ONC INTERIM FINAL RULE DELAYS INFORMATION BLOCKING RULE INITIAL COMPLIANCE DEADLINE

Date: 29 October 2020

U.S Health Care Alert

On Thursday, 29 October 2020, the HHS Office of the National Coordinator for Health IT (ONC) released an interim final rule (Interim Final Rule) that: (a) delays the compliance dates and timeframes for certain regulatory requirements finalized in the 1 May 2020 ONC 21st Century Cures Act Final Rule (Final Rule); (b) updates several ONC certification standards for health IT products; and (c) makes a number of technical corrections to the language of the Final Rule and associated regulations. The Interim Final Rule will be published in the Federal Register in the coming days, and will be effective immediately upon publication. A link to the Interim Final Rule is available on ONC's Cures Act Final Rule webpage.

Of primary interest for health care providers, the Interim Final Rule delays the compliance date for the prohibition on information blocking under 45 C.F.R. Part 171 (Information Blocking Rule), from its original date of 2 November 2020 to **5 April 2021**. The Interim Final Rule also delays compliance dates for a number of new Conditions of Certification (CoCs) for developers of ONC-certified health IT. The updated compliance dates for each CoC vary, but in no case will any such CoC become effective earlier than 5 April 2021. ONC expressed that these delays are intended to allow health care providers and other actors subject to the Information Blocking Rule additional time and flexibility to cope with the ongoing COVID-19 public health emergency.

During a stakeholder conference call facilitated by ONC the morning the Interim Final Rule was released, Don Rucker, M.D., ONC's National Coordinator for Health Information Technology, emphasized that ONC's decision to delay compliance deadlines—in particular those related to the Information Blocking Rule—represents ONC's balancing of the interests of heath care providers in battling the COVID-19 pandemic with the interests of the Information Blocking Rule's drive toward consumer (a/k/a patient) access and empowerment. Ironically, Dr. Rucker pointed out that the COVID-19 public health emergency has only highlighted the importance of the Information Blocking Rule in allowing timely patient access to up-to-date electronic health information (EHI) through applications of the patient's choice, including through their smart phones, and stated that furthering these goals will greatly assist health care providers and patients. Secretary Rucker pointed out that patient access to EHI in an “unfettered way” is still “extraordinarily important,” particularly in the midst of social distancing and enhanced patient acuity due to the pandemic, and suggested that efficiently tracking patient health data during the COVID-19 public health emergency would have been made easier if the Information Blocking rule had been in place from the beginning of the pandemic.

ONC's comments in relation to the delay are illustrative of a movement toward heightened patient engagement and empowerment, which is an ongoing theme throughout the Information Blocking Proposed and Final Rules, and they are helpful in understanding the nuances of the Final Rule. A few attendees to the 29 October conference call asked for further guidance on various aspects of the Final Rule, and Elise Sweeney Anthony, Executive Director of ONC's Office of Policy, indicated that ONC will hold a conference call Monday, 2 November,

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at 3:00 p.m. EST. In addition, ONC plans to issue FAQs based on questions presented to ONC through its feedback and inquiry portal, and it encouraged stakeholders to continue to submit questions through that portal (www.healthit.gov).

Other updates, corrections, and clarifications made in the Interim Final Rule are largely technical in nature. We are analyzing the Interim Final Rule in its entirety and, to the extent they are applicable to our clients, we will provide additional information in the coming days.

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