



December 4, 2020

Dr. Donald Rucker, National Coordinator
The U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Rucker,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Office of the National Coordinator for Health Information Technology's (ONC's) interim final rule with comment period (IFC), titled "Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency." ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 163,000 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.

ACP greatly appreciates the effort of ONC to provide regulatory relief and flexibilities to support our health care system in response to the national threat of the Coronavirus Disease 2019 (COVID-19). While we are supportive of the extension of certain compliance and applicability dates included in the Cures Act Final Rule, we remain concerned that the newly published timelines associated with information blocking provisions do not go far enough, and those related to health IT certifications are problematic. The College is supportive of the Cures Act's purposes to increase information sharing, improve patient care, and ensure a patient's health information follows the patient across the health care continuum. We also agree that the PHE has substantiated even greater the urgency of these goals. However, any applicability date prior to the end of 2021 is simply not feasibleⁱ and the certification timelines add another layer of complexity to an already over-burdened clinical workforce. In the IFC, ONC correctly outlined the devastating impact that COVID-19 has had on our country, but failed to fully account for the fact that the U.S. is already approaching another major crisis point as COVID-19 cases continue to rise – and any new regulatory requirements and implementation cannot begin until the pandemic is under control.

In light of such considerations, ACP strongly urges ONC to extend information blocking applicability dates to at least the end of 2021, or as long as the COVID-19 pandemic continues to impact physicians' and other clinicians' ability to implement and comply with the information blocking requirements. While we understand ONC's views that the information blocking provisions are not necessarily technical changes, we disagree that this means it will not take a significant amount of time for physicians and other clinicians to prepare for additional health data requests and make sure they are not inadvertently blocking information. Additionally, neither the Cures Act Final Rule nor the IFC established any specific steps to ensure compliance, which shifts the burden to practice groups that are already overtaxed by pandemic response and fleeting resources. As the clinical community continues to grapple with these regulations, ACP remains deeply concerned about the pending burden of educating clinicians on necessary requirements and compliance processes, and the COVID-19 pandemic has only exacerbated the readiness concerns of the clinical community – even in light of the extension provided in the IFC. **The College encourages ONC to take this additional time to develop comprehensive guidance on implementation and compliance with these regulations.**

The College also agrees with ONC's determination that extensions provided for certain 2015 Edition health IT certification criteria are needed. Particularly, we appreciate ONC highlighting the reality that some upgrades necessitate training staff on the 'how-to' and require time for clinicians to familiarize themselves with operationalization updates. However, the College is greatly concerned that the IFC maintains different timelines for information blocking applicability and the health IT vendor compliance timelines. Specifically, the IFC requires clinicians to provide all data in the United States Core Data for Interoperability (USCDI) under the information blocking provisions (now required by April 5, 2021) before health IT vendors are required to provide the capability in the certified electronic health record (EHR) systems to support this (now required by December 31, 2022). **ACP urges ONC to either align these differing timelines or, in the event that a clinician's system is not capable of delivering all USCDI data, the clinician should be recognized as having met the requirements for one of the provided exceptions, such as the 'infeasibility exception'.** The College additionally encourages **ONC to specify the documentation required of clinicians requesting this exception.** Moving forward, ONC must provide clear guidance and complete certification criteria on what data it expects to be included in the full definition of electronic health information (EHI), and it must do so well in advance of clinician applicability dates and health IT vendor compliance dates.

ACP is equally concerned about the lack of guidance or detail regarding enforcement of information blocking provisions. As of publication of the IFC, the U.S. Department of Health and Human Services (HHS) and the Office of the Inspector General (OIG) have yet to identify the appropriate agency or agencies charged with handling referrals of alleged information blocking – nor has HHS issued a proposed rule to begin the process of establishing appropriate means to curtail clinician information blocking. ACP has previously voiced to OIG our concern about the absence of compliance guidance materialsⁱⁱ, **and the College continues to encourage ONC, in coordination with HHS, OIG, and the Office of Civil Rights (OCR), to develop clear regulatory language or guidance around how and what types of information blocking claims will be assessed.** Likewise, ACP maintains its recommendation that the official enforcement date for

physicians and other clinicians should be no sooner than one year after the applicability deadline for information blocking.

The ONC Cures Final Rule is also closely related to the Centers for Medicare and Medicaid Services' (CMS') "Patient Access" Final Rule. As the College previously expressed in a letter to CMSⁱⁱⁱ, a central tenet to effective interoperability is improving the patient experience by way of empowering patients to take control and access their personal health information. While ACP continues to urge CMS to delay compliance with its respective requirements, **the College encourages ONC to work with CMS to harmonize implementation timelines for both the "Patient Access" rule and the dates set forth in the IFC.** With the U.S. health care system already operating at maximum capacity and the number of COVID-19 cases trending upward, it is exceptionally important that we are on the same page in building a health system that supports a successful introduction at the most appropriate time.

The College greatly appreciates the provided extensions and flexibilities within the IFC, as well as the opportunity to further comment on the IFC. ACP hopes ONC will take into account these concerns as the COVID-19 pandemic continues to strain our health systems and disrupt each aspect of the clinical experience and workflow. If you have any questions or would like additional information, please contact Brooke Rockwern, Senior Associate for Health IT Policy and Regulatory Affairs, at brockwern@acponline.org.

Sincerely,



Zeshan A. Rajput, MD, MS
Chair, Medical Informatics Committee
American College of Physicians

ⁱ https://www.acponline.org/acp_policy/letters/joint_letter_re-coalition_urges_onc_to_delay_enforcement_of_information_blocking_compliance_deadlines_sept_2020.pdf

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https://www.acponline.org/acp_policy/letters/acp_comments_to_oig_regarding_information_blocking_enforcement_proposed_rule_june_2020.pdf

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https://www.acponline.org/acp_policy/letters/acp_subspecialty_joint_letter_to_cms_regarding_patient_access_rule_timelines_oct_2020.pdf