American College
of Radiology™

August 2, 2024

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

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

Re: Cures 2.0 Request for Input; June 6, 2024; Comments of the American College of Radiology

Dear Representatives DeGette and Upton:

The American College of Radiology (ACR)—a professional association representing more than 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists—is pleased to provide the below recommendations in response to your request for input on "Cures 2.0." The ACR generally supports the policies from the 21st Century Cures Act of 2016 (or "Cures") that advance biomedical research, data interoperability, and drug and device innovation. Likewise, ACR engaged in prior "Cures 2.0" policy discussions and provided written comments to your offices in 2019.[1] We are pleased that some concepts from those 2019 discussions, such as creation of the Advanced Research Projects Agency for Health (ARPA-H), have been realized through other legislation.

On June 6, 2024, your offices requested public input on the below questions.

1. *Do the policies included in Cures 2.0 that have advanced through legislation or executive action meet the needs that the original Cures 2.0 bill aimed to address?*
2. *What elements might be missing that are essential for further progress?*
3. *What additional reforms, support mechanisms, or incentives are needed to enhance or improve the effectiveness of the steps already taken, including any structural reform to agencies, offices, or programs involved?*

The following ACR recommendations provide responses to these questions as they apply to various Cures- and/or Cures 2.0-related subtopics. These recommendations are intended to inform future Cures 2.0 legislative efforts.

ACR Recommendation 1: Broaden FDA's Authority Over Health Care AI

Cures Section 3060 amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exempt certain types of software functions from FDA jurisdiction. The exemption focused on functions in electronic health record (EHR) products subject to voluntary certification by the HHS Office of the National Coordinator for Health IT (ONC). Prior to 2016, FDA used enforcement discretion for these same software functions.

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[1] https://www.acr.org/-/media/ACR/Files/Advocacy/Regulatory-Issues/acr_comments_cures2-12-16--2019.pdf

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Medical device software and "non-device" EHR software have evolved significantly over the past decade. Health care AI is increasingly utilized in ways not envisioned in 2016, including in EHR-integrated clinical decision support tools that are unregulated because of the Cures Sec. 3060 exemption. Public health and safety would benefit from an updated, unified approach that advances trustworthy innovation by leveraging FDA's regulatory expertise to ensure the safety and effectiveness of current "non-device" AI.

To that end, Congress should consider new legislation to broaden FDA's authority to encompass all health care AI software functions, including those previously exempted by Cures Sec. 3060. Additionally, Congress should provide FDA with expanded and/or clarified authorities to develop a dynamic, balanced, and safety- and effectiveness-tiered AI oversight system. As part of this paradigm, FDA should collaborate with medical societies and other stakeholders to develop a clear strategy for overseeing rapidly evolving functions enabled by generative AI/large language models/foundation models deployed within healthcare institutions.

ACR Recommendation 2: Create Payment Incentives for Quality Use of High-Value AI

Congress should mandate payment incentives for safe and effective medical uses of high-value AI tools authorized by FDA and identified through Centers for Medicare and Medicaid Services (CMS) engagement with physician stakeholders. These incentives should focus on the clinical value of the AI tool to the Medicare patient population as well as the health care facility's implementation of appropriate AI governance, quality assurance, and medical use practices. For example, the ACR initiated the ACR-Recognized Center for Healthcare AI (ARCH-AI) program in 2024, which is the nation's first AI quality assurance program for radiology facilities designed to recognize adherence to best practices in the medical use of imaging AI.[2] Further discussion of this policy recommendation is included in the ACR's comments to Rep. Ami Bera in a May 6, 2024, response to the Congressman's Request for Information on the "State of AI in Health Care."[3]

Importantly, any AI quality payment requirements should also carefully consider equitable access to tools by small and rural providers who may not have extensive resources for AI performance analytics. CMS should collaborate with medical societies such as ACR to provide small/rural providers with the AI quality assurance programs and assistance they need to ensure safe, effective, and appropriate care for their patients.

ACR Recommendation 3: Mandate a National Strategy to Advance Image Exchange

Cures Section 4004, the "Information Blocking Provision," was intended in part to ensure provider-to-provider and vendor-to-provider exchange of images, imaging orders, and associated imaging data, and to prohibit the siloing of patients or patients' data within specific institutions or proprietary solutions. However, many imaging IT solutions still use optical disc-based sharing of imaging data, which requires that another provider or patient have the hardware and software infrastructure to access data stored on the disc. Organizations such as the ACR, Radiological Society of North America, and others have promoted awareness efforts and image sharing standards that would enable the health care industry to "Ditch the Disk." Moving forward, Congress could help by mandating that HHS collaborate with physician organizations, patients, and industry stakeholders to develop a national strategy to advance

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[2] https://www.acrdsi.org/DSI-Services/ARCH-AI
[3] https://www.acr.org/-/media/ACR/Files/Advocacy/AIA/acr_bera-rfi_05-06-2024.pdf

electronic image exchange leveraging existing radiology standards[4] and regulatory/sub-regulatory programs.

ACR Recommendation 4: Improve Medicare Local Coverage Determination Process

The Cures Act directed HHS to improve the transparency of the Local Coverage Determination (LCD) process. As a result of this mandate, in October 2018, CMS revised the Medicare Program Integrity Manual (PIM), Chapter 13 - LCDs (Pub 100-08), which outlines the LCD process and serves as a roadmap for Medicare Administrative Contractors (MACs).

Despite Cures Act requirements to increase transparency in the LCD process, the general responsiveness of MACs to physician concerns has been suboptimal, and MACs have effectively omitted Contractor Advisory Committee (CAC) physician representatives from the LCD process. Further improvements are needed to restore opportunities for the physician community to meaningfully engage with the MACs to inform the development of local coverage policies. For example, CAC meetings are now at the discretion of the MACs, whereas before CMS' revised LCD guidelines, MACs were required to hold a minimum number of CAC meetings per year to discuss draft LCDs and other Medicare-related issues. CAC meetings now occur less frequently, randomly, or not at all, due to how contractors have deprioritized CAC/physician engagement and devalued their advisory responsibilities. MAC decisions do not have adequate public notice and comment opportunities, resulting in misinformed policymaking. Moreover, MACs do not have clear guidelines for the representative selection of subject matter experts.

Moving forward, Congress should require CMS to mandate LCD process requirements that are more aligned with federal transparency standards. Regular CAC meetings should be held at least twice per year per jurisdiction. For LCD topics under consideration, a minimum of 8 weeks of advance notice should be required to allow sufficient time for specialty societies to select subject matter experts. Finally, MACs should be required to publish the draft coding/billing policies associated with LCDs for meaningful public comment in local coverage articles (LCAs). Specific approaches to meaningful physician inclusion in sound coverage policies are described in the Principles of Sound Local Coverage, developed by a coalition of 18 national medical societies.[5]

ACR Recommendation 5: Support ARPA-H Progress

The Advanced Research Projects Agency for Health (ARPA-H) was established in 2022 and has provided research funding opportunities for a variety of high-risk, high-reward projects, including imaging advances. The ACR recommends that Congress continue to appropriate adequate funding levels for ARPA-H distinct from funding for traditional National Institutes of Health (NIH) research programs.

ARPA-H was established within the NIH to accelerate biomedical research and innovation through grants, contracts, cash prizes, and other means. ACR serves as a partner in various ARPA-H initiatives, including the Biomedical Data Fabric Toolbox (BDF). The BDF aims to help make research data easier and more reliable to use, reduce effort for data integration, and enable new capabilities and models that can be applied across disciplines and generalized across disease domains.

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[4] https://www.healthit.gov/isp/uscdi-data-class/diagnostic-imaging#level-2
[5] https://www.acr.org/-/media/ACR/Files/Advocacy/Medicaid/PRINCI_1.pdf

Additionally, ACR is a member of the Customer Experience and Investor Catalyst Hubs within ARPANET-H, an ARPA-H established nationwide health innovation network. ACR is poised to serve as a resource and leading voice in the Customer Experience Hub's Advancing Clinical Trial Readiness initiative, seeking to improve the nation's ability to conduct clinical trials safely, quickly, and equitably. ACR seeks to engage on the Investor Catalyst Hub's Sprint for Women's Health initiative, an effort to fundamentally change the trajectory of women's healthcare research and radically accelerate the next generation of discoveries through areas of interest including making care available at home through home testing and monitoring, ovarian health, and imaging methods that would help assess brain lymphatic function.

Prior Cures 2.0 discussions indicated that the U.S. Food and Drug Administration (FDA) should work with ARPA-H to expedite the development of medical products through specified activities. To that end, the FDA and ARPA-H established a joint Medical Imaging Data Marketplace (MIDM) to advance innovation in artificial intelligence (AI)/machine learning (ML)-enabled medical devices. The MIDM aims to organize and manage medical imaging data at scale by connecting existing databases, marketplaces, and data providers to a platform that researchers and customers can use to find and access data needed to develop and test new algorithms.[6] This initiative will include the development of new tools to give users of the marketplace confidence that the accessed data will be consistent with FDA's regulatory requirements for future pre-market authorization pathways.

ACR Recommendation 6: Fund Translational Research

Basic, translational, and clinical research are each important priorities and function interdependently to benefit patient care; however, there is an unmet need with respect to certain types of translational research in the domains of real-world outcomes, economics, and policy. This research is critical for moving science into everyday practice with broad, equitable access. Currently, there is insufficient funding for translational research outside of the private sector, which creates opportunities for bias in the information used for decision making. Congress could address this need by providing the necessary authorizations/appropriations.

ACR Recommendation 7: Improve NIH Efficiency and Data-Sharing

The ACR is a long-standing partner in federally funded clinical trials, specifically, National Cancer Institute (NCI) sponsored clinical trials. The infrastructure supporting NCI-sponsored clinical trials could be more efficient and effective by considering a streamlined approach for clinical application reviews, including the design and approval processes. The specific Institute/Center (IC)-sponsored leadership should be included in the initial stages of a trial review to reduce burden on NIH staff and streamline this process. IC staff should be involved in helping with design studies early in the process to increase efficiency, address any budgetary and funding interests, and ultimately quicken the launch of trials.

Additionally, there should be a focus on the mandatory component of data sharing in all NIH studies after publication of the primary study results. Due to underfunding, researchers struggle to make data available because it requires substantial work and time after the study funding has lapsed. These datasets could be valuable for the development and testing of new diagnostic and therapeutic tools, including AI algorithms. In addition, consideration should be given to sequestering some of this data for use by the FDA and other federal agencies to validate AI

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[6] https://investorcatalysthub.org/medical-imaging/

algorithms. Datasets are only valuable with appropriate data dictionaries and annotations of imaging and other data. All of this requires funding, which is frequently not included in the budget for the primary research study.

Thank you for your consideration of these recommendations. Please contact Cynthia Moran, ACR Executive Vice President of Government Relations, Economics, and Health Policy, at cmoran@acr.org with any questions.

Sincerely

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