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Subject: (79 FR 73319; 2014-28855) Office of the National Coordinator for Health Information Technology; Federal Health IT Strategic Plan: 2015-2020 Open Comment Period; Comments of the American College of Radiology

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—appreciates the opportunity to comment on the Office of the National Coordinator for HIT's (ONC) "Federal Health IT Strategic Plan: 2015-2020," published in the *Federal Register* on December 10, 2014. The ACR Commission on Informatics-Government Relations Committee compiled the following comments.

In general, the ACR supports the goals and objectives for federal agencies highlighted in the strategic plan, and we stand ready to assist federal partners in reaching the outlined HIT policy milestones. We agree that standardization and widespread adoption of health IT, together with advancing interoperability and health information exchange, will improve the quality, safety, and cost effectiveness of care for our patients. We encourage all government agencies to proactively engage with their stakeholder communities, particularly physician specialty societies, to inform any and all future implementation activities aligned with the Federal HIT Strategic Plan.

The ACR is similarly engaged in an ongoing effort to advance IT and informatics initiatives to improve the ordering and delivery of radiology services. Our progressive "Imaging 3.0" initiative is designed to change the way radiologists practice radiology for the better, and to provide information technology-centric tools to enhance care coordination and patient communication. Thus, the following comments address agencies' HIT-oriented goals and objectives from the perspective of a national physician association working to advance many of the same ideals as our federal partners.

Goal 1: Expand Adoption of Health IT

Objective 1A: Increase the adoption and effective use of health IT products, systems, and services

The ACR supports the 3-year outcome of increasing the percentage of Meaningful EHR Users. The Centers for Medicare and Medicaid Services (CMS) can increase this percentage by simplifying the requirements or adding alternative pathways/specialization options (or a combination thereof). Some ideas include:

- Eliminating all core and menu objectives, and requiring only those few minimal components of "meaningful use" that are explicitly listed in the statute.
- Making all MU objectives selectable/optional.
- Deeming all eligible professionals (EPs) who work in MU-compliant eligible hospitals to also be MU-compliant.

- Deeming PQRS participants to have also completed all MU participation requirements.
- Working with national specialty societies to establish specialty-specific alternative measures corresponding with each MU objective.
- Adding flexible, scope of practice-based exclusions for every core and menu objective/measure.
- Working with national specialty societies and the specialized HIT industry to identify specialty-specific bundles of ONC EHR certification criteria/CEHRT definitions, eCQMs/CQM reporting options, and CMS Meaningful Use requirements.

In addition to the above, CMS should provide an alternative process for EPs to obtain "hospital-based" status (and thus program ineligibility) if they predominantly work in hospitals that are not enabling EP MU compliance. Please see the November 2013 letter from ACR and the Radiology Business Management Association to CMS for background information.

In terms of Strategy 5 under Objective 1A, any expansion by ONC of its HIT Certification Program beyond the umbrella of the Medicare/Medicaid EHR Incentive Program must be done cautiously and separately from the current regulatory structure. If established, such an expansion should focus on interoperability and exchange, and avoid duplication and confusion with the existing EHR certification criteria designed to support Meaningful Use. Most importantly, such a certification expansion should be reserved for software designed for non-physician allied health professionals and patients. Developers of HIT solutions designed for physician end-users should be proactively encouraged by ONC to certify their products for use in the Medicare/Medicaid EHR Incentive Program to help those providers meet their regulatory obligations.

Objective 1B: Increase user and market confidence in the safety and safe use of health IT products, systems, and services

The ACR supports the 3-year outcome of refining and implementing frameworks for health IT safety and innovation. We submitted comments on the Food and Drug Administration/Federal Communications Commission/ONC proposed framework in July 2014, and look forward to participating in the establishment of the Health IT Safety Center. We continue to recommend extensive specialist and specialty IT industry involvement in the governance structure of the future Center.

The ACR also support Strategy 6 under Objective 1B to "promote data portability and interoperability to encourage competition, foster innovation, improve individuals' and providers' choices, and reduce barriers to change health IT products, systems, and services." This strategy, however, should go beyond promotion—interoperability should be the primary focus of HIT regulation as well by implementing all of the following recommendations:

- Strict monitoring and enforcement by the HHS Office of Inspector General and CMS of the interoperability prerequisites of the EHR safe harbor/exception from anti-kickback/self-referral requirements.
- Disallowing vendors of EHR technology or their clients to charge fees to ancillary service providers for being added to the directory/ordering functionality of software used by referring providers.
- Disallowing vendors of EHR technology to charge fees for data access by other health information systems, such as CDS, that need to gather clinical data for more personalized patient care.
- Disallowing vendors, hospitals, or health systems to charge excessive connectivity fees of any kind to disparate/unaffiliated providers.
- Requiring hospitals to participate in State-administered, statewide health information exchange networks (where they are operational) as a condition of continued participation in federal programs; or, alternatively

requiring hospitals to engage in data-sharing activities with appropriate disparate/unaffiliated providers who request it.

- Funding the establishment by state government agencies of open, inclusive, state-administered, statewide HIE networks.

Objective 1C: Advance a national communications infrastructure that supports health, safety, and care delivery

The ACR agrees with all outcomes and strategies under Objective 1C, in that the relevant government agencies should facilitate the establishment of broadband and wireless networks in areas of the country that do not currently have options. This will be critical for physicians in rural areas as they increasingly use web-based tools to comply with federal mandates, including using appropriate use criteria-based clinical decision support (CDS) for obtaining feedback on diagnostic imaging orders, as well as future participation in the Medicare/Medicaid EHR Incentive Program.

Goal 2: Advance Secure and Interoperable Health Information

Objective 2A: Enable individuals, providers, and public health entities to securely send, receive, find, and use electronic health information

Objective 2A is arguably the most important part of this strategic plan for relevant federal agencies. There are various regulatory and policy levels available to the government to standardize the industry and end anti-competitive behaviors that disable or discourage health information exchange. Regulatory agencies should implement all of the following:

- Strict monitoring and enforcement by the HHS Office of Inspector General and CMS of the interoperability prerequisites of the EHR safe harbor/exception from anti-kickback/self-referral requirements.
- Disallowing vendors of EHR technology or their clients to charge fees to ancillary service providers for being added to the directory/ordering functionality of software used by referring providers.
- Disallowing vendors of EHR technology to charge fees for data access by other health information systems, such as CDS, that need to gather clinical data for more personalized patient care.
- Disallowing vendors, hospitals, or health systems to charge excessive connectivity fees of any kind to disparate/unaffiliated providers.
- Requiring hospitals to participate in State-administered, statewide health information exchange networks (where they are operational) as a condition of continued participation in federal programs; or, alternatively requiring hospitals to engage in data-sharing activities with appropriate disparate/unaffiliated providers who request it.
- Funding the establishment by state government agencies of open, inclusive, state-administered, statewide HIE networks.

Objective 2B: Identify, prioritize, and advance technical standards to support secure and interoperable health information

The ACR generally supports the advancement of standards and interoperability described in the outcomes and strategies for Objective 2B. It is critical that the relevant government agencies proactively work with national standards organizations such as Integrating the Healthcare Enterprise (IHE), national specialty societies, and the specialized HIT industry on such efforts.

Goal 3: Strengthen Health Care Delivery

Objective 3A: Improve health care quality, access, and experience through safe, timely, effective, efficient, equitable, and person-centered care

The ACR enthusiastically supports the outcomes and strategies highlighted in Objective 3A, and we recommend that related research and regulatory agencies proactively reach out to national specialty societies to help accomplish those milestones.

The ACR and others in the radiology community are currently engaged in the Imaging 3.0 initiative, which has at its core the ideals of patient-centeredness, engagement/access, and quality improvement. To help providers reach the aspired practice enhancements, we are offering various resources including (but not limited to):

- *ACR Select*—ACR Appropriateness Criteria-based CDS to inform referring physicians during radiology order entry of the appropriateness of imaging procedures for the given patient.
- *ACR National Radiology Data Registry*—ACR's national specialty registries enable the comparison of practice performance to regional and national benchmarks, quality measurement (NRDR is a CMS Qualified Clinical Data Registry [QCDR]), and more.
- *TRIAD (Transmission of Imaging and Data)*—A standards-based system built by the ACR for the seamless exchange of images and data for accreditation, clinical trials and registries.
- *Image Wisely* and *Image Gently*: Multi-organization campaigns led by ACR and others to promote radiation safety considerations to referring physicians and imaging providers/professionals for adult and pediatric medical imaging.
- *RadiologyInfo.org*—A website hosted by the Radiological Society of North America (RSNA) and ACR designed to provide patients with descriptions of imaging and radiation therapy procedures, exams, and related diseases.
- In addition to the proven resources listed above, the ACR is engaged with industry partners and others to deliver the next generation of IT innovations related to radiology CDS, critical findings reporting, quality measurement, and more.
- Beyond ACR, RSNA and other organizations also offer resources and initiatives aligned with Imaging 3.0 priorities, including the RSNA's *Radiology Cares* campaign and *radiology reporting initiative*.

Objective 3B: Support the delivery of high-value health care

Federal research and regulatory agencies should reach out to national specialty societies to enable the outcomes and strategies of Objective 3B.

As one of many examples of IT-enabled value enhancements, the aforementioned ACR Select provides appropriate use criteria-based CDS to referring physicians during radiology order entry. This service is widely available and in clinical use in several institutions and practices across the country. Avoiding potentially inappropriate or inefficient imaging examinations for the given clinical conditions directly contributes to a patient's health and safety, particularly if the modality involves radiation or other potential risks. Moreover, this results in significant cost savings for the health care system as a whole and for individual patients who are increasingly burdened with out-of-pocket costs for diagnostic tests by their health plans. We encourage CMS, ONC, DOD, VA, and others to incorporate this service into their various programs/systems and to proliferate appropriateness criteria-informed imaging radiology order entry via relevant regulatory levers.

Objective 3C: Improve clinical and community services and population health

The ACR generally agrees with the outcomes and strategies associated with Objective 3C. We encourage CMS to expand its QCDR reporting efforts to other incentive programs (for example, QCDR-enabled participation in PQRS as a substitute to MU participation for specialists). We also encourage military/veteran and research agencies to work with ACR on leveraging NRDR in their related initiatives.

Goal 5: Advance Research, Scientific Knowledge, and Innovation

Objective 5A: Increase access to and usability of high-quality electronic health information and services

The ACR supports the outcomes and strategies of Objective 5A, in that every effort should be made by the government to publicly release data sets that would enable contextualized evaluation of federal programs, such as the Medicare/Medicaid EHR Incentive Program. We recommend that CMS and ONC release monthly de-identified data sets that allow interested parties to discern participation rates in MU and other government programs *by specialty* (and for every physician specialty). Currently, detailed MU participation data sets with specialty information are released approximately every 4-8 months, with only high-level summary data available on a monthly basis. We also encourage CMS, and HHS in general, to expedite the release of these de-identified data sets by shortening the internal review time prior to publication.

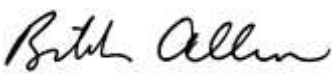
Any federal program data sets with *identifiable* physician/practice information, however, should not be expeditiously pushed through the review process. If released, all identified individuals/practices should be notified and given ample opportunity to preview/amend their data, and proper context must be provided to the public alongside the data to avoid undue confusion.

Objective 5B: Accelerate the development and commercialization of innovative technologies and solutions

The ACR supports the outcomes and strategies identified in Objective 5B—arguably the second-most important part of the strategic plan after Objective 2A. Related federal agencies have the critical role of providing support for the research and commercialization of promising HIT innovations that may otherwise go underfunded. Beyond research, it is similarly critical for *regulatory* agencies to incentivize or require use of underutilized and/or proven HIT capabilities in the context of, or as a prerequisite to participation in, their programs. Likewise, federal health care providers should serve as an example to others by integrating these capabilities into their systems. To that end, the ACR invites federal agencies to partner with us on Imaging 3.0 and other initiatives.

Thank you in advance for your consideration of these comments. As always, the American College of Radiology welcomes the opportunity for continued dialogue and partnership with ONC and other federal agencies. Should you have any questions on the issues addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 202-223-1670 / mpeters@acr.org.

Sincerely,



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