



August 2, 2024

The Honorable Diana DeGette  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Larry Bucshon, M.D.  
U.S. House of Representatives  
Washington, DC 20515

Dear Representatives DeGette and Bucshon,

On behalf of the American College of Physicians (ACP), I write to commend your commitment to exploring proposals that would build upon the advances made by the 21<sup>st</sup> Century Cures Act of 2016 (Pub. Law 114-255). The College appreciates the opportunity to offer a physician perspective on the gaps and challenges in health care delivery that could be improved upon under the 21<sup>st</sup> Century Cures initiative. Our comments and recommendations are specific to approaches to bolster pandemic preparedness, enhance our nation's public health infrastructure, and improve health care interoperability.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

**What elements might be missing in Cures 2.0 that are essential for further progress? (Question #2 from the request for information (RFI)):**

The College has previously written in support of several provisions within the [Cures 2.0 Act, H.R. 6000](#). In addition to the [recommendations](#) in our previous statements on Cures 2.0, we would like to underscore the following policy proposals for consideration as part of the next iteration of the 21<sup>st</sup> Century Cures initiative.

***Enhance Pandemic Preparedness***

The onset of the COVID-19 pandemic highlighted significant gaps in our country's pandemic and public health emergency (PHE) response. If the status quo remains, our country will not be prepared for future PHEs. In ACP's policy paper, [Preparing for Future Pandemics and Public Health Emergencies](#), **we recommended that Congress sufficiently and consistently fund and support pandemic preparedness and that the federal government develop and maintain a comprehensive and unified federal pandemic preparedness and response plan.** It is critical that the plan should cut across agencies and levels of government and incorporate feedback and input from relevant stakeholders, including from physicians. **ACP strongly encourages Congress to pass the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization, which is essential to improving our country's unified preparedness approach.**

A comprehensive preparedness plan should include approaches to minimize the impact of supply shocks in future pandemics. ACP recommends that relevant agencies should be provided supply chain monitoring capabilities during PHEs to better detect shortages and redirect resources where needed. **The College supports bolstering the Strategic National Stockpile (SNS) and is encouraged to see reauthorization for it included in the Pandemic and All-Hazards Preparedness and Response Act (PAHPARA), S.2333 and the Preparing for All Hazards and Pathogens Reauthorization Act, H.R. 4421.** We urge Congress to support policies that would facilitate collaboration between the federal government with state and local governments and hospitals to ensure that the SNS's capacity is sufficient to respond to future pandemics.

### **Strengthen the Public Health Infrastructure**

When looking at approaches to mitigate the potential harmful effects of future PHEs, it is essential to examine policies that would strengthen the country's public health infrastructure. In ACP's recently published policy paper, [\*Modernizing the United States' Public Health Infrastructure\*](#), we provided recommendations for improving the country's public health data sharing capabilities. Assessment and surveillance are core components of public health infrastructure. Public health departments rely on data from physicians, hospitals, laboratories, and others to make informed decisions, measure the health of the community, detect emerging threats, and track how certain populations are affected by health disparities and social drivers of health. However, the current public health infrastructure lacks common data standards, interoperable systems to share information, and the capability to share data in real-time.

**The College supports the development of a modern national public health data infrastructure capable of real-time bidirectional data sharing.** Efforts to allow information sharing among health care and public health entities should include strong patient privacy and confidentiality protections and establish clear, understandable, adaptable, and enforceable rules on how data will be used. ACP supports investments in traditional and emerging epidemiology technologies, such as wastewater surveillance, which was used during the COVID-19 pandemic to successfully track disease outbreaks and direct resources where they were most needed. **We support Section 204 in S. 2333 that would establish a pilot program for public health data availability. The pilot would provide support to state and regional public health departments to track situational awareness activities and improve coordination across the Department of Health and Human Services so that deidentified, aggregated data on potentially catastrophic infectious disease outbreaks can be made publicly available close to real-time.**

### ***Improve Data Interoperability***

The College is supportive of the Cures Act's goals to increase information sharing, improve patient care, and ensure a patient's health information follows the patient across the health care continuum. Since the passage of the 21<sup>st</sup> Century Cures Act in 2016, there has been growing demand for timely and high-quality electronic health information (EHI) across the health care and technology innovation ecosystems. **We strongly encourage a renewed focus on health data exchange and information blocking as you look at bipartisan policy reforms to advance widespread health care interoperability.**

ACP has written multiple statements and letters [\*sharing ACP's positions\*](#) on the Cures Act's provisions regarding interoperability, information blocking, and the Assistant Secretary for

Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) certification program. While we support these initiatives, we remain concerned about regulations that could increase physician burden and lead to higher health care costs.

**ACP does not agree that focusing on moving large quantities of data from one place to another will improve interoperability.** Efforts to improve interoperability should focus on the breadth and depth of information involved in useful clinical management of patients as they transition through the healthcare system, the exchange of useful, meaningful data at the point of care, and the ability to incorporate clinical perspectives and query health IT systems for up-to-date information related to specific and relevant clinical questions. Improved interoperability initiatives, including those that give patients rightful access to their EHI, should be implemented iteratively, so their effects on patient care are adequately demonstrated and the risks of data overload and data without context are mitigated.

Another area of concern for ACP is the complexity of information blocking regulations. **The College [continues](#) to have significant concerns regarding the complexity of ASTP/ONC's information blocking provisions and how that complexity will affect our physician members in their daily practice.** Not only are the information blocking provisions, exceptions, and sub-exceptions complicated in and of themselves, they can overlap with requirements under the Health Insurance Portability and Accountability Act (HIPAA), making it difficult to understand what information a clinician is permitted versus required to share for any individual patient. For those clinicians who do not understand the complexity of the information blocking provisions and how they intersect with longstanding HIPAA regulations, they will inevitably lean towards not sharing the information.

#### ***Enhance Patient Matching***

While we appreciate that Congress has prioritized interoperability and digital data exchange in the 21st Century Cures Act and other legislation, we believe that progress towards these national priorities is inhibited by patient matching and identification issues. **The College supports the [Patient Matching and Transparency in Certified Health IT \(MATCH IT\) Act of 2024, H.R. 7379](#), which aligns with ACP's policy to support best practices for patient matching and identification to improve patient safety and expand interoperability efforts in health care.**

#### **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? (Question #3 from the RFI):**

In a 2021 [position paper](#) entitled, *Health Information Privacy, Protection, and Use in the Expanding Digital Health Ecosystem*, ACP examines the growing privacy issues surrounding digital technologies. Health IT and other digital technologies, including personalized digital health products, should incorporate privacy and security principles within their design as well as consistent data standards that support privacy and security policies and promote safety.

The 21st Century Cures Act, and subsequent regulations from the Centers for Medicare and Medicaid (CMS) and ASTP/ONC aimed to enhance both patient and clinician access to personal



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health information (PHI). These regulations promote the use of standards-based application programming interfaces and outline information-blocking rules and enforcement policies. They focus on putting patients in control of their PHI and allowing for more person-mediated exchange using mobile health apps, wherein patients can rightfully access and disclose their PHI to an app of their choice. However, once information is disclosed to the app or other digital health tool, it loses its HIPAA privacy protections. The limits of these interoperability and access initiatives further support the need for broader industry guardrails and public and private consensus on a national privacy framework that incorporates the expanding digital health landscape.

ACP supports oversight and enforcement to ensure that all entities not currently subject to the HIPAA rules and regulations and that interact with PHI are held accountable for maintaining the confidentiality, privacy, and security of that information. New approaches to privacy and security measures should be tested before implementation and regularly reevaluated to assess the effect of these measures in real-world health care settings. **Thus, we strongly encourage Congress to pass the [American Privacy Rights Act \(APRA\)](#), which would establish the nation's first comprehensive federal consumer data privacy framework.**

#### Conclusion

ACP greatly appreciates your inviting input from the physician community. We stand ready to continue to serve as a resource and welcome the opportunity to continue to work with you in developing policy to advance the next iteration of 21<sup>st</sup> Century Cures initiative. Please contact Vy Oxman, Senior Associate of Legislative Affairs, by phone at 202-261-4515 or via email at [voxman@acponline.org](mailto:voxman@acponline.org) with any further questions or if you need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Isaac O. Opole".

Isaac O. Opole, MBChB, PhD, MACP

President