Association of
American Medical Colleges
655 K Street, NW, Suite 100, Washington, DC 20001-2399
T 202 828 0400
aamc.org

December 16, 2019

The Honorable Diana DeGette
United States House of Representatives
Washington, DC 20515

The Honorable Fred Upton
United States House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Upton:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide comments in response to the recently issued request for feedback on "Cures 2.0" which will build on your landmark 21st Century Cures Act efforts in order to modernize health care coverage and ensure access to scientific breakthroughs. The AAMC supports these efforts and will work with our members, policymakers, and other health care stakeholders to participate in and provide input to this important conversation.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC was pleased to support the 21st Century Cures Act and commends the legislation's effort to sustain investments in medical research, address administrative burden on researchers, address the role of socioeconomic status in Medicare Hospital Readmissions Reduction Program, and more. As you move forward on "Cures 2.0," we are pleased to provide the following preliminary items for consideration from AAMC staff in three areas you have identified: digital health technologies; reforming Medicare coding, coverage, and payment policies; and harnessing data to empower patients and improve their health. The AAMC hopes to be a resource to you and your staff as you craft "Cures 2.0."

Digital Health Technologies

Electronic Health Record Usability

The limitations of EHR use are a leading factor in clinician burnout. Health care institutions provide ongoing training to clinicians using health IT systems; however, training alone will not resolve the current administrative burden associated with EHR use and clinical documentation. It is important Congress incentivize the use of health IT products that capture and present data in a standardized manner so that it is uniform regardless of which health IT system is used. Standardizing data across products will both enhance usability and increase patient safety. Improving usability will facilitate interoperability, data transfer, and development of real-world evidence. Increased investment in research, such as through the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ), is needed

to understand the use of digital health in the clinical environment, and what elements support the delivery of the best quality of care for patients.

Implications for Exacerbating Health Disparities

When developing digital technologies to improve health care, it is important to consider how innovations may exacerbate health disparities and understand their influence on patient engagement. Efforts to advance digital technologies in health care should also account for populations with low literacy or limited English proficiency that may make engagement with electronic platforms more difficult.

Research has shown that health care providers' explicit and implicit biases disadvantage racial and ethnic minorities in the health care system and must be accounted for when devising new technologies to ensure relevant information is present, appropriately represents diverse populations, and fosters enhanced patient-provider relationships. Research has also shown that minority and underserved populations are less likely to participate and engage with health technology due to mistrust. To improve levels of trust and uptake, we recommend that Congress incentivize health IT vendors and developers to engage with minority-serving community organizations during the design, implementation, and dissemination of digital health technologies.

Reforming Medicare Coding, Coverage, and Payment Policies to Support Innovation

Medicare Coverage of Interprofessional Internet Consults and Telehealth

The AAMC strongly supports efforts to incentivize use of telehealth services, including the change the Centers for Medicare and Medicaid Services (CMS) made in the 2020 Medicare Physician Fee Schedule Final Rule to allow a payment for interprofessional internet consults. Payment for these services can improve quality and efficiency, improve timely access to specialty input, and enhance the patient experience through more effective communication and coordination between providers.

While the AAMC recognizes there are typically limited scenarios where coinsurance is waived in the Medicare program, we continue to believe that requiring coinsurance for these consults will stifle use of these value-promoting, physician-to-physician services that analyses of the Center for Medicare and Medicaid Innovation (CMMI)-funded Coordinating Optimal Referral Experiences (CORE) model show to be cost-saving to CMS. Therefore, Congress should explore waiving the patient coinsurance for these services. At a minimum, we believe the coinsurance should be waived in circumstances where there is a straightforward mechanism to do so, such as CMMI's ability to do so for specific services in Alternative Payment Models (APM).

Advanced APM Thresholds and Participation

The AAMC participates in an informal coalition working to build upon and improve Accountable Care Organizations (ACOs) and APMs. We recommend that lawmakers work with stakeholders on legislative efforts that would set the thresholds to be qualified participants in an advanced APM (AAPM) at an appropriate level to encourage AAPM participation. The AAMC also supports other health care stakeholder's legislative efforts to extend the AAPM 5% bonus beyond 2024.

Advance Delivery System Reform

To achieve the goals of delivery system reform, Congress should explore changing federal laws and regulations affecting hospital-physician arrangements that were enacted many years ago, including the Physician Self-Referral Law (also known as "Stark"), the Anti-kickback law, and the Civil Monetary

Penalties (CMP) Law. Since enactment of the physician self-referral law (referred to as the Stark law) over 25 years ago, there have been major changes in health care delivery and payment, including many initiatives to align payment with quality and to improve coordination of care. Our members report that provisions in these laws which were enacted to address issues in a fee-for-service system, present significant barriers to clinical and financial integration aimed at improving the quality of care, population health, and reducing costs. Specific concerns relate to prohibitions under the compensation standards of the Stark law and regulations, including "fair market value," "volume or value," and "other business generated" standards. These provisions make it difficult to structure incentive payments that reward physicians for improvements in quality and efficiency.

Given the increasing prevalence of payment programs that focus on meeting well-defined quality standards combined with requiring participants to accept more risk, and the need to, at a minimum, allow for gain-sharing with physicians and others, it is time for Congress to consider the many changes that should be made to various fraud and abuse laws. With the ample protections against program and patient abuse that are now, and increasingly will be, part of the Medicare program, the focus should be on simplifying the criteria for exceptions and making them broadly available as an important tool to encourage wider participation.

Support for Innovative Models in Continuity of Care and Addressing Provider Hesitancy

The AAMC supports and recognizes Project ECHO (Extension for Community Health Outcomes), an innovative telehealth model, and Project CORE (Coordinating Optimal Referral Experiences), an innovation in referral to specialty care, as two national efforts to promote comprehensiveness and continuity in primary care settings and timely and efficient access to specialty expertise. Enabling inter-provider consultation models such as these is directly in alignment with value-based care goals. However, payment policies restrict these innovations from scaling to their full potential, and Congress should explore steps to facilitate and incentivize these types of programs.

Additionally, there is widespread recognition in the provider community of the typical delay in incorporating new clinical evidence into practice. With technological advances and increasing use of telehealth, the whole paradigm of clinical care is changing. Our data suggests that one-third of physicians in practice today are opposed to shifting their practice to telehealth, and another one-third are undecided. To increase patient access to technological advances, Congress should also explore improving reimbursement for telehealth services, reducing administrative burden on providers, and establishing support for infrastructure development and incentives for provider engagement and adoption of telehealth services.

High-cost, Life-saving Technologies

As you proceed, it is important that any discussion needs to address the issue of high-cost technologies that have the potential to dramatically improve patients' health and quality of life. Chimeric Antigen Receptor (CAR) T-cell immunotherapy is an example of a high-cost, innovative technology that is changing lives. However, current Medicare reimbursement for CAR T-cell treatments is inadequate. Cutting-edge treatments such as CAR T-cell immunotherapy are performed almost exclusively at teaching hospitals that already struggle with negative Medicare margins. As new and innovative cures come to market, Congress must fully consider the disproportionate burden faced by teaching hospitals because of those payments, which jeopardizes beneficiary access to these life-saving treatments.

Expand the Use of Real-World Evidence to Evaluate Long-term Clinical Effectiveness and Inform Coverage Decisions

Targeted medications and technologies are being approved with smaller clinical trials and are coming to market sooner. Some of these therapies have limited to no benefit over current technologies, yet many of these therapies continue to command high list prices upon entry into the market, with substantial price increases over time. As Congress looks to address high drug prices, investment in improved post-market surveillance of these new technologies that includes the use of real-world patient experiences should be expanded to evaluate long-term clinical effectiveness of approved drugs and technologies and to inform coverage decisions in federal programs.

Harnessing Data to Empower Patients and Improve Their Health

Privacy and Confidentiality of Patients and Research Subjects

The AAMC recognizes that further deliberations on digital health will also spur discussions on ways to further protect the privacy and confidentiality of patients and research subjects. The AAMC has vigorously supported such protections, but also understands the necessity and importance of data from diverse sources in medical research. Any future proposals should ensure that health data are made available to medical researchers and health care providers to advance discovery, while reasonably protecting privacy and confidentiality. The expertise of the research and health care communities can help inform any potential efforts in this space, clarify the protections already afforded by regulations, and help achieve the balance between individual protections and the public benefits of research.

Patient and Provider Access to Data

We appreciate efforts by Congress and the Administration to expand patient and consumer access to their clinical and claims data via consumer-facing applications (apps). We believe a similar focus is essential to ensure that providers and clinicians have timely and efficient access to data—especially real-time information on their patients at the point of care. Providers need robust, scalable, and interoperable health information technology (health IT) systems and electronic health records (EHRs) to improve clinical decision making and deliver safe, coordinated and effective care and to improve outcomes. Importantly, providers and clinicians need to be able to implement and use any third-party applications of their choosing.

With the ever-advancing field of health IT, the AAMC recommends Congress incentivize the convening of thought leaders from across government, industry, and the medical and research sectors to develop a strategy for addressing challenges that exist for current and future innovations in digital health. For example, the National Academies of Sciences, Engineering and Medicine (the Academies) has a strong history of bringing together experts through "action collaboratives" that address topics of immediate importance to the health of society. As one potential opportunity to explore existing and emerging challenges, the Academies could be charged with establishing an Action Collaborative on Technology Innovation in Digital Health, with working groups that include representatives from a wide range of federal agencies, the research community, clinicians, health system leaders, and private sector technology companies.

Patient-Centered Health IT Data Standards

There is a need to establish patient-centered health IT data standards. If data structures in the health information vary, or if the measurements or models for collecting data differ, the full potential for digital health advancement cannot be achieved. It is critical that the medical and research communities develop common data models and standards for clinical data, and that the EHRs, and other digital health

technologies, capture data according to established standards. Any work in this area should be done collaboratively with existing standards-setting efforts. Given the NIH's National Library of Medicine (NLM) expertise in research, development, and training in biomedical informatics and health IT, we believe that, with the appropriate level of support, the NLM/NIH could be well-equipped to lead the engagement across other federal agencies (including ONC, FDA, CMS, ARHQ, VA, and DoD) as well as bringing together clinicians, researchers, and private sector technology companies to collectively establish common data models and standards for clinical data.

Other Considerations

Research Policy Board

One of the key recommendations of the 2016 report from the National Academies of Sciences, Engineering, and Medicine "Optimizing the Nation's Investment in Academic Research" was the formation of a Research Policy Board, a recommendation that was incorporated into the 21st Century Cures Act. This body, comprised of federal and non-federal members, was intended to make recommendations "regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research." This essential function to streamline regulations and minimize burden has not been implemented, and we suggest that Cures 2.0 could include a mechanism to ensure the formation of the Research Policy Board as already mandated by Congress.

The Innovation Account

The 21st Century Cures Act established the Innovation Fund to provide multiyear support for specific initiatives at the NIH and FDA. We are immensely grateful that Congress has provided above-inflation increases to the NIH while also including the funding provided through the 21st Century Cures Act. Sustainable, predictable funding growth for medical research and all federal agencies that support the public health continuum is key in ensuring that our nation can fully benefit from the wide range of scientific opportunity and build on developing knowledge to improve health over the long term.

As you move forward to craft "Cures 2.0", we note that the expertise of the Appropriations Committee will be valuable to optimize the Innovation Fund's future functionality and to avoid any unintended consequences of targeted funding, particularly as the Innovation Account approaches its expiration at the end of FY 2026. We welcome the collective and ongoing efforts of Congress in support of medical innovation and appreciate that you continue to make funding for these important agencies a top priority.

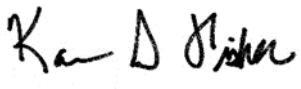
Increasing Support for the Physician Workforce

In addition to the specific focus areas referenced in your call for input, it also is critical to recognize that a significant challenge that patients face in accessing care and new discoveries is that demand for physicians continues to grow faster than supply. The United States is facing a projected shortfall of between 46,900 to 121,900 physicians by 2032, with predicted shortages in both primary and specialty care. Physicians are a critical element of our national health care infrastructure and workforce, and if we do not address this impending problem, patients from all communities will find it difficult to access the care they need.

Congress should address one of the key components of the physician shortage and improve care delivery and health outcomes by ending the 20-plus year freeze on Medicare support for graduate medical education (GME). Specifically, the AAMC strongly supports the Resident Physician Shortage Reduction Act of 2019 (H.R. 1763), bipartisan legislation introduced by Reps. Terri Sewell and John Katko, that would partially lift hospital-specific resident funding caps and enable teaching hospitals to train more physicians. Additionally, Reps. Brad Schneider, Susan Brooks, Ann Kuster, and Elise Stefanik introduced the Opioid Workforce Act of 2019 (H.R. 3414), which the AAMC also supports. This more targeted, bipartisan legislation would address the widespread need for additional physicians who are specialized to treat patients with substance use disorders and chronic pain. The Ways & Means Committee passed the Opioid Workforce Act in June, and we urge Congress to pass this important bill in order to meet the needs of communities struggling with substance use disorders and the opioid crisis.

Thank you again for your efforts to build upon 21st Century Cures and ensure patient access to new cures. We welcome the opportunity to expand on the information we have provided above and serve as a resource to you as you continue these efforts. Please feel free to contact Len Marquez, Senior Director, Government Relations, at lmarquez@aamc.org or (202) 828-0525, or me, with any questions.

Sincerely,



Karen Fisher, JD
AAMC Chief Public Policy Officer