



QUALITY IS OUR IMAGE

July 3, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: (Docket No. FDA-2014-N-0339; 79 FR 19100) Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology Report; Comments of the American College of Radiology

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we appreciate the opportunity to comment on the Food and Drug Administration (FDA), Federal Communications Commission (FCC), and Office of the National Coordinator for HIT (ONC) report to Congress, “FDASIA Health IT Report: Proposed Risk Based Regulatory Framework” (April 7, 2014). The following comments were compiled by the ACR Commission on Informatics-Government Relations Committee.

General Comments

FDA’s Role in Regulating Health IT

The ACR agrees with the three-tier, risk-based categorization of IT functionality in the proposed framework. Additionally, the ACR agrees with FDA’s proposed approach to only regulate “medical device IT functionality” without engaging in new, previously unregulated areas. We believe the clear messaging within the report provides ample assurance to the stakeholder community that innovation will continue as before without additional oversight from FDA, while at the same time, empowering the industry and others to engage in safety enhancement activities for the “health management IT functionality” category.

Transparency and Representativeness of Non-Regulatory Safety Enhancement Activities

The proposal in the report for the middle category of “health management IT functionality” is that it would be subject to safety enhancement activities through ONC-coordinated initiatives, the future Health IT Safety Center, private sector initiatives, and additional public-private collaborations. We recommend that those activities be fully transparent to the public and representative of all stakeholders, including end-users. Moreover, we recommend that related ONC federal advisory

committee workgroups, the HIT Safety Center’s leadership board, and other pertinent advisory bodies include several voting positions for non-primary care specialists and specialty IT representatives. Finally, the professional organizations and standards groups that represent specialized stakeholder communities at the national level should be proactively targeted for meaningful input by ONC and the HIT Safety Center via specialty-centric workgroups, “town hall” listening sessions, and other engagement efforts.

Evaluating/Testing “Interoperability”

The ACR agrees that “interoperability” of data, players, systems, product types, products, etc., contributes to patient safety. ONC-coordinated and/or private sector activities should continue to explore ways to promote interoperability and the ease of health information exchange activities.

While a private sector approach could influence technical/standards issues related to interoperability, it is imperative for regulatory agencies under HHS—particularly ONC through the EHR technology certification criteria regulations, and the Centers for Medicare and Medicaid Services (CMS) and HHS Office of Inspector General (OIG) through the self-referral/anti-kickback regulations—to tackle some of the nontechnical drivers behind insufficient interoperability and exchange. CMS and OIG made significant advances in the 2013 rules to renew and revise the EHR exception/safe harbor from self-referral/anti-kickback requirements. Moving forward, rigorous and proactive enforcement is needed.

Also, quality incentive/measurement programs, including the Medicare/Medicaid EHR Incentive Program, should be leveraged to discourage anti-competitive behavior employed by those who intentionally or unintentionally misuse technology to contain patient referrals for specialist services within a dominant regional health system or hospital. HHS and the HIT Safety Center should use all available levers of influence to prohibit denying or taxing connectivity between referring physicians and specialists who use competitors’ products, and between those who work in competing practices.

Finally, steps should be taken through ONC’s EHR certification criteria regulations and/or other levers to ensure that all EHR data is available to the clinical decision support (CDS) functionality in the same, or accompanying, system. CDS functionality within a given EHR system can sometimes be cut-off from accessing additional data. Intra-system openness and interoperability is critical to enabling innovation and evolution of CDS and quality measurement functionality. I.e., certain data elements not needed for certain functionality today, might be important for that functionality to work even better (and safer) tomorrow.

ACR Answers to Report Questions

Create an Environment of Learning and Continual Improvement (pages 22-25)

Q: What should be the governance structure and functions of the Health IT Safety Center, in order for it to serve as a central point for a learning environment, complement existing systems, facilitate reporting, and promote transparent sharing of adverse events, near misses, lessons learned, and best practices?

A: The first point of order for ONC in putting together the basic infrastructure of the HIT Safety Center should be to release a call for nominations for an autonomous (though still publicly accountable) board of governors or similar executive leadership body. The Center’s board should be comprised of a representative sample of physician specialists, other physicians, hospitals/providers, allied health workers, patient groups, privacy/security advocates, standards organizations, and various HIT industry representatives. The board, informed by proactive and continuous public engagement, should devise and implement a dynamic resource repository and non-punitive adverse event reporting paradigm, as well as other HIT safety-oriented activities. All deliberations of the board and its subgroups should be public, except if a discussion would compromise the non-punitive nature of adverse event reporting.

Q: What role should government play in creating an environment of learning and continual improvement for health IT?

A: After setting up the infrastructure/board of the HIT Safety Center, ONC’s primary objective should be to continue to ensure the Center’s public transparency, representativeness, and accountability. The ONC, with public input, should also influence the agenda and priorities of the Center as needed.

Clinical Decision Support (pages 26-27)

Q: What types of CDS functionality should be subject to the health management health IT framework? Which types should be the focus of FDA oversight?

A: The ACR generally agrees with the examples of CDS types in the “health management” and “medical device” categories that were specified in the report. We agree with FDA that most CDS would naturally fall in the unregulated, safety-informed “health management IT functionality” tier.

Appropriateness-guided CDS during order entry is a prime example from the radiology domain of “health management IT functionality.” This type of CDS informs referring providers during the order entry workflow about the appropriateness of diagnostic imaging studies for the patient. The ACR has collaborated successfully with industry partners, EHR technology/computerized physician order entry (CPOE) vendors, and other stakeholders to seamlessly integrate ACR’s Appropriateness Criteria guidelines into the CPOE process to help reduce inappropriate imaging through education for those placing the orders. This functionality provides information and relative appropriateness ratings to help inform one’s decisions, but does not force one to proceed with an automated or otherwise unchecked follow-up action. As such, this functionality does not pose a safety risk.

Conversely, examples of regulated “medical device” CDS included in the report are radiation treatment planning and computer aided detection (CAD) software—functionality that has already been under active FDA oversight. While whether or not these are true examples of “CDS” is debatable, we agree with FDA that these products/features could meet the medical device definition, and could potentially

pose a patient risk if they did not function as intended. The ACR agrees that FDA should regulate CDS that both poses a substantial risk to patient safety and meets the medical device/accessory definition.

Q: Are there additional safeguards for CDS, such as greater transparency with respect to CDS rules and information sources that are needed to appropriately balance patient safety and the promotion of innovation?

A: The transparency of the information sources underlying CDS is critical for determining the trustworthiness of the information being relayed. In the case of appropriateness CDS during radiology order entry, for example, national specialty society guidelines should be prioritized over customized/localized rule sets because facility/system-developed or insurer/Radiology Benefit Manager-developed rule sets could be influenced, in part, by nonclinical motivations. Any assumed connection between trustworthiness and patient safety should be explored by ONC or the HIT Safety Center before diverting significant resources to addressing that topic.

Q: Does the certification of CDS functionalities, such as those functionalities currently certified under the ONC Health IT Certification Program, sufficiently balance patient safety and the promotion of innovation?

A: The ONC's HIT certification program was designed to test and certify software that participants use to comply with the various requirements of the Medicare/Medicaid EHR Incentive Program—it was not intended to ensure an appropriate balance of safety and innovation. Likewise, ONC's 2014 Edition EHR certification criterion for CDS does not apply to the full spectrum of CDS in the "health management" category because it was tailored to leverage specific data elements captured during Meaningful Use.

The ACR submitted comments to ONC on the previous 2011 Edition, 2014 Edition, and 2015 Edition EHR certification criteria rulemakings. We continue to recommend that ONC require certified EHR technology to have appropriateness CDS during radiology CPOE. This would assist physicians and other providers with ordering the most appropriate imaging study for the patient. This functionality exemplifies the quality improvement potential and cost savings promise of EHR technology. The ACR welcomes continued discussion with ONC and CMS on this issue.

Q: How can the private sector help assure the facilitation of the development, application and adoption of high quality CDS with health management health IT functionality in lieu of a regulatory approach? What role, if any, should government play?

A: The ACR has had success working with innovators in industry to develop and integrate appropriateness criteria-guided CDS into HIT solutions used by referring physicians to order imaging studies. Based on our experience thus far, we agree with the report's proposal to focus on non-regulatory safety promotion activities for CDS and other IT functionality in the "health management" category.

When it comes to “health management IT functionality,” we believe the role of government, particularly ONC, should center on ensuring the representativeness, transparency, public engagement, and accountability of the future HIT Safety Center. ONC could also encourage any desired safety behaviors by industry and end-users through its certification criteria regulations for EHR technology to support Meaningful Use. Also, the nontechnical barriers to interoperability and exchange should be addressed through the existing regulatory mechanisms available to HHS, such as strict enforcement by CMS and HHS OIG of the EHR exception/safe harbor to self-referral/anti-kickback requirements.

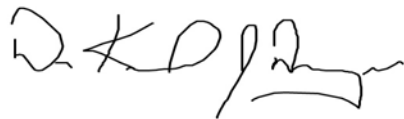
Conclusion

As always, ACR welcomes the opportunity for continued dialog between the radiologist community and the agencies on all things related to implementation of the FDASIA HIT Report’s proposed framework. Please contact Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 202-223-1670 / mpeters@acr.org if we can be of further assistance.

Sincerely,



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