information for care coordination purposes; and (4) initiating the reporting of clinical quality measures and public health information."<sup>16</sup> The set of core objectives represent an essential starting point for meaningful use of EHRs and encompass basic functions that facilitate EHRs ability to support improved health.<sup>17</sup> Some of these core functions address the tasks essential to creating any medical record, including entering basic data (i.e. patient vital signs and demographics, up-to-date lists of current and active diagnoses, active medications and allergies, and smoking status).<sup>18</sup> Other meaningful use core objectives include using software applications that aid EHRs in the improvement of safety, quality, and efficiency of care, as well as using records to enter clinical orders and medication prescriptions.<sup>19</sup>

The HITECH legislation also includes quality objectives that must be met to satisfy the meaningful use standard. In addition to the clinical criteria, the Final Rule requires clinicians to report data on three core quality measures in Stage 1: (1) blood-pressure level; (2) tobacco status; and (3) adult weight screening and follow-up.<sup>20</sup> However, the Final Rule allows alternative quality measures for instances where these three Stage 1 quality measures do not apply. Additionally, clinicians must choose three other measures from a menu of 38 metrics to be incorporated into EHRs.<sup>21</sup>

#### *ONC Final Rule- The EHR Technology Certification Criteria*

The ONC concurrently released the Certification Criteria Final Rule together with CMS's Final Rule. ONC's Final Rule related to meaningful use, which establishes

the required capabilities and standards, implementation specifications, and the certification criteria that EHR technology must meet to support the successful adoption of Stage 1 Meaningful Use.<sup>22</sup> The ONC Final Rule states: "*Developers of EHR technology who design their EHR technology in accordance with the Final Rule and subsequently get their EHR technology tested and certified by an ONC authorized testing and/or certified entity are assured that their EHR technology can be adopted by eligible healthcare providers who seek to achieve meaningful use.*"<sup>23</sup>

Providers' approach to meaningful use may impact their future interactions with regulators, private payors, and competitors. Providers must consider how to strategically select a vendor and implement an EHR system that not only meets the various meaningful use criteria, but also positions the provider to adapt to the ever-changing competitive, regulatory, reimbursement, and technology landscape of the healthcare industry.

<sup>1</sup> The American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111-5

<sup>2</sup> "The 'Meaningful Use' Regulation for Electronic Health Records" By David Blumenthal and Marilyn Tavenner, New England Journal of Medicine, www.NEJM.org, <http://healthcarereform.nejm.org/?p=3732> (Accessed 07/20/2010)

<sup>3</sup> "The 'Meaningful Use' Regulation for Electronic Health Records" By David Blumenthal and Marilyn Tavenner, New England Journal of Medicine, www.NEJM.org, <http://healthcarereform.nejm.org/?p=3732> (Accessed 07/20/2010)

<sup>4</sup> "CMS and ONC Final Regulations Define Meaningful Use and Set Standards for Electronic Health Record Incentive Program," Center for Medicare and Medicaid Services. July 13, 2010. <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3787&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cbOrder=date>. (Accessed 07/20/2010).

<sup>5</sup> "CMS and ONC Final Regulations Define Meaningful Use and Set Standards for Electronic Health Record Incentive Program," Center for Medicare and Medicaid Services. July 13, 2010. [http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3787&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&](http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3787&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cbOrder=date)

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**Robert James Cimasi**, MHA, ASA, FRICS, MCBA, AVA, CM&AA, serves as President of **HEALTH CAPITAL CONSULTANTS (HCC)**, a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including: valuation consulting and capital formation services; healthcare industry transactions including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and, certificate-of-need and other regulatory and policy planning consulting.

Mr. Cimasi holds a Masters in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA – American Society of Appraisers); Fellow Royal Intuition of Chartered Surveyors (FRICS – Royal Institute of Chartered Surveyors); Master Certified Business Appraiser (MCBA – Institute of Business Appraisers); Accredited Valuation Analyst (AVA – National Association of Certified Valuators and Analysts); and, Certified Merger & Acquisition Advisor (CM&AA – Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics, the author of several books, the latest of which include: *“The U.S. Healthcare Certificate of Need Sourcebook”* [2005 - Beard Books], *“An Exciting Insight into the Healthcare Industry and Medical Practice Valuation”* [2002 – AICPA], and *“A Guide to Consulting Services for Emerging Healthcare Organizations”* [1999 John Wiley and Sons].

Mr. Cimasi is the author of numerous additional chapters in anthologies; books, and legal treatises; published articles in peer reviewed and industry trade journals; research papers and case studies; and, is often quoted by healthcare industry press. In 2006, Mr. Cimasi was honored with the prestigious *“Shannon Pratt Award in Business Valuation”* conferred by the Institute of Business Appraisers. Mr. Cimasi serves on the Editorial Board of the Business Appraisals Practice of the Institute of Business Appraisers, of which he is a member of the College of Fellows.



**Todd A. Zigrang**, MBA, MHA, ASA, FACHE, is the Senior Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where he focuses on the areas valuation and financial analysis for hospitals and other healthcare enterprises. Mr. Zigrang has significant physician integration and financial analysis experience, and has participated in the development of a physician-owned multi-specialty MSO and networks involving a wide range of specialties; physician-owned hospitals, as well as several limited liability companies for the purpose of acquiring acute care and specialty hospitals, ASCs and other ancillary facilities; participated in the evaluation and negotiation of managed care contracts, performed and assisted in the valuation of various healthcare entities and related litigation support engagements; created pro-forma financials; written business plans; conducted a range of industry research; completed due diligence practice analysis; overseen the selection process for vendors, contractors, and architects; and, worked on the arrangement of financing.

Mr. Zigrang holds a Master of Science in Health Administration and a Masters in Business Administration from the University of Missouri at Columbia, and is a Fellow of the American College of Healthcare Executives. He has co-authored *“Research and Financial Benchmarking in the Healthcare Industry”* (STP Financial Management) and *“Healthcare Industry Research and its Application in Financial Consulting”* (Aspen Publishers). He has additionally taught before the Institute of Business Appraisers and CPA Leadership Institute, and has presented healthcare industry valuation related research papers before the Healthcare Financial Management Association; the National CPA Health Care Adviser's Association; Association for Corporate Growth; Infocast Executive Education Series; the St. Louis Business Valuation Roundtable; and, Physician Hospitals of America.



**Anne P. Sharamitaro**, Esq., is the Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where she focuses on the areas of Certificate of Need (CON); regulatory compliance, managed care, and antitrust consulting. Ms. Sharamitaro is a member of the Missouri Bar and holds a J.D. and Health Law Certificate from Saint Louis University School of Law, where she served as an editor for the *Journal of Health Law*, published by the American Health Lawyers Association. She has presented healthcare industry related research papers before Physician Hospitals of America and the National Association of Certified Valuation Analysts and co-authored chapters in *“Healthcare Organizations: Financial Management Strategies,”* published in 2008.