



July 14, 2021

The Honorable Diana DeGette
Chair
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Fred Upton
Ranking Member
Subcommittee on Energy
House Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Re: 21st Century Cures 2.0 Discussion Draft

Dear Chair DeGette and Ranking Member Upton,

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 133,500 family physicians and medical students across the United States, we write to provide feedback on the following provisions in the Cures 2.0 Act discussion draft released last month.

Similar to the original Cures Act, the Cures 2.0 discussion draft reflects a goal to safely and efficiently modernize health care delivery – particularly as we are still fighting the coronavirus pandemic. The AAFP has long advocated for better integration of primary care in our health care system. Primary care is the only health care component where increased access is associated with better population health and more equitable outcomes. The COVID-19 pandemic has also underscored the urgency of building and financing a robust and accessible primary care system in our country.

The AAFP is pleased that you have included the importance of many pressing issues including, achieving clinical trials that reflect the diversity of the patient population; leveraging real-world data to create closer alignment between medical progress and patient need; improving health literacy to improve patient outcomes; and advancing solutions for individuals confronting long COVID.

Sec. 101. Further Understanding the Implications of Long COVID

The AAFP supports the Department of Health and Human Services (HHS) conducting a national survey to better understand the impact of long COVID on our health care system. We have [called](#) for federal research efforts, including a [comprehensive national plan](#), to better understand the impact and causes of long COVID, particularly in vulnerable populations, and urge the inclusion of primary care physicians, who will play a vital role in identifying long COVID, helping patients manage symptoms, long term treatment, and referring to sub-specialists when appropriate.

Sec. 102. National Testing and Response Strategy for Future Pandemics

The Academy supports the need for a national strategy for future pandemics and has [stressed](#) that national preparedness efforts must include a clearly defined primary care strategy. A future national response strategy must include plans for stockpiling and distributing personal protective equipment (PPE) to primary care and other frontline clinicians in an efficient and effective way. Family physicians [struggled](#) to find adequate and usable PPE during the beginning the COVID-19 pandemic, forcing them to pay extremely high prices to keep themselves, their staff, and their patients safe. PPE shortages also contributed to practices temporarily and permanently closing their doors.

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Consistent and accurate messaging among federal agencies on testing and treatment options is vital to successfully address a pandemic. A future national response strategy should include processes that support consistent messaging that is rooted in science and data. Testing and treatment options should be authorized based on stringent criteria and updated with frequent and coordinated communication as information evolves. Testing supplies and reagents should be included in stockpiles with PPE.

Lastly, community primary care practices must be incorporated in any national vaccination campaign from the outset. In the future, existing distribution pathways should be used to ship new vaccines to community primary care physicians, in addition to retail pharmacies, mass vaccination sites, and community health centers. Data confirms that patients would prefer to receive the COVID-19 vaccine from their own primary care physician.ⁱ Making vaccines more immediately available in primary care clinics could mitigate disparities in vaccination status and foster trust.

Sec. 104. Vaccine and Immunization Programs

The AAFP has long [called](#) for upgrading and the modernization of the Immunization Information System (IIS). We [endorsed](#) the Immunization Infrastructure Modernization Act (H.R. 550); and have highlighted the important role that the IIS system plays in facilitating coordinated care. Currently, family physicians struggle to find the vaccination records for patients who receive various vaccines from retail pharmacies or other locations. This contributes to care fragmentation and administrative burden. Additionally, a national immunization registry should be integrated into existing state registries, so it does not add administrative burden to physicians.

Sec. 202. Increasing Health Literacy to Promote Better Outcomes for Patients

The Academy is supportive of federal efforts to increase health literacy among patients. We would urge the inclusion of strategies to combat misinformation, particularly seen during the COVID-19 pandemic, due to its negative impact on health literacy. Misinformation is even more prevalent in underserved and diverse populations where low health literacy skills and unique health information needs play a part in making people in these groups more vulnerable to predatory practices.

National data indicate that more than one-third of U.S. adults have limited health literacy, which contributes to poor health outcomes and affects patient safety, and health care access and quality.ⁱⁱ The AAFP [champions](#) the promotion of health literacy throughout all aspects of the health care system including but not limited to strategic and organizational design, research and quality improvement metrics and provision of direct patient care, especially to patients with low health literacy.

Sec. 203. Increasing Diversity in Clinical Trials

The AAFP strongly [supports](#) the inclusion of diverse populations in clinical trials, surveys, and other research since it is the only way to understand the drivers of health disparities and their impact on health, whether it be increased risk for disease or differences in treatment efficacy. Women's representation remains low in clinical trials, particularly in phase I trials (about 22%). Pregnant and lactating women continue to be excluded from clinical trials. These evidence gaps present difficulties for physicians who need to advise pregnant and breastfeeding women requiring drug treatment.ⁱⁱⁱ

It is equally important that once the drivers of disparity are identified, to develop a national strategy to address them. This will be the only way to comprehensively address disparities over time.

Sec. 401. GAO Study and Report

This section requires a GAO report on enhancing coverage and reimbursement approaches under Medicare for innovative technologies that "increase access to health care, improve health care quality, decrease expenditures, or otherwise improve the Medicare program or health care for beneficiaries under such program." We urge the inclusion of primary care as a focus in the GAO report, because primary care is the only health care component where increased access and supply is associated with better population health and more equitable outcomes.^{iv} Research also confirms that advanced primary care, such as

patient-centered medical homes and other accountable care models, help fulfill the “quadruple aim”: high-quality care, better health, lower costs, and improved experience for clinicians and staff in the delivery of care.^v

Sec. 402. Strategies to Increase Access to Telehealth under Medicaid and Children’s Health Insurance Program

Before the COVID-19 pandemic, Medicaid coverage and payment for telehealth services varied significantly across states and patient populations. Given that the availability of telehealth services can improve access to needed care and care continuity, it is vital that Medicaid beneficiaries have equitable coverage and access to telehealth services within their medical home. The AAFP supports the creation of guidance for states to assist in effectively integrating telehealth in their Medicaid programs, including in existing value-based care models.

The AAFP has stressed that CMS guidance should encourage states to cover audio-only telephone E/M visits in the Medicaid & CHIP program to preserve telehealth access for patients who may lack broadband access and help address health equity. Until longer-term solutions can be deployed to address these barriers, telephone visits will be essential for ensuring that telehealth expands access to care for vulnerable populations and does not worsen health disparities.

Concerning the commissioned GAO study for the Telehealth Improvement for Kids’ Essential Services (TIKES) Act, the Academy stresses the inclusion of key demographic information such as race, ethnicity and language to analyze how telehealth is impacting equity in access.

The AAFP also supports the GAO study on coordination of telehealth policies across federal programs. Payment models should support the patients’ ability to choose their preferred modality of care (i.e., audio-video or audio-only) and ensure appropriate payment for care provided. For example, E/M services require the same level of physician work regardless of the modality of care. Family physicians report that there are unique costs associated with implementing telehealth in their practices and altering clinical workflows to ensure successful telehealth visits. Payment for telehealth services must appropriately account for these costs.

Sec. 403. Extending Medicare Telehealth Flexibilities

Telehealth benefit [expansions](#) must increase access to care and promote high-quality, comprehensive, continuous care. Telehealth, when implemented thoughtfully, can improve the quality and comprehensiveness of patient care and expand access to care for under resourced communities. The AAFP [stresses](#) that any telehealth benefit expansion should enhance the physician-patient relationship rather than disrupt it, and incentivize coordinated, continuous care provided by the medical home.

The AAFP [supports](#) permanently removing the section 1834(m) geographic and originating site restrictions to ensure that all Medicare beneficiaries can access telehealth care at home. The COVID-19 pandemic has demonstrated that enabling physicians to virtually care for their patients at home cannot only reduce patients’ and clinicians’ risk of exposure and infection but also increase accessibility for patients who may be homebound or lack transportation. It can also offer opportunities for physicians to engage distant family members and caregivers. Telehealth visits allow physicians to get to know their patients in their home, observe things they normally cannot during an in-office visit, and develop a more personalized treatment plan.

In order to make long-term investments in telehealth platforms and workflow modifications, physician practices need advanced notice of changing Medicare telehealth policies. While more data will be needed to make determinations on whether to permanently continue certain telehealth services, temporary policies should be avoided for well-established, high-value telehealth services such as E/M office visits and mental health services.

The AAFP also recognizes concern about telehealth benefit expansion and preventing waste, fraud, and abuse and considering policy options to reduce those risks. We recommend relying on existing Medicare policies to minimize confusion and administrative burden imposed on physician practices. For example, Medicare defines an established patient as one that has received professional services from a clinician in the same practice and of the same medical specialty within the last three years. This definition should be repurposed in any new telehealth policies, instead of creating a new definition for an established patient that could conflict with current coding guidelines.

Sec. 404. Coverage and Payment for Breakthrough Devices Under the Medicare Program

The AAFP supports Medicare coverage and payment for breakthrough devices that the Food and Drug Administration has approved, while also ensuring patient safety. Physicians should receive payment for services that are reasonable and necessary, safe and effective, medically appropriate, and provided in accordance with accepted standards of medical practice.

Sec. 405. Secretary of Health and Human Services Report on Coverage for Innovative Technologies

The AAFP supports the creation of this report and believes it would help modernize coverage and payment of digital adjunct devices and services that may improve patient outcomes. The Secretary of HHS and the CMS Administrator should consult with family physicians, patients, and other stakeholders throughout the development of this report. We also suggest the term be "digital adjuncts and alternatives" to reflect the broader solution space.

Sec. 406. Secretary of HHS Report on CMS Computer Systems

The AAFP agrees there is a strong need to modernize the CMS information technology infrastructure. With any modernization, CMS should leverage the same standards and APIs required of covered entities to access Medicare data under federal regulations. This will help drive adoption and utilization of the standards and allow certified EHR technology to connect to Medicare APIs more easily. We also recommend the inclusion of solutions be part of the report to the Secretary of HHS, as well as a timeline for CMS to address any deficiencies.

The AAFP commends your actions to build upon the success of the original Cures Act and hopes to be a resource to you and your staff as you finalize Cures 2.0. Should you have any questions, please contact John Aguilar, Manager of Legislative Affairs at jaguilar@aafp.org.

Sincerely,



Gary L. LeRoy, MD, FAFPP
Board Chair
American Academy of Family Physicians

¹ Hamel, L., Sparks, G., & Brodie, M. (2021, March 9). KFF COVID-19 Vaccine Monitor: Experiences With Vaccine Access And Information Needs. <https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-experiences-vaccine-access-information-needs/>.

² Hersh L, Salzman B, Snyderman D. Health Literacy in Primary Care Practice. *Am Fam Physician*. 2015 Jul 15;92(2):118-24. PMID: 26176370.

³ Ravindran, T. K. S., Teerawattananon, Y., Tannenbaum, C., & Vijayasingham, L. (2020, October 27). *Making pharmaceutical research and regulation work for women*. *The BMJ*. <https://www.bmj.com/content/371/bmj.m3808>.

⁴ National Academies of Sciences, Engineering, and Medicine 2021. *Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25983>.

⁵ Gross, A. (2018, August 8). *ACOs + ADVANCED PRIMARY CARE = WINNING COMBO FOR TRIPLE AIM?* Primary Care Collaborative. <https://www.pcpcc.org/2018/08/08/acos-advanced-primary-care-winning-combo-triple-aim>.