



December 16, 2019

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
United States House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

AcademyHealth, the professional society for health services research and health policy, welcomes the opportunity to provide these comments in response to your request for policy proposals to be considered for inclusion in CURES 2.0. We appreciate your commitment to stakeholder input, and are pleased to have this opportunity to work with you to build upon the progress made by the 21st Century Cures Act by modernizing coverage and access to life-saving cures for patients.

AcademyHealth's 4,000 members produce and use health services research which gives us the evidence to understand and improve our complex health system, enabling better health outcomes for more people at greater value. The 21st Century Cures Act has supported research and driven innovative ideas that are already benefiting patients and the Innovation Fund, an essential aspect of the 21st Century Cures Act, provided a much-needed infusion of federal funding for targeted priorities into the research ecosystem. It is of critical importance that Congress reauthorize and expand upon the Innovation Fund before its expiration at the end of fiscal year (FY) 2020. We strongly support the goals of CURES to modernize coverage and access to life-saving cures in this country and across the globe, and we believe that CURES 2.0 can build on the progress to date by transforming patient care, empowering patients and their families, and harnessing real world data and digital health. Cures and Care are two sides of the same coin – we must have both to achieve optimal health and reduce healthcare costs.

As such, we respectfully request that you consider the following policies for inclusion in Cures 2.0. We believe these recommendations, if enacted, will build on existing efforts to collect real-world evidence across the federal healthcare system to empower patients and their caregivers to make informed decisions about their care by ensuring they have access to the best data and therapies available.

- **Transform Patient Care by Promoting Access to Effective Interventions and Cures.** We know that on average, it takes 17 years for new research findings to benefit patient care. We can do so much better! CURES 2.0 should include major implementation and innovation research initiatives to more rapidly get cures to patients everywhere, including rural communities which often lag in access to medical innovation. Congress provides strong support for the National Institutes of Health (NIH), and with that funding, NIH is developing new treatments and cures for patients suffering from diseases like cancer and diabetes. We recommend that Congress add a new section to Title I, Section 1004, to establish Innovation Projects at the Agency for Healthcare Research and Quality (AHRQ). This new section would charge the Director of AHRQ to work collaboratively with NIH, NCATS, FDA, and other HHS agencies to measurably improve the delivery of care to patients across the country.

Over the last 20 years we have learned much about what works to prevent and treat diseases; however, we know much less about how to get that effective treatment into routine clinical practice, whether that practice is in rural Montana, Detroit, or suburban Miami. Thus,



this new Section 1004 would support the Implementation Innovation Initiative (I3) and complement the efforts of the NIH and FDA Innovation Projects in the other Sections of Title I.

The Implementation Innovation Initiative (I3) should be led by the Agency for Healthcare Research and Quality (AHRQ) because of this Agency's mandate to improve health care and outcomes and address the systems level challenges facing patients today, and its expertise and programs already underway in this area. AHRQ was authorized in 1999 on a broadly bipartisan basis to improve the safety and quality of American health care. AHRQ-funded research has identified where waste, inefficiencies, and gaps exist within health care, and allows patients, providers, payers, and others to harness American innovation and make the health care system safer, more efficient, and more effective. There has been an explosion of promising innovations in health care treatment, but without AHRQ-funded research and data to ensure that these new innovations are delivered to patients in need as optimally as possible, we are falling short of our promise to patients.

However, twenty years later, Congress has not yet reauthorized the agency, even though AHRQ is the only federal agency with the sole focus to generate evidence on how to deliver the highest quality care, at the greatest value, with the best outcomes. ***We therefore recommend that Congress use CURES 2.0 as an opportunity to reauthorize and modernize AHRQ with this added focus on implementation and innovation.*** The CURES 2.0 Implementation Innovation Initiative (I3) would also task AHRQ to work in partnership with NIH and private entities, including health systems, to ensure the rapid and efficient translation of research findings into practice and capitalize on private sector innovation to achieve faster impact.

- **Authorize a Health Data Research Initiative to Improve Research on Patient Care and Outcomes.** Congress, the healthcare system, and ultimately patients are navigating rapidly evolving challenges related to protecting patients' privacy while improving accessibility to personal health data and permitting appropriate uses of this data for research and care improvement. The expanded use of artificial intelligence (AI) and health data apps are accelerating the need for new data innovations, new research methods, and updated policies for governance, curation and access to ensure evidence is generated, care improved and patients are both protected and empowered by the data available to them. To date, commercial entities have taken the lead in this area and we believe CURES 2.0 provides an opportunity to better define the federal government's role in this rapidly evolving ecosystem. AcademyHealth believes action must be taken to ensure this data is being incorporated into research to improve the value and outcomes of care being delivered to patients and the systems in which care is delivered.

We respectfully request that CURES 2.0 also include within the new Section 1004, a health data initiative that tasks AHRQ with supporting research using data from all sources (not just HIPAA regulated entities). This health data initiative would fund researchers and innovators to work collaboratively to solve the thorny challenges of turning masses of noisy data into reliable evidence about which treatments will work for which patients and when. AHRQ is already doing work in this area and is well positioned to design and lead this initiative as it would build on its existing programs and its many robust data assets and expertise. In fact, AHRQ was a pioneer in this area having created the first-of-its-kind "Electronic Data Methods Forum" in 2011 that provided essential support to partner with a community of experts in the collection and use of clinical data for delivery system improvement. This program resulted in the development of an innovative consumer consent application by Sage Bionetworks that was ultimately included by Apple in its ResearchKit, a framework for running clinical studies on the iPhone. Much more must be done to support and harness these types of innovations which, if used properly, can transform healthcare. Initiatives like this could be supported by a prize competition modeled on Section 2002, EUREKA Prize Competitions included in the original CURES legislation.

AcademyHealth thanks you for your work to develop CURES 2.0 and leadership in this area and looks forward to working with you on this important effort. If you have any questions, please contact our Washington Representative, Erika Miller at 202-484-1100 or emiller@dc-crd.com

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Simpson". The signature is fluid and cursive, with a large initial "L" and "S".

Lisa Simpson, MB, BCh, MPH, FAAP
President and Chief Executive Officer