



Statement for the Record
American College of Physicians
Hearing before the House Energy and Commerce Subcommittee on Health
“The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight”
March 17, 2022

The American College of Physicians (ACP) is pleased to submit this statement and appreciates that Chairman Pallone and Chairwoman Eshoo are examining legislation designed to streamline development and approval processes for drugs and therapeutics, strengthen program integrity, and improve diversity and equity in biomedical research. We hope that this important discussion will provide a pathway to act on bipartisan solutions that will provide greater access to care and ensure that the United States remains a leader in the discovery, development, and delivery of medical treatments and cures. As outlined below, we welcome this opportunity to offer our perspective on specific provisions of legislation under consideration today where we have established policy.

The American College of Physicians 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 (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. Internal medicine specialists treat many of the patients at greatest risk from COVID-19, including the elderly and patients with pre-existing conditions like diabetes, heart disease and asthma.

THE DIVERSIFYING INVESTIGATIONS VIA EQUITABLE RESEARCH STUDIES FOR EVERYONE TRIALS ACT

H.R. 5030, the DIVERSE Trials Act, is designed to improve diversity in clinical trials and data collection for the coronavirus disease of 2019 (COVID-19) and future public health threats to address social drivers of health. Specifically, the Food and Drug Administration (FDA) must issue guidance on decentralized clinical trials to promote meaningful demographic and geographic diversity in patient engagement, enrollment, and participation. Decentralized clinical trials include those executed through telemedicine or other digital technologies to allow for the remote collection and assessment of clinical trial data. In addition, the Department of Health and Human Services (HHS) may support community education, outreach, and recruitment activities for clinical trials of treatments for conditions that disproportionately impact populations underrepresented in clinical trials. Laboratories that test for and diagnose COVID-19 must report additional demographic data, including information about social drivers of health.

ACP fully supports the goals of this bipartisan legislation as medical research, including clinical trials, must adapt to ever-evolving pandemics and be inclusive of key factors such as digital technologies and social factors that impact health. ACP has developed extensive policy on [health information privacy](#) and [social drivers of health](#), both of which have taken on greater significance since the emergence of COVID-19. The College has also commented extensively on the need to address disparities and improve public health emergency responses, as detailed in a recent [statement](#) regarding the PREVENT Pandemics Act.

Medical progress and improved patient care depend on innovative and rigorous research, honest communication of research results, and continued evaluation of patient outcomes following implementation of research findings. ACP policy supports the adequate and efficient funding of federal, state, tribal, and local agencies in their efforts to address social drivers of health, including investments in programs and social services shown to reduce health disparities or costs to the health care system and agency collaboration to reduce or eliminate redundancies and maximize potential impact. We also advocate for increased research into the causes, effects, prevention, and dissemination of information about social drivers of health. A research agenda should include short- and long-term analysis of how social drivers affect health outcomes and increased effort to recruit disadvantaged and underserved populations into large scale research studies and community-based participatory studies.

ACP supports a key provision in this legislation that requires HHS to contract with the National Academy of Medicine to study and propose a design for an interoperable platform to facilitate data sharing during public health emergencies. ACP believes that a key component for health information sharing is the need to obtain consensus on the appropriate technical specifications to facilitate data exchange. Clinical entities should recognize the formal standards and certification criteria as well as the annual directional statements published by the Office of the National Coordinator for Health Information Technology (ONC) when considering the technical specifications for health information exchange. It is also vital that mechanisms be in place to ensure the security and integrity of data during their transmission.

ACP remains concerned that physicians' existing health information technology (IT) systems lack the ability to seamlessly report COVID-19 cases and state and local public health departments vary in their ability to accept these reports. The goal for improving these processes should focus on automating data sharing from health IT systems with minimal additional effort required by clinicians and implementing these programs through a coordinated effort focused on agreed upon standards that are implemented consistently across vendors and states. Further, Congress should consider and incorporate necessary privacy guardrails as these surveillance and analytics systems are improved and expanded.

THE CURES 2.0 ACT

H.R. 6000, the Cures 2.0 Act, attempts to build on advances made in the 21st Century Cures Act with the goal of accelerating the discovery, development, and delivery of medical treatments

and cures. ACP supports the following provisions in this bipartisan legislation, as outlined below, and is pleased to offer recommendations to further strengthen these policies.

Sec. 102. National Testing and Response Strategy for Future Pandemics: This provision requires the President to establish a national strategy, based on lessons learned, and best practices developed, as a result of the COVID-19 pandemic, that addresses testing, data sharing infrastructure, administration of vaccines and therapeutics, and medical supply readiness to mitigate future pandemics and public health emergencies.

While ACP supports the creation of a national strategy, we urge that it entail the establishment of a congressionally mandated bipartisan commission to examine the U.S. preparations for and response to the COVID-19 pandemic, in order to inform future public policy and health systems preparedness. Earlier in the 117th Congress, the ACP [supported](#) the National Coronavirus Commission Act of 2021, S. 412, which would establish a ten-member independent body comprised of prominent Americans with expertise in government service, public health, commerce, scientific research, public administration, intelligence gathering, national security, and/or foreign affairs.

We strongly believe that it is essential that any entity established to examine the U.S. preparedness and response effort with respect to COVID-19 should include physicians with expertise in pandemic preparedness and response, including primary care physicians who have been on the frontlines of treating patients with COVID-19. Our physicians have the experience, expertise, and knowledge to guide the commission to determine—in a thorough non-partisan manner—the areas in which we can improve our nation’s preparedness and response to future pandemics.

Sec. 104. Vaccine and Immunization Programs: This provision includes the authorization of funds for awareness campaigns to educate the public with respect to the safety and importance of vaccines and to strengthen the capacity of the Immunization Information System (IIS) within the U.S. Centers for Disease Control and Prevention.

As part of this effort, ACP believes that more needs to be done to educate populations about the misinformation and myths surrounding COVID-19 vaccination. Contributing to the spread of misinformation that is not factual or based on the best available evidence puts the health of patients, families and communities at risk and thwarts the efforts of all physicians, health care workers, researchers, and others who are working tirelessly to fight COVID-19. ACP has joined the effort to combat misinformation, including partnering with YouTube, and has developed extensive [resources](#) the topic.

ACP also believes that pharmacists and primary care teams must be involved and collaborate to educate patients about vaccines, address vaccine hesitancy, ensure patients do not forego medically necessary care, and ensure vaccines are distributed equitably, especially to communities of color and medically underserved areas. Ethical and equitable allocation of vaccines has presented challenges in the U.S.; the rest of the world faces these challenges, too.

More than 85 percent of the world's population lives in low- and middle-income countries, with additional challenges of access to COVID-19 vaccines. To promote equity, special efforts may be necessary to deliver vaccines to marginalized and underserved populations (recognizing that how these populations are defined is local context-specific). Discrimination against classes or categories of patients is unethical and measures must be taken to prevent it. Also, reflecting physicians' duties to care for all patients without discrimination, ACP cautions against approaches that systematically disadvantage certain groups of patients, including the "life years" approach, which is biased against older individuals or those living with disabilities, or approaches based on perceived social worth or economic value. The goal should be to maximize lives saved, using a science-based data-driven approach.

Sec. 202. Increasing Health Literacy to Promote Better Outcomes for Patients: This provision requires the Centers for Medicare and Medicaid Services (CMS) to solicit input on how the agency can work with federally subsidized health care program stakeholders to encourage and promote greater health literacy.

ACP believes that public policies should reflect the unique effects that country of origin, language, immigration status, workplace, and culture have on health disparities among various distinct communities associated with their personal identities. Physicians and other clinicians must make it a priority to meet the cultural, informational, and linguistic needs of their patients, with support from policymakers and payers. Health literacy among those facing disparities based on personal characteristics must be strengthened in a culturally and linguistically sensitive manner. Funding and support should be made available for clinicians to implement and expand health literacy interventions and adapt their practice to accommodate the cultural, informational, and linguistic needs of their patients. Health care communications must be made in a language the patient understands. Clinicians should be reimbursed by public and private payers for translation services needed in providing care for those with limited English proficiency or who are deaf.

Sec. 403. Extending Medicare Telehealth Flexibilities: This provision would permanently remove Medicare's geographic and originating site restrictions which require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services. It would also allow the Secretary of HHS to permanently expand the types of services that can be reimbursed under Medicare.

ACP appreciates that Congress included as part of the recently enacted FY2022 Omnibus spending bill a provision that temporarily extends the lifting of geographic site restrictions so telehealth services can continue to be provided to those in both rural and urban areas and allows for audio-only telehealth services past the end of the declared public health emergency. Expanding the role of telehealth as a method of health care delivery has the potential to enhance patient-physician collaboration, improve health outcomes, increase access to care, access to members of a patient's health care team, and reduce medical costs. Over the course of the pandemic internal medicine specialists and other physicians have provided care, uninterrupted, to their patients with the expanded use of telehealth. ACP believes that the

opportunities provided by the increased use of telehealth will continue to be an important piece of health care delivery. The College has repeatedly advocated for extending telehealth flexibilities with both [CMS](#) and [Congress](#).

Sec. 410. Generally Accepted Standard for Electronic Prescribing: This provision ensures that advances to e-prescribing technology more swiftly benefit patients. Specifically, it provides that the Secretary shall designate through rulemaking a standards maintenance organization with the authority to establish, maintain, and modify generally accepted standards for electronic prescribing and electronic prior authorization. The standards maintenance organization shall include in its membership pharmacies, prescribers, prescription drug plans, health IT developers, and representatives from CMS and FDA. ACP urges that physician stakeholders, including primary care physicians, be represented as well.

The College broadly supports the development and implementation of e-prescribing technology within the health care system. It recognizes the potential for benefits in care quality, patient safety, administrative efficiencies and lower costs associated with the introduction of this technology. E-prescribing systems must interact with the HIPAA Security standards, address issues such as what physical safeguards are necessary to guard data integrity, personal authentication, encryption, and patient confidentiality, and address the impact of e-prescribing on access to Drug Enforcement Agency-controlled drugs, which in many states can only be provided through a triplicate (or other special paper) prescription order.

The College has also supported CMS' efforts to develop foundation standards for the primary e-prescribing functions, the creation of safe harbors to the Medicare Anti-kickback Act and exceptions to the Stark laws promoting donation of e-prescribing technology to practices, and efforts at the federal, state and private sector level to provide increased payment, loans and grants to facilitate e-prescribing adoption at the practice level. The College recognizes that efforts to facilitate e-prescribing adoption at the practice level must address significant barriers. These barriers, which affect all practices, but have the greatest effect on small and medium size practices and rural practices, include:

- The significant software, hardware, implementation and maintenance costs to the practice.
- The substantial practice workflow changes that are required to effectively implement e-prescribing into the practice.
- The limited evidence for a "business case" to implement e-prescribing technology at the practice level. Most benefits and costs savings are received by the patient, the pharmacy benefit manager, the pharmacy and the payer.
- The significant technical difficulties being encountered in implementing current e-prescribing products in the marketplace being reported by our members and in the literature.

- The lack of a system to certify and ensure that the e-prescribing products available in the marketplace are functionally effective.

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 CMS and ONC, aimed to enhance both patient and clinician access to personal health information. These regulations promote the use of standards-based application programming interfaces and outline information-blocking rules and enforcement policies and focus on putting patients in control of their personal health information and allowing for more person-mediated exchange using mobile health apps, wherein patients can rightfully access and disclose their personal health information 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. We urge Congress to further examine the need for such guardrails.

ACP supports oversight and enforcement to ensure that all entities not currently subject to HIPAA rules and regulations and that interact with personal health information are held accountable for maintaining 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.

CONCLUSION

ACP appreciates this opportunity to provide feedback and recommendations on these legislative proposals designed to encourage innovation and improve oversight of biomedical research. We look forward to working with the subcommittee to advance these policies and others and stand ready to offer the perspective of internal medicine specialists on future legislation. Should you have any further questions, please contact Jonni McCrann at jmccrann@acponline.org.