

December 17, 2020

Don Rucker, M.D.

National Coordinator for Health Information Technology

Office of the National Coordinator for Health Information Technology
330 C St SW

Washington, DC 20201

Re: RIN 0955-AA02; Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency

Dear Dr. Rucker,

On behalf of the American Academy of Family Physicians (AAFP), representing more than 136,700 family physicians and medical students across the country, I appreciate the opportunity to provide comments on the <u>interim final rule</u> regarding Information Blocking and the Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency, as published in the November 4, 2020 version of the *Federal Register*.

Family physicians provide comprehensive primary care services to patients across the lifespan and have been serving on the frontlines of the COVID-19 pandemic. The AAFP appreciates the actions taken by the Office of the National Coordinator for Health Information Technology (ONC) to respond to the pandemic, including efforts to delay new requirements and minimize additional burdens on family physicians and other clinicians. We are strongly supportive of ONC's work to improve interoperability and accessibility of patient health records and look forward to continued collaboration.

## Information Blocking

ONC previously established regulations that prohibit physicians and health information technology (IT) developers from unnecessarily blocking the sharing of patients' health information. The AAFP was supportive of these regulations, while also raising concerns with the complexity of the exceptions and other requirements physicians must meet. In this interim final rule, ONC extends the applicability date for information blocking regulations to April 5, 2021 due to the COVID-19 pandemic.

The AAFP strongly supports delaying the applicability date of information blocking regulations for physicians, other clinicians, and health care organizations. Given the latest surge in COVID-19 cases across the nation, we recommend that ONC further extend this delay through the end of the national public health emergency or until July 31, 2021, whichever comes later.

ONC recognizes in the final rule that family physicians and other frontline clinicians are facing significant challenges due to the COVID-19 pandemic, including financial strain on their practices and worsening administrative burden. A recent survey of primary care practices found that 54 percent

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have experienced pandemic-related furloughs and layoffs, while 43 percent believe it will take more than one year to recover from financial losses incurred during the pandemic. <sup>1</sup> 52 percent of primary care clinicians report being overwhelmed by constantly changing protocols and billing codes and 20 percent are taking on additional administrative tasks to assist patients with food and housing insecurity. <sup>2</sup> Given the complexity of the finalized framework of information blocking exceptions, it will be challenging and costly for family physicians to modify their administrative processes and clinical workflow to ensure compliance while they continue to respond to the COVID-19 pandemic. We agree with ONC that the applicability date must be delayed.

However, as COVID-19 cases surge across the country, we are concerned that the new applicability date of April 5, 2021 will not be sufficient. In fact, it seems likely that the pandemic will be ongoing and that family physicians will be engaged in widespread COVID-19 immunization efforts in the spring. In order to provide needed reprieve to our members and to ensure they can focus on caring for their patients during this challenging time, the AAFP strongly recommends delaying the compliance date until the end of the PHE or July 31, 2021, whichever comes later.

We further recommend that, in the interim, ONC streamline the requirements for physicians and provide more clarity through additional guidance on how to meet information blocking exceptions and otherwise comply with these new requirements. The AAFP is concerned that the information blocking exceptions previously finalized by ONC are overly complex and will result in additional administration burdens for family physicians. It is unclear to family physicians how and when to appropriately utilize the information blocking exceptions and what their obligations are when information isn't easily sharable. For example, our members have asked what the appropriate course of action is if they receive a request to share a patient's health information that originated outside of their practice and can only be further shared in image format. Many report that their EHRs do not have the capability to export certain types of data in a structured format and asked for clarity on how to handle information sharing requests for those data. The AAFP recommends that ONC include an extended list of reasonable and unreasonable uses for each of the exceptions to information blocking when additional quidance that is released.

ONC must also provide physicians information regarding documentation and other requirements in the event of an information blocking investigation. When Meaningful Use was implemented, physician practices experienced significant challenges when documentation requirements were established long after regulatory requirements went into effect. In order to minimize the burden on physicians and their practices, ONC and the Office of the Inspector General should clearly outline documentation and other requirements before the information blocking applicability date. This would allow practices to modify their administrative and clinical workflows to obtain the necessary documentation at the same time as making any changes necessary to comply with the information blocking regulations. Additional guidance on information blocking exceptions and documentation requirements for compliance must be provided before these regulations take effect.

Health IT developers have not been impacted by the COVID-19 pandemic as significantly as family physicians and other frontline health care workers. Information blocking practices by developers, such as contractual limitations on the sharing of information and charging excessive fees to connect EHR systems for the purposes of sharing patient information, continue to occur and are harmful for physicians and their patients. For these reasons, we believe that the delay provided in the interim final rule is sufficient for health IT developers and we do not recommend further extension of the information blocking applicability date for health IT developers.

## Conditions of Certification

ONC previously finalized regulations and compliance timelines for certification requirements that electronic health records (EHRs) must meet in order to be considered Certified EHR Technology (CEHRT). The Centers for Medicare and Medicaid Services (CMS) requires that physicians, other clinicians, and health systems use CEHRT in order to participate in various programs. In the interim final rule, ONC extends the timeline for several previously finalized certification criteria until December 31, 2022 or December 31, 2023. Most notably, ONC delays the compliance timeframe for the Electronic Health Information (EHI) export requirement for CEHRT to December 31, 2023. The EHI export requirement will enable physicians to send all of a patient's relevant health information in a single electronic file, improving sharing of information between members of a patients' care team.

The AAFP does not support delaying the EHI export requirement beyond December 31, 2022. Achieving interoperability is vital for improving patient care and reducing administrative burdens for family physicians. A recent study found that primary care physicians spend about half of their time on administrative tasks, which was more time than they spent on clinical activities. EHI export capabilities will help mitigate this burden and improve care coordination and communication between primary care physicians and other clinicians, such as subspecialists. In addition to furthering these goals, requiring compliance with the EHI export requirement by December 31, 2022 will align all new CEHRT criteria to the same date, simplifying implementation by physicians and health systems. Given the significant benefits of enabling physicians to share patients' EHI, compliance with the EHI export requirement should not be delayed beyond December 2022.

In the IFR, ONC extends the time period for which the definition of EHI be limited to only data elements that are in the United States Core Data for Interoperability (USCDI). The data elements that are included in the definition of EHI determine what type of information must be shared in order to meet information blocking prohibitions. The AAFP previously supported limiting the definition of EHI to data elements that are contained in the USCDI.

We are also supportive of extending the time period for which the definition of EHI is limited to data elements in the USCDI and recommend that the ONC further delay the implementation of the broader definition of EHI. The limited definition provides clarity to physicians and other actors on what information must be shared. Before the limited definition expires, we recommend that ONC provide additional guidance to physicians and other clinicians about what types of information are included in the EHI. The AAFP is concerned that the extension to October 22 may not provide sufficient time for ONC to clearly define the EHI and ensure that physicians are able to easily share the information required by the broader definition.

Finally, the broad definition of EHI should not be implemented before the EHI export certification requirements are effective. The AAFP is concerned it will be very burdensome for physicians to respond to all EHI sharing requests in a timely manner if the EHI export functionality is not required and implemented. Instead, we recommend that ONC implement the broader definition of EHI after EHI export functionality is required of CEHRT developers and there is more guidance for HHS on how information blocking claims will be evaluated and enforced. For these reasons, we strongly recommend that ONC further extend the time period for which the definition of EHI is limited to data elements in the USCDI.

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Thank you for the opportunity to provide comments on the interim final rule. Should you have any questions, please contact Meredith Yinger, Senior Regulatory Strategist, at <a href="mailto:myinger@aafp.org">myinger@aafp.org</a> or 202-235-5126.

Sincerely,

Gary LeRoy, MD, FAAFP

**Board Chair** 

American Academy of Family Physicians

Lary S. Le Roy, MD, FAAFP

<sup>&</sup>lt;sup>1</sup> Larry A. Green Center. Quick COVID-19 Primary Care Survey: Series 21 Fielded September 18-21, 2020. Available at:

https://www.pcpcc.org/sites/default/files/news\_files/C19%20Series%2021%20National%20Executive%20Summary\_0.pdf

<sup>&</sup>lt;sup>2</sup> Larry A. Green Center. Quick COVID-19 Primary Care Survey: Series 23 Fielded November 13-17, 2020. Available at: <a href="https://www.pcpcc.org/sites/default/files/news\_files/COVID-19%20Round%2023%20National%20Executive%20Summary.pdf">https://www.pcpcc.org/sites/default/files/news\_files/COVID-19%20Round%2023%20National%20Executive%20Summary.pdf</a>

<sup>&</sup>lt;sup>3</sup> Sinsky C, Colligan L, Li L, Prgomet M, Reynolds S, Goeders L, Westbrook J, Tutty M, Blike G. Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties. Ann Intern Med. 2016 Dec 6;165(11):753-760. Available at: <a href="https://pubmed.ncbi.nlm.nih.gov/27595430/">https://pubmed.ncbi.nlm.nih.gov/27595430/</a>