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AMERICAN COLLEGE OF RADIOLOGY
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December 16, 2019

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 20515-4329

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

The American College of Radiology (ACR)—a professional organization representing more than 38,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to comment on the "call to action" from U.S. Representatives Diana DeGette (D-CO) and Fred Upton (R-MI) regarding Cures 2.0. The ACR continues to support many of the core policies from the 21st Century Cures Act, particularly the mandates for the U.S. Department of Health and Human Services (HHS) related to interoperability, information blocking, and oversight of medical software/digital health products. Additionally, we believe that any future Cures 2.0 legislation should build upon 2016's interoperability gains by advancing patient access to, and provider-to-provider exchange of, medical images.

I.   Maintain Congressional Intent of the 2016 Cures' Information Blocking Prohibitions

For years, radiology practices across the country have shared concerns about health IT-enabled anticompetitive behaviors that can generally be categorized as "referral lock-in," or "information blocking." These behaviors are sometimes perpetrated by hospitals and health systems/networks seeking to leverage their regional influence, health IT capabilities, and policies to discourage or prevent patient referrals to unaffiliated imaging providers. Information blocking can be passive and discrete, such as hospitals/health systems avoiding communications with ambulatory imaging providers seeking to enable bidirectional exchange. Information blocking can also be overt, such as implementing prohibitively expensive connectivity fees, artificially reducing health IT capabilities for exchanges between affiliates and non-affiliates, disabling electronic ordering functionality to unaffiliated imaging providers unless they pay for special status and referrals, and various other tactics designed to

discourage or prevent exchange with competitors regardless of quality, cost, technological capability, or patient preference.

To help address these concerns, the ACR strongly supported Cures Section 4004's expansion of authority for the HHS Office of Inspector General (OIG) to investigate and penalize information blocking practices by providers, developers of certified heath IT, and health information exchange networks. Section 4004 defined information blocking as "*a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information,*" with additional specifications depending on whether the perpetrator of the behavior was a healthcare provider or a developer/network. The intent of this section—which evolved from prior ACR-endorsed legislation—was to comprehensively protect the exchange of all types of electronic health information (EHI), including electronic imaging orders/referrals and results.

The HHS Office of the National Coordinator for Health IT (ONC) published a proposed rule in April 2019 that would appropriately implement key aspects of Cures Section 4004, including an ACR-supported definition of EHI. However, ONC received criticism about the broad applicability of the proposed EHI definition from some stakeholders who sought to narrow the scope of the information blocking prohibitions. The final rule has not yet been promulgated, and it is unclear whether ONC will finalize the proposed EHI definition, or if the agency will bow to pressure.

Depending on the outcome of this ONC rulemaking, some stakeholders may lobby Congress to step in with statutory limitations via Cures 2.0 on data that can be categorized as EHI, and thus scale down the applicability of the information blocking prohibitions. In the context of Cures 2.0, ACR urges Congress to help ensure the comprehensive EHI definition that was proposed by ONC in April 2019 is finalized; and more specifically, that electronic imaging referrals/orders, results, and other imaging data are indeed covered by the final EHI definition, as originally intended by Congress in 2016.

II.   Modernize Access to Medical Images, or "Ditch the Disk"

While Congress and federal agencies, such as ONC, have made admirable progress toward interoperability and health information exchange, these efforts have been mostly targeted at limited types of data managed by electronic health record (EHR) technology. "Non-EHR" data from medical devices and specialty health IT systems that are equally important to patient care, such as medical images, remain largely unaddressed by major federal initiatives. Thus, many hospitals and imaging providers transfer diagnostic quality images to other providers and patients on outdated physical media (e.g. CDs, DVDs, etc.) instead of via modern health information exchange methods.

The ACR, the Radiological Society of North America (RSNA), and other major organizations and companies have been working collaboratively on a "ditch the disk" initiative to modernize medical imaging-sharing capabilities across the nation, such as through open application programming interfaces (APIs). Access to medical images can improve quality and reduce costs by enhancing available information and eliminating duplicative imaging. Congress could help the radiology community advance this critical "ditch the disk" objective.

To that end, Cures 2.0 should direct the Secretary of HHS to work with radiology stakeholders to develop a national strategy to modernize medical image-sharing. This national strategy should address provider-to-provider exchange and patient access to medical images via open APIs. Moreover, Congress should mandate that ONC's U.S. Core Data for Interoperability (USCDI) dataset include medical images, and that health information networks participating in the Trusted Exchange Framework and Common Agreement (TEFCA) facilitate image-sharing.

III. Maintain FDA Authority over Software that Acquires, Processes, or Analyzes Medical Images

Cures Section 3060 amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to limit and clarify the types of software functions that meet the "medical device" definition and thus are subject to FDA oversight. In its wisdom, Congress included important language preserving FDA's continued authority over software functions that acquire, process or analyze medical images. For Cures 2.0, certain stakeholders may advocate for additional limitations on the "medical device" definition to allow currently regulated digital health products to avoid FDA oversight in the future.

The ACR believes that FDA is the appropriate federal regulatory agency for overseeing artificial intelligence/machine learning (AI/ML)-enabled software functions that analyze or otherwise use medical imaging data, such as computer-aided detection and diagnostic tools. The agency's current statutory authority over imaging-related digital health products is necessary to provide reasonable assurance of the safety and effectiveness of these important innovations. We ask Congress to not limit FDA's jurisdiction over imaging-related medical software.

Additionally, the ACR recommends that FDA collaborate with physician stakeholder organizations to ensure that emerging AI/ML-enabled software functions related to radiology care are clinically useful, adequately vetted by the agency before entering the market, and validated and monitored on an ongoing basis by trusted third parties, such as the ACR's Data Science Institute (DSI).

Thank you for your leadership on Cures 2.0 and your efforts to gather preliminary feedback from stakeholders. The American College of Radiology stands ready to serve as a resource on these important topics. Please contact Cynthia Moran, ACR Executive Vice President of Government Relations, Economics and Health Policy, at (202) 223-1670 or cmoran@acr.org with questions or concerns.

Sincerely,

Geraldine B. McGinty, MD, MBA, FACR
Chair, Board of Chancellors
American College of Radiology