

Statement for the Record American College of Physicians Hearing before the U.S. Senate Committee on Health, Education, Labor and Pensions On

Implementing the 21st Century Cures Act:

Making Electronic Health Information Available to Patients and Providers

March 26, 2019

The American College of Physicians (ACP) is pleased to submit this statement and appreciates that Chairman Alexander and Ranking Member Murray convened this hearing. Thank you for your shared commitment to ensuring that both patients and clinicians have the increased ability to access electronic health information (EHI) in order to make informed health decisions. ACP appreciates that the Health, Education, Labor and Pensions (HELP) Committee is holding this hearing to exercise oversight over the implementation of the 21st Century Cures Act (Cures Act), especially because the Office of the National Coordinator for Health Information Technology (ONC) and the U.S. Department of Health and Human Services (HHS) issued a notice of proposed rulemaking (NPRM), entitled "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program," on March 4, 2019. While the College is still formulating its comments to the NPRM, which are due on May 3, 2019, we appreciate the opportunity to share with the committee ACP's views thus far about the Cures Act's provisions about interoperability, information blocking, and certification program as wells as ONC's proposed implementation of those provisions. We wish to assist in the HELP Committee's efforts by offering our input and suggestions about ways that patients and their clinicians can gain better access to their EHI that would result in more efficient delivery of health care and better health outcomes. In 2017, ACP released a forward-looking document that provides a prescription for Congress to implement an array of solutions to improve the functionality and usability of electronic health records (EHRs), to improve the interoperability of EHRs, and to reduce the burden of health information technology (health IT)-related regulations to better deliver on the promise of EHRs.

ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 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.

PREVIOUS FEEDBACK ON 21ST CENTURY CURES DEVELOPMENT AND IMPLEMENTATION

In 2016, ACP <u>wrote</u> to the HELP Committee about a discussion draft of a bill to improve health IT, which later was incorporated into the Cures Act, where the College outlined its recommendations to reduce regulatory and administrative burden to improve quality care, improve clinical documentation,

enhance certification, address information blocking, define interoperability and empower patients by improving their access to EHI. Later in 2016, after the Cures Act was released, ACP <u>expressed</u> its appreciation for developing and supporting a voluntary model framework and common agreement for the secure exchange of information combating business practices that inhibit the flow of information by establishing authority for the HHS Office of Inspector to investigate claims of information blocking and assign penalties for activities found to be interfering with the lawful sharing of electronic information. The College was also pleased to see the inclusion of provisions that specifically protect the physician community by (1) ensuring that health care clinicians are not penalized for the failure of developers of health IT in the case of information blocking; (2) establishing hardship exemptions from what is now the Promoting Interoperability Program and the Merit-Based Incentive Payment System (MIPS) payment adjustments due to the decertification of an EHR; and (3) committing to develop a strategy around reducing regulatory and administrative burdens. We are also pleased that the bill supports the certification and development of patient-centered EHRs so that patients have better access to current and secure health information.

With the Cures Act now in law, the College has provided feedback to ONC as they continue to implement specific provisions of the legislation. In early 2018, the College submitted comments on ONC's draft Trusted Exchange Framework and Common Agreement (TEFCA), expressing our appreciation for the work involved in developing the proposed policies, procedures, and technical standards outlined in the draft TEFCA. We support the underlying goals to achieve secure, seamless, and sustainable health information exchange to support the entire care continuum; however, we outlined our concerns around how the initial use cases described in the draft TEFCA are focused on moving large quantities of data from one place to another. Focusing on these types of use cases increases the risk of data overload for the clinician at the point of care, which does not help clinicians access the truly meaningful information needed at the point of care and in some cases hinders care delivery.

ACP's recent <u>comments</u> to ONC on the Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs provided additional recommendations for reducing clinical documentation burden, prior authorization burden, and EHR and public health reporting burden, and provided recommendations for how to further improve EHR and health IT usability. The College also reiterated our ongoing concerns about the federal government's focus on and definition of interoperability. Specifically, the College believes that efforts to improve interoperability should not focus solely on large volumes of data transferred from one place to another or provide access to every piece of health information ever collected. Efforts to improve interoperability should focus on what is needed for high-value clinical management of patients as they move throughout the health care system.

On March 1, 2019, ACP was pleased to share its <u>views and recommendations</u> with the HELP Committee about how to lower healthcare costs while improving health outcomes and increasing the patient's access to EHI to make informed health decisions. ACP believes that Congress and the administration should consider incorporating into federal rulemaking the cohesive framework for assessing administrative tasks outlined in ACP's position paper "<u>Putting Patients First by Reducing Excessive Administrative Tasks in Health Care</u>." The framework provides a method for better understanding any

given task as well as the foundation for specific recommendations on revising or eliminating administrative tasks entirely. Specifically, the College calls on all external sources of administrative tasks to provide impact statements for public review and comment. For those tasks that cannot be eliminated, they must be regularly reviewed and revised or aligned to reduce any associated burden. All key stakeholders must also collaborate on aligning performance measures to minimize burden; collaborate in making better use of existing health IT to facilitate the elimination, reduction, and alignment of administrative tasks; and focus on value over volume of services when reviewing and aligning or eliminating tasks. More research is needed on the impact of administrative tasks on the US health care system and on evidence-based best practices to help physicians reduce administrative burden within their organizations.

While we are supportive of the intent of the Cures Act and appreciate the work of both Congress and the administration to pass and implement the legislation, the College would like to take this opportunity to highlight some areas of support as well as areas of concern within the recent NPRMs that could potentially increase physician burden and health care costs. The College is still conducting our analysis of the NPRM and will provide comments through the formal rulemaking process; however, the following provides a high-level overview of the College's initial observations within the NPRM.

INITIAL FEEDBACK ON 21ST CENTURY CURES INTEROPERABILITY, INFORMATION BLOCKING, AND ONC HEALTH IT CERTIFICATION PROGRAM NPRM

Improved Interoperability. As mentioned in the above section of this statement, ACP remains concerned about the federal government's approach to improve interoperability that is focused on moving large quantities of data from one place to another. Clinicians do not need access to every element of a patient's EHI – and in some cases having access to every element of data can in fact hinder care delivery. 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 perspective 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.

Privacy. We support the concept of patients having seamless access to their health information and have long advocated for the use of standard Application Programming Interfaces (APIs) to help promote EHI exchange. However, from the physician perspective, we are concerned about patient privacy issues that will arise when allowing third-party app developers to access EHI on behalf of the patient when the patient is unaware of who they are actually allowing to access their data. As the health IT app ecosystem continues to evolve, patients need to be provided clear guidance and need to have a full understanding of what they are agreeing to when signing into an app and that their personal EHI could be at risk.

Information Blocking. The ONC NPRM outlines detailed examples of what constitutes information blocking as well as the multiple exceptions to information blocking that any one of the regulated actors

can claim. Even provided these thorough explanations and examples, understanding how the complex information blocking provisions will affect our members in their daily practice will prove to be extremely complicated. Not only are the information blocking provisions and exceptions complicated in and of themselves, the provisions overlap with existing Health Insurance Portability and Accountability Act (HIPAA) regulations, and it will be unclear what information a clinician is permitted vs. required to share – imposing additional workflow burden into clinical practice. 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.

Health IT Standards and Standard APIs. ACP has long advocated for the promotion and adoption of Fast Healthcare Interoperability Resource (FHIR) standards and the use of standard API functionality to promote interoperability. We commend both ONC and the Centers for Medicare and Medicaid Services (CMS) for proposing these standards. Alignment in health IT standards and implementation of standards is critical to improving interoperability and allowing disparate health IT systems to communicate effectively. As these standards continue to evolve and mature, and new versions are made available, we support ONC's approach to provide sub-regulatory guidance on newer, approved standards versions that will better support EHI exchange, access, and use. Moreover, the College supports ONC's proposals to limit the fees vendors can charge physicians to implement new technology; however, we have concerns about physicians' being expected to pay for the installation and operation of APIs without being permitted to charge for providing the service to patients.

Development, Implementation, and Deployment Timelines. Due to the complexity of the ONC NPRM as well as the CMS Interoperability NPRM, there are a number of overlapping timelines that are not fully aligned and do not seem entirely feasible. For example, the information blocking provisions go into effect long before the technology upgrades to facilitate EHI exchange are required. Additionally, there are numerous updates to the Health IT Certification program and we strongly reiterate our previous concerns around rushing implementation timelines to meet regulatory requirements. The College recommends that physicians be given at least six months, if not a full year, for implementation of upgraded health IT systems before they are regulated on the use of their new technology. Moving to more up-to-date standards and functions is important, but it is important physicians have adequate time to train clinical staff and test and implement the upgrades once the new versions of 2015 CEHRT are available from their vendors to help ensure patient safety and a smooth transition to the new technology.

In order to effectively deal with the development, implementation, and aligning timeline issues discussed above, it is imperative that ONC's funding not only be maintained but increased. Accordingly, ACP would ask that the HELP Committee work with congressional appropriators to ensure that ONC has enough resources to meet the challenges of implementing the EHI provisions of the Cures Act and reject any recommendation to cut ONC's funding.

CONCLUSION

ACP sincerely applauds Chairman Alexander and Ranking Member Murray for holding this hearing about EHI and the Cures Act and appreciates the shared bipartisan commitment to help contain health care costs through appropriate congressional oversight and to ensure that patients have access to

quality primary care services. We appreciate the HELP Committee's inviting input from the health-care community, and our hope is that the information we shared will provide the Committee with a clinician perspective. We stand ready to continue to serve as a resource and welcome the opportunity to continue to work with you in developing policy on EHI-related issues during the 116th Congress. Please contact Jared Frost, Senior Associate, Legislative Affairs, by phone at (202) 261-4526 or via email at irrost@acponline.org with any further questions or if you need additional information. Thank you.