



March 12, 2010

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Subject: RIN 0991–AB58; Comments of the American College of Radiology, Radiological Society of North America, and Society for Imaging Informatics in Medicine

On behalf of the American College of Radiology (ACR)¹, American Board of Radiology (ABR)², Radiological Society of North America (RSNA)³, and the Society for Imaging Informatics in Medicine (SIIM)⁴, we appreciate the opportunity to comment on the Office of the National Coordinator for HIT's (ONC) Interim Final Rule (IFR) regarding the initial set of standards, implementation specifications, and certification criteria for electronic health record (EHR) technology as applied to the radiology community.

We estimate that approximately 74 percent (or over 22,200) of 30,000 post-training professionally active radiologists perform some of their services outside of the hospital setting, and thus would be "eligible professionals (EPs)" for the meaningful use incentives program. Furthermore, most radiologists participate extensively in the Medicare program due to the general age demographic of patients in need of diagnostic imaging. As diagnostic radiologists will be among the most impacted by Medicare incentives and penalties, it is imperative that "certified EHR technology" be defined in such a way that is clinically relevant to the practice of radiology.

¹ The **American College of Radiology (ACR)** is a professional organization representing more than 36,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists. ACR works collaboratively to maximize the value of radiology, radiation oncology, interventional radiology, nuclear medicine, and medical physics while making imaging safe, effective, and accessible to those who need it.

² A Member Board of the American Board of Medical Specialties, the **American Board of Radiology (ABR)** examines and certifies the nation's practicing diagnostic radiologists, radiation oncologists, and radiologic physicists. In its 76-year history, the ABR has certified more than 66,000 individuals. More recently, under guidelines adopted by the ABMS, ABR's Maintenance of Certification (MOC) program has been developed to assure the public of the high quality of care and continuous professional development of ABR diplomates. Indeed the mission of the ABR is to serve patients, the public, and the medical profession by certifying that its diplomates have acquired, demonstrated, and maintained a requisite standard of knowledge, skill, and understanding essential to practice.

³ The **Radiological Society of North America (RSNA)** is a professional membership society committed to excellence in patient care through education and research. More than 40,000 medical imaging professionals are members of RSNA, including radiologists, radiation oncologists, medical physicists and allied scientists.

⁴ The **Society for Imaging Informatics in Medicine (SIIM)** is devoted to advance computer applications and information technology in medical imaging through education and research. SIIM membership exceeds 2,200 individual, 90 institutional, and 35 corporate members.

General Comments

Historically, radiology has been the forerunner in the physician community in terms of adoption and innovation of health information technology (HIT) and health information exchange (HIE) because of the specialty's natural reliance on technology and data sharing. The radiology community created what became DICOM—a standard for communication of digital image information which is currently implemented by almost all imaging device manufacturers—throughout the 1980s and culminating in 1993; as well as Integrating the Healthcare Enterprise (IHE) initiative in 1997, which later branched out to other areas in medicine. Radiology boasts the most widespread HIT adoption of any specialty, with Radiology Information Systems (RIS) and/or Picture Archiving and Communication Systems (PACS) already implemented in the vast majority of hospitals and practices. Radiologists understand firsthand how technology can contribute to improved patient care outcomes, and encourage HIT adoption by colleagues in all sectors of the medical community.

In the following comments, we propose specific ways ONC could improve its rule on the standards, specifications, and certification criteria for EHR technology so that the definition of “certification EHR technology” would be reflective of radiology's unique HIT needs.

“EHR Modules” versus “Complete EHRs”

We applaud ONC's creation of the concept of certified “EHR Modules” as a way to broaden the appeal of HIT adoption to all EPs. Medical specialists use various modular HIT products designed specifically for their respective practice management and patient data needs. ONC's “EHR Module” concept reflects the desire of Congress to proliferate the use of EHR technology in general, beyond merely the comprehensive EHR products that have limited clinical utility for specialists.

Earlier in these comments, we discussed the widespread proliferation of RIS and PACS products in the radiology community. RIS products commonly feature functionalities such as scheduling and assessment, patient list management, workflow management, request and document scanning, results entry, reporting, clinical report transmittal, tracking, modality and media/agent management, and more. PACS products offer image storage, retrieval, distribution, and presentation options, including providing patients with digital copies of their diagnostic imaging studies. Neither line of radiology HIT products would meet the ONC's definition of a Complete EHR; however, many of these modular products provide for diagnostic radiology's HIT needs.

The challenge is that while these radiology modules cover the various HIT functionalities needed by diagnostic radiologists, they do not cover all of the ONC's certification criteria. Thus, radiologists would need to add other EHR Modules for which they have no clinical use to their combination of modules in order to receive Medicare/Medicaid incentives and avoid penalties.

“Certified EHR Technology”

In our comments to CMS on the corresponding proposed rule, we argued that individual EPs should choose the specific HIT functionality measures they need, as all 25 HIT functionality measures are not clinically relevant to all EPs. Likewise, we strongly disagree that a “proper combination” of multiple certified EHR Modules should cover all certification criteria listed in

the IFR before being considered “certified EHR technology.” **Instead, a proper combination of certified EHR Modules should only need to cover the specific certification criteria that correspond with HIT functionality measures that are applicable to the individual EP.** If a physician does not order services, that physician should not need to add an EHR Module that covers the computerized order entry-related certification criteria. If a physician does not have a need for transmission of prescriptions, that physician should not need an eRx EHR Module. In other words, EPs should only need to incorporate into their combination of EHR Modules those particular modular products that they would normally use.

Vocabulary Standards

Radiology has a standard terminology, RadLex, which unifies and supplements other lexicons and standards, such as SNOMED-CT and DICOM, and is currently supported by the National Institutes of Health. Just as ONC recognizes LOINC for lab-tests, we strongly recommend that ONC recognize RadLex as the adopted vocabulary standard for radiology.

Future Considerations: Radiation Dose, Image Sharing, and CPOE/CDS

There is an immediate need for including radiation dose data in a structured form within the patient’s electronic record. Capturing radiation dose data must be a core meaningful use requirement for all EPs who provide radiologic procedures, including non-radiologists, and the functionality to do so must be included in the ONC’s certification criteria for EHR technology. ONC and CMS should leverage the programs and expertise of the ACR, RSNA, and SIIM—which, among their numerous initiatives and programs, including the ACR Dose Index Registry (DIR)—to best incorporate radiation dose data. All available radiation dose data must be accessible to, and considered by, referring physicians during the ordering process in the form of CDS. Referring physicians have a responsibility to ensure all radiologic procedures they order for their patients are necessary and provide a probable benefit that outweighs the risk.

We recommend that ONC and CMS explore image sharing in the Stage 2 and Stage 3 rulemakings. Currently, the exchange of diagnostic images often requires a physical medium, such as a CD or DVD, to be printed and given to patients for sharing with other providers. There is a need within the patient and provider communities for a more transparent paradigm of interoperability via electronic exchange of diagnostic images, which would reduce radiation risk and costs by eliminating duplicative procedures if providers have immediate access to patients’ existing images and reports. Any discussion of HIE facilitated by EHR technology should also include radiology considerations, such as the ability to export and import patient image data amongst providers and personal health records using Integrating the Healthcare Enterprise (IHE) profiles. This is an area in which the radiology community continues to make headway, and the associated standards (DICOM and XDS) are already well established. We support leveraging and extending the work of IHE in radiology and across other clinical and infrastructure domains to establish effective interoperability and exchange of health information.

Also in Stage 2 and Stage 3, CPOE for radiology services should inherently include CDS to provide real-time, actionable, evidence-based guidance to ordering physicians about the appropriateness of any requested imaging procedures based on the clinical scenario/indications. This feedback should be drawn from authoritative and transparent sources, such as ACR Appropriateness Criteria, and should consider both standard procedure descriptions and clinical

scenario assertions (i.e., signs, symptoms, known diagnoses, demographics, co-morbidities). Optimally, the source and strength of the evidence should be transparent and accessible to the ordering physician at the time of clinical decision making. These radiology order entry systems with integrated clinical decision support capabilities exist now and directly target the imaging overutilization concerns expressed by the HIT Policy Committee and others in the federal government.

Closing

In summary, the “certified EHR technology” definition must support radiology’s scope of practice to the extent possible, as it should for all EPs. The ONC’s conception of the “EHR Module” is an excellent start, but the requirement that a proper combination of EHR Modules must cover all certification criteria does not make clinical sense. It is imperative that a solution be implemented whereby EPs can adopt only those EHR Modules that cover those certification criteria that are relevant to their practice needs, and not be forced to adopt extra EHR Modules that are not useful in order to have a proper combination of products that meets the ONC’s definition of “certified EHR technology.”

As always, the radiology community welcomes the opportunity for continued dialogue with ONC and CMS on all topics related to HIT and HIE in radiology. Please contact Michael Peters, ACR Assistant Director of Regulatory and Legislative Portfolio, at 202-223-1670 / mpeters@acr.org if our organization can be of assistance.

Sincerely,



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