February 21, 2025

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

Dear Representative DeGette,

On behalf of the American Academy of Family Physicians (AAFP), representing more than 130,000 family physicians and medical students across the country, I write to thank you for your leadership on issues impacting family physicians and their patients and to offer our comments on your white paper entitled "A Roadmap for 21st Century Cures" and the broader 21st Century Cures initiative. The AAFP has previously shared recommendations on ways to advance Cures 2.0, and we appreciate the opportunity to offer additional recommendations on advancing innovation and modernization in the health care system to strengthen primary care and improve patient outcomes.

In 2016, the 21st Century Cures Act was signed into law containing provisions related to National Institutes of Health funding and administration, reducing opioid use, medical research, and drug development. Cures 2.0 was intended to be the successor of the 21st Century Cures Act and proposed provisions to further accelerate medical research, increase patient access to novel therapeutics, and enhance telehealth services. Some provisions from the bill were signed into law including the development of the Advanced Research Projects Agency for Health (ARPA-H) and reforms to the Food and Drug Administration (FDA). Cures 2.0 aimed to build on the success of 21st Century Cures by focusing on ways we can modernize coverage for and access to life-saving cures.

As you continue to develop legislation to build upon the work already undertaken as part of the 21st Century Cures initiative, we are reminded that a modernized system of developing new cures will require a delivery system capable of getting them to patients in need. With that in mind, the AAFP is pleased to share to the following comments on the successor to Cures 2.0, often referred to as Cures 2.1.

Telehealth in Medicare (and Beyond)

As the usual source of care for patients across the lifespan, family physicians are uniquely trained to practice across care settings and meet the needs of their communities, including offering care by their patient's preferred and most appropriate modality. This has more frequently included care delivered via telehealth, which has seen increased utilization as a result of the pandemic. Telehealth claims jumped from 0.1% in 2019 to about 5% at the end of 2021.[i] In 2023, a quarter of all eligible Medicare beneficiaries utilized telehealth.[ii] And according to an AAFP survey, nine in ten family physicians practice telehealth today.

The AAFP strongly believes that permanent telehealth coverage and payment policies should:

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- Ensure coverage and access to audio/video and audio-only telehealth services for all Medicare patients, regardless of their physical or geographic location;
- Include guardrails to ensure care continuity and quality by encouraging the use of telehealth with a patient's usual primary care physician or another trusted care relationship; and
- Enable patients, in consultation with their trusted primary care physician, to determine the most appropriate modality of care for each encounter.

The AAFP supports expanded use of telehealth and telemedicine as an appropriate and efficient means of improving health, when conducted within the context of appropriate standards of care. Telehealth technologies can enhance patient-physician collaborations, increase access to care, improve health outcomes, and decrease costs when utilized and coordinated with longitudinal care.

Any permanent expansion of telehealth benefits should be structured to not only increase access to care but also promote high-quality, comprehensive, continuous care, as outlined in the joint principles for telehealth policy put forward by the AAFP, the American Academy of Pediatrics, and the American College of Physicians. The appropriateness of a telemedicine service should be dictated by the standard of care and not by arbitrary policies. Available technology capabilities, as well as an existing patient-physician relationship, impact whether the standard of care can be achieved for a specific patient encounter type.

Telehealth, when implemented thoughtfully, can improve the quality and comprehensiveness of patient care and expand access to care for rural and under-resourced communities and vulnerable populations. As discussed in the Academy's comments on the CY25 Medicare Physician Fee Schedule proposed rule and our aforementioned joint principles, the AAFP believes telehealth policies should advance care continuity and the patient-physician relationship.

The AAFP strongly believes telehealth is most appropriate when provided by a patient's usual source of care. We have significant concerns about the rapid proliferation of direct-to-consumer (DTC) telehealth vendors and the resulting interference with the established patient-physician relationship. In the last several years we've seen new and different types of DTC telehealth vendors emerge, including many for-profit start-ups that market themselves in ways that lead consumers to believe they are providing true, person-centered health care. The dangers of these types of companies extends beyond disrupting the established patient-physician relationship and can range from misusing patient data to making patients vulnerable to medical misinformation, which can even lead to patient harm.

In light of these concerns, the AAFP supports the implementation of telehealth coverage guardrails to protect the quality and continuity of care delivered virtually, such as requiring an established patient relationship for some telehealth services. Ensuring patients receive telehealth services from a clinician that knows them and can access their health record will help ensure patients receive appropriate care, including in-person services when needed.

A report from the HHS Office of the Inspector General (OIG) found that 84% of Medicare fee-for-service telehealth visits are already being provided by clinicians who have an established relationship with the patient. Other studies indicate patients prefer telehealth services provided by their usual source of care. Implementing additional guardrails would help ensure high-quality services are being delivered to patients without unduly restricting access to care, while also safeguarding program integrity.

Telehealth is essential for many rural residents, who may encounter significant logistical and financial barriers when trying to access in-person care. However, the lack of modern broadband infrastructure has proven to be a sizable barrier to equitable telehealth and digital health access for rural Americans, who are ten times more likely to lack broadband access than their urban counterparts, leading to fewer audio/video visits. We urge Congress to address these barriers that continue to hinder the ability of individuals in rural communities to access quality telehealth services.

In many instances, family physicians have reported that some of their patients, particularly seniors, are most comfortable with or can only access audio-only telehealth visits. A recent study of federally qualified health centers found that, by mid-2022, one in five primary care visits and two in five behavioral health visits were audio-only, and audio-only visits were still more common than video visits.[iii] Therefore, permanent telehealth policies must include coverage of and proper payment for audio-only telehealth services across programs.

The AAFP calls for the reintroduction and passage of the Protecting Rural Health Access Act, which would ensure rural and underserved community physicians can permanently offer telehealth services, including audio-only telehealth services, and provide payment parity for these services. The available data clearly indicate that coverage of and fair payment for audio-only services is essential to facilitating access to care.

This legislation would also permanently remove the current section 1834(m) geographic and originating site restrictions to ensure that all Medicare patients can continue to access care at home, which the AAFP has advocated in favor of previously. The COVID-19 pandemic demonstrated that enabling physicians to virtually care for their patients at home could not only reduce patients' and clinicians' risk of exposure and infection but also increase access and convenience for patients, particularly those who may be homebound or lack transportation. Telehealth visits can also enable physicians to get to know their patients in their homes and observe things they normally would not during an in-office visit, which can contribute to more personalized treatment plans and better referral to community-based services.

Further, **the AAFP supports the removal of remaining telehealth restrictions on alternative payment models**. Currently, telehealth flexibility is limited to a narrow set of Accountable Care Organizations (ACOs) with downside risk and prospective assignment—even though other tools apply to all ACOs. Since all participants in the Medicare Shared Savings Program are being held accountable for quality, cost, and patient experience, they should all have the flexibility to use telehealth tools to deliver care.

Medical Record Maintenance and Exchange

The AAFP strongly supports the 21st Century Cures Act's vision of health information technology (IT), including an electronic health record (EHR) that would exist "in a single, longitudinal format that is easy to understand, secure, and may be updated automatically," requiring no special effort by the patient or physician. We believe EHRs can support and enable care coordination, continuity, and patient-centeredness, which results in safer, higher-quality care for patients, families, and communities. The AAFP appreciates and has supported many of the efforts the Assistant Secretary for Technology Policy's (ASTP/ONC) office has undertaken to advance the interoperability of health IT, which can reduce administrative tasks for physicians and facilitate patients' access to their health data. We agree with the authors that there is much still to do to achieve the EHR Cures envisioned.

The AAFP recommends federal incentives be used to support the application of uniform standards and a national system of interoperability that recognizes the importance of the patient-physician relationship and prioritizes care communication among health care team members. Health IT must facilitate efficient information sharing without undue financial or administrative burden on physician practices – regardless of the size of the facility or care setting – and privacy protections must apply to all parties that store, organize, manage, and transfer patients' personal health information, not only to Health Insurance Portability and Accountability Act (HIPAA)-covered entities.

Other Cures 2.1 Proposals

As you continue to craft legislation and build upon this white paper, the Academy would strongly encourage the inclusion of additional proposals from Cures 2.0 that have not yet been enacted. We continue to believe in the value of those ideas and offer recommendations below on those we consider most important. The AAFP believes including the following pieces in any future Cures legislation is vital to support the original intent of the bill.

National strategy to prevent and respond to pandemics

The AAFP believes there is a need to develop a national strategy for future pandemics, and we have emphasized that national preparedness efforts must include a clearly defined primary care strategy. The AAFP submitted detailed comments on the PREVENT Pandemics Act discussion draft, including how to best invest in primary care and integrate it into public health infrastructure to improve the system's response to future pandemics. Family physicians provide comprehensive health care to patients of all ages and are often the first line of defense for preventive care, chronic care management, and acute illness. The longitudinal relationships family physicians have with their patients make them well-positioned to counsel patients about personal risk factors, encourage mitigation measures, and address health-related social needs, which can be exacerbated during pandemics and public health emergencies. Additionally, evidence indicates that patients prefer to receive vaccines and related counseling from their primary care physician.[iv] For these reasons, Congress should ensure pandemic preparedness and response plans include close coordination with primary care practices.

The AAFP supports funding for modernization efforts that would build workforce capacity, expand laboratory systems, and improve health IT systems at the local, state, and federal level. As outlined in the AAFP's position paper, family physicians play an integral role in achieving public health goals. Primary care activities – including clinical preventive services, early diagnosis and intervention, quality-driven and evidence-based care, health promotion, and health advocacy – reinforce public health activities. Public health activities such as population surveillance; disease control; health promotion; and interventions based on determinants of health, injury prevention, and policy formation facilitate primary care's ability to function within the health care system. We were encouraged by ASTP/ONC's Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability proposed rule, which proposes public health departments use the data standards that are part of ASTP/ONC's certified electronic health record technology (CEHRT) certification program. If finalized, this change would significantly improve data exchange and data usability between public health departments, private payers, and physicians.

During past pandemics and natural disasters, immunization information systems (IIS) have been able to respond to the unique and pressing issues that these public health emergencies present. However, IIS vary across states in terms of their capabilities and the breadth of patient information contained. Now is the time to modernize interoperability and bidirectional data exchange between IIS and community immunization providers. We urge Congress to strongly support ASTP/ONC's ongoing work to advance health care system interoperability through proper funding and to invest in our nation's public health to build workforce capacity, expand laboratory systems, and improve health information systems.

Consistent and accurate messaging among federal agencies on testing and treatment options is vital to successfully addressing a pandemic. A future national response strategy should include processes that support consistent messaging 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 personal protective equipment. 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.

Vaccine and immunization programs

Vaccines are one of the safest and most cost-effective public health technologies we have, and the AAFP has long called for upgrading and modernizing IIS. Current adult vaccination coverage yields an estimated 65 million averted disease cases and $185 billion in averted case costs over a 30-year period.[v] The COVID-19 pandemic was a real-time demonstration of the invaluable role that vaccines play in saving lives when they are affordable and accessible. Yet each year, the U.S. spends $27 billion on four vaccine-preventable illnesses in adults over the age of 50: flu, pertussis, pneumococcal pneumonia, and shingles.[vi]

This is in part due to remaining barriers that prevent many individuals from being able to readily access and receive all recommended vaccines in their physician's office. For example, Medicare currently splits vaccine coverage between Part B (outpatient care) and Part D (prescription drug coverage). New vaccines, such as RSV, are only covered under Medicare Part D, which was designed for pharmacies to submit claims and makes it particularly challenging for primary care physicians to deliver recommended vaccines in their office.

Approximately 8.5 million Medicare enrollees have Part B but not Part D coverage, leaving them without affordable access to Part D vaccines.[vii] For those with Part D coverage, physicians can give patients a bill to submit to their Part D plan for reimbursement, but this forces patients to pay a potentially high out-of-pocket cost upfront, which creates barriers to access. There is an online clearinghouse that allows physicians to check Part D coverage and electronically submit an out-of-network Part D claim, but physicians must pay for this service by sharing a portion of their payment. Because of these barriers to administering the vaccine in-office, physicians can recommend or prescribe a Part D-only vaccine to a patient, who must then identify and secure a separate appointment at an in-network pharmacy in order to be vaccinated.

Legislative action is needed to ensure that physicians can easily provide all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines to Medicare patients. **We urge Congress to pass legislation to require Medicare Part B coverage of all vaccines, allowing patients to more readily access vaccines from their usual source of care and improving our nation's uptake of one of the most cost-effective public health measures.** Recently, the AAFP also joined a coalition letter with detailed recommendations on funding levels for immunization efforts for Congress' consideration.

Increasing diversity in clinical trials

The AAFP strongly believes participants in clinical trials should be selected without regard to race, ethnicity, economic status, or gender; this is fundamental to ethical medical research. We believe women, children, and people from historically underrepresented groups should be included in clinical trials applicable to their health issues. It is well-documented that underrepresentation of people of color and women in clinical trials negatively impacts research outcomes, and therefore negatively impacts patient care.[viiix] The AAFP urges Congress to work with the FDA to specify required levels of racial, ethnic, and gender diversity in clinical trials. We recommend Congress consider a variety of ways to increase diversity in clinical trials, including a public education campaign to build trust and potential incentives like transportation subsidies or other financial compensation.

Additionally, the AAFP is supportive of two bills from the 118th Congress that would encourage participation in studies by two demographic groups that are typically unrepresented or underrepresented in clinical trials. The Advancing Safe Medications for Moms and Babies Act would establish programs and requirements to support the inclusion of pregnant and lactating women in clinical research. Historically, pregnant and lactating women have been excluded from clinical trials, which severely limits the medications that are considered safe. Separately, the Innovation in Pediatric Drugs Act would make improvements

to two existing pediatric drug laws: the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). The bill would increase the number of rare disease drugs studied in children, help ensure that required PREA studies actually get completed, and give the National Institutes of Health's BPCA program its first funding increase in 22 years. The AAFP calls for the reintroduction of these proposals as standalone legislation or to be included within any future Cures 2.1 package.

A note on health data privacy

The AAFP strongly agrees that the regulation of health-related data is outdated, and we have repeatedly acknowledged that ensuring health data privacy long-term is going to require a federal citizen data privacy law and regulatory framework. We have long supported policies that guarantee the appropriate security of protected health information while working to improve patients' access to their data, as well as the ability to share patients' health information across the care team. The AAFP is strongly supportive of making data reliably interoperable while maintaining patient confidentiality. We agree that patients must be informed of how their data is used and who it is shared with, and we believe transparency must be required of all stakeholders who hold information related to any facet of health care services, including public and private payers, hospital systems, and other care delivery organizations.

Thank you for the opportunity to offer comments on this white paper. We appreciate being able to offer recommendations on advancing innovation and modernization in the health care system to strengthen primary care and improve patient outcomes. The AAFP looks forward to continuing to work with you to ensure the implementation of reforms that best support family physicians and the patients they serve. If you have any questions, please contact Natalie Williams, Senior Manager of Legislative Affairs, at nwilliams2@aafp.org.

Sincerely,

Steve Furr, M.D., FAAFP

Steve Furr, MD, FAAFP
American Academy of Physicians, Board Chair

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