AcademyHealth

August 5, 2024

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Dr. Larry Bucshon
2313 Rayburn House Office Building
Washington, DC 20515

RE: Reps. DeGette, Bucshon Seek Stakeholder Input on Next-Generation Cures Bill

Dear Congresswoman DeGette and Congressman Bucshon:

AcademyHealth welcomes the opportunity to provide input to your offices on priority areas and continuing gaps for realizing the goals of the 21st Century Act and Cures 2.0 ("Cures"). AcademyHealth is the professional home of health services and systems researchers, policy experts, and practitioners. As the leading organization and broker of information for a field devoted to improving health and healthcare for all, we are grateful for and share your offices' goals in modernizing and enhancing our healthcare system to develop better cures, support patients and providers in choosing the proper care, create patient-centered care models, and improve how that care is delivered.

In response to the three questions posed in the request for information, our comments outline what AcademyHealth identifies as the leading priorities to further codify and implement initiatives and programs included in Cures 2.0. We urge that future Cures legislation include a parallel focus on innovation in biomedical discovery with innovation in care delivery, which requires additional support mechanisms, incentives, and reforms through substantial investments in health services research. Health services research is vital for translating cures to care and necessary to understand the impact of regulatory reform and biomedical innovation on the health and lives of millions of Americans.

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?***

Some areas outlined in the original Cures 2.0 bill have received increased attention since the bill was first introduced and have advanced through legislation, executive action, or both, while gaps remain in other areas. Recent legislative and executive actions are highlighted below.

- **Long COVID**: The Office of Long COVID Research and Practice was established through an executive order launched in 2023 with funding for two full-time employees. Limited staffing may signal additional legislative efforts are warranted. Five bills related to research and healthcare for long-term COVID patients were introduced during the 118th Congress. However, they have yet to pass.

- **Direct care workforce:** The Department of Health and Human Services released a 2022 National Strategy to Support Family CaregiversHH. Stakeholders have noted that this strategy needs a precise measurement and evaluation plan to track implementation and increase government

1666 K Street NW
Suite 1100
Washington, DC 20006
202 292 6700 PHONE
www.academyhealth.org

accountability. In 2023, the Biden Administration issued executive order 14095, Increasing Access to High-Quality Care and Supporting Caregivers, which called for actions from the U.S. Department of Health and Human Services (HHS), the Administration for Community Living and the Agency for Healthcare Research and Quality (AHRQ) to support family caregivers (Section 2d).

- **Representativeness of clinical trials:** The Food and Drug Omnibus Reform Act of 2022 (FDORA) requires that clinical trial sponsors submit a diversity action plan outlining an enrollment strategy for recruiting underrepresented populations. The FDA solicits comments until September 26, 2024, on the updated draft guidance, "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." This is a welcome step, given the limited effectiveness of strategies under the FDA's previous five-year action plan designed to improve diversity in clinical trials.

- **Digital health technologies:** Before Cures 2.0, the FDA launched the Digital Health Center of Excellence (DHCoE) to improve further the development and deployment of digital health technologies, including medical devices, mobile health devices, and medical software. The Center for Devices and Radiological Health's (CDRH) 2023 annual report summarizes DHCoE's work on AI and digital health innovation, new regulatory approaches, and international harmonization.

- **Real-world evidence (RWE):** FDORA required the FDA to issue guidance on facilitating the use of RWE (Section 3628) and advancing the use of decentralized clinical trials (Section 3606-3607), both of which align with Cures 2.0 provisions under Title III.

- **Telehealth:** Several pandemic telehealth policies were made permanent through legislation and administrative action. AHRQ-funded research has evaluated facilitators of and remaining barriers to new telehealth models. The Consolidated Appropriations Act of 2024 authorizes extensions for several Medicare telehealth flexibilities through December 31, 2024. Medicaid telehealth flexibilities vary by state, highlighting disparities between Medicaid expansion states and non-expansion states. CMS has provided guidance to states on updating state plan amendments to improve telehealth care delivery, and in February this year, CMS released a Telehealth Toolkit for State Medicaid and CHIP programs.

- **Coverage for breakthrough devices:** Transitional Coverage for Emerging Technologies (TCET) builds off CMS' national coverage determination (NCD) and coverage with evidence development (CED) processes to expedite and streamline Medicare coverage of specific FDA-designated breakthrough devices. Recent research has identified ongoing implementation challenges and strategies for future policy action. The TCET pathway is a statutory rule that can easily be repealed as its predecessor, the Medicare Coverage of Innovative Technology (MCIT) pathway, was under the Biden Administration.

- **ARPA-H:** Advanced Research Projects Agency for Health (ARPA-H), initially proposed in Cures 2.0, was funded through the Consolidated Appropriations Act, 2022 (signed March 15, 2022), and then formally authorized through the PREVENT Pandemics Act (signed December 29, 2022). EO 14081 (signed September 12, 2022), Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, includes some research directives that

align with provisions outlined in Cures 2.0 related to biomedical innovation and regulatory reforms. ARPA-H has focused on patient-centered engagement and real-world delivery of innovations, and Congress needs to continue this prioritization.

2. ***What elements might be missing that are essential for further progress?***

In addition to gaps in existing policy actions instead of Cures legislation, the original Cures Act has a limited scope in the following areas:

- **Health services research:** While Cures focuses heavily on innovation in biomedical research and the development of new digital health technologies (i.e., devices used by physicians and professionals, are prescribed to patients, or embedded on consumer-level equipment), it lacks an emphasis on healthcare services that are supported or enabled by digital technology (such as, for example a physician's use of generative AI) and therefore lacks sufficient emphasis on health services research (HSR). Health Services Research examines how healthcare is organized, financed, and delivered, as well as its quality and cost-effectiveness. Investments in biomedical research without a concurrent investment in ensuring that patients have access to the interventions and that the health system is equipped to deliver them effectively can worsen health disparities by creating or entrenching barriers to care. Health Services Research can inform how the emergence of new therapies or regulatory pathways outlined in Cures affect changes in care delivery and vice versa. HSR is the right method for evaluating whether health care services that use digital technology are efficacious.

  AHRQ is the leading federal funder and evidence base for HSR and patient-centered outcomes research (PCOR)—and the only federal agency that funds research on health systems nationwide. Despite AHRQ-led initiatives being an essential component of the success of Cures provisions, AHRQ is only referenced once in the bill, highlighting a significant gap. Research initiatives and funding opportunities from AHRQ and AcademyHealth have been critical to identifying actionable solutions to address problems in our healthcare system. AcademyHealth leads numerous health services research-focused projects in collaboration with partners and lends an HSR perspective to a range of topics outlined in the original Cures bill, including projects on understanding the impact of long COVID on vulnerable populations, building trust in healthcare, and understanding the economic implications for patients and caregivers.

- **Community and patient engagement**: Although sections of Cures focus on improving access to care and novel therapeutics for patients, increasing support for caregivers, and improving coverage for Medicare, Medicaid, and CHIP beneficiaries, it does not sufficiently include provisions to support community and patient input in the development of medical products and digitally supported health care services, design of clinical trials, or implementation of related research. Community and patient engagement play a crucial role in biomedical innovation by ensuring that new treatments and health technologies are developed with the patient's needs and perspectives at the forefront. For example, pragmatic clinical trials, which evaluate treatments and outcomes in real-world clinical settings, represent one approach to enhancing patient and community engagement in research. Pragmatic clinical trials often involve diverse patient populations, use practical endpoints, and use broad eligibility criteria. The original Cures legislation lacks provisions to build capacity in this vital area.

For example, several sections of Cures (e.g., Sections 103, 105, 201, 302) authorize the Secretary of HHS to award grants to support research advancements and policy reforms. However, no sections call for efforts to enhance equity in delivering and implementing such grant programs. The legislation must include provisions to support grant programs for community-based organizations and already trusted entities in their communities and have the expertise needed to improve clinical trial outreach, access to care, caregiver training, and public health communication. In another example, the ARPA-H section misses acknowledging the need to scale community-based participatory research and patient-led research methods. Finally, Cures calls for HHS and CMS to develop recommendations for increasing patient and family caregiver health literacy by "identifying culturally competent, evidence-based interventions" (Section 202a) but lacks language on linguistic competency, which is a related but distinct concept. Linguistically competent interventions and language diversity (e.g., bilingual providers, trained interpreters, translators, and oral and written communication offerings in different languages) are essential to improve equitable healthcare delivery.

- **Workforce burnout and strain:** While Cures includes provisions that can help reduce the burden on providers and other healthcare workers (e.g., expanding telehealth services, streamlining administrative processes, and improving efficient care delivery), the bill lacks provisions specific to addressing workforce burnout and strain. One remaining question is how provisions in future Cures legislation can help mobilize a healthy and thriving healthcare workforce and deliver and implement the innovative care strategies outlined in the bill. Experts at AcademyHealth are thinking through some of the most pressing workforce challenges (e.g., the impact of extended working hours and workplace conditions on patient outcomes) and identifying solutions to respond to them (e.g., new provider incentives, initiatives to reduce nurse turnover, improve the valuation of nursing, improve workplace environments, and technologies to reduce administrative burdens).

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?***

Health services research is invaluable in informing the diffusion, adoption, adherence, and accessibility of technological developments and innovative therapies. Additional reforms and support mechanisms needed to advance further initiatives included in Cures legislation are summarized:

Recommendations

1. **Institutionalize HSR focus alongside National Institutes of Health (NIH) grants:** Including an AHRQ-managed grant on any NIH grant or a joint grant program between the agencies can help ensure synergy between biomedical innovation and healthcare delivery. Evidence generation on novel therapeutics and interventions should be paralleled with evidence generation on innovations in healthcare delivery to patients and communities. This type of grant program would enhance interagency collaboration. Including an HSR focus on all NIH grants can fill gaps in current Cures legislation, particularly related to workforce shortages, provider burnout and patient- and community-centered approaches. The Secretary of HHS can authorize the inclusion of HSR through federal grant programs that have implications for human health. HSR research can inform best practices around integrating breakthrough therapeutics and devices in real-world settings through pragmatic clinical trials and evaluate various payment models to increase patient access

to new therapeutics. An HSR focus can also inform best practices for ensuring the healthcare system is prepared for and can absorb the shocks of future crises like the COVID-19 pandemic. Additionally, future Cures legislation can codify an HSR-focused ARPA-H program, which can inform policy and practice on improving patient health outcomes by enhancing access to and acceptance of novel therapeutics.

2. **Development of participatory grant-making processes for NIH and other federal agencies**: A participatory grant-making process is a bottom-up alternative to traditional grant allocation, in which community members drive decision-making around what and who gets funded. The NIH supports "collaborative interventions that involve scientific researchers and community members to address diseases and conditions disproportionately affecting populations experiencing health disparities," however, this initiative is siloed within the National Institutes of Minority Health Disparities (NIMHD) and currently has no active funded projects. A participatory grant-making process and community granting programs could engage patients and communities in financing and research prioritization decision-making. This can all have important implications in linking provisions in Cures legislation with implementation actions that address patient needs. A participatory grant-making process could inform funding priorities and frameworks for high-value pragmatic clinical trials (PCTs) are integrated into real-life and community-based settings. This initiative would align with the latest research highlighting the importance of having communities as full partners and leaders in health innovation and the efficacy of participatory grant-making. The NIH Director could authorize such an initiative by acting through the Secretary of HHS.

3. **National program on high-value, equitable care:** Our healthcare system faces several challenges in achieving high-value and equitable care. A national program involving interagency collaboration and focusing on health system accountability, affordability, accessibility, and sustainability for innovation in biomedicine and health care delivery is essential. Building off ongoing efforts from the Centers for Medicare and Medicaid Innovation (CMMI), this initiative could be authorized by the CMS Director through the Secretary of HHS. To keep pace with advancements in Medicare and address persisting inequities experienced by Medicaid beneficiaries, future Cures legislation could provide a legislative basis for beneficiaries to access new FDA-approved cures when there are evident disparities based on variable state Medicaid budgets. One example of a program that could be scaled is Medicaid's new Cell and Gene Therapy (CGT) Access Model, launched by CMS on January 30, 2024. Further, Congress could authorize CMS and other agencies to support care delivery models that employ community health workers in partnership with providers delivering high-value, equitable care. Recent research has outlined strategies to advance community health worker models in health system reforms.

To summarize, several initiatives have addressed elements of Cures 2.0, representing a patchwork of legislative and executive actions aimed at modernizing our healthcare delivery system. However, Cures legislation also includes unique provisions that have yet to maintain momentum despite the demonstrated need. There are also notable gaps in current Cures legislation related to health services research, patient- and community-centered approaches, and workforce burnout. More federal attention is needed for HSR- and AHRQ-funded research. Reforms to federal grant-making processes, meaningful inclusion of community- and patient-facing stakeholders, and a national program on high-value, equitable care are essential strategies to realize the goals of Cures 2.0.

Thank you for the opportunity to discuss the perspectives and concerns of the health services research community. For further comments, clarifications, or inquiries, please email Josh Caplan at Josh.Caplan@AcademyHealth.org.