AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for
Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Dear Dr. Rucker:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Office of the National Coordinator for Health Information Technology (ONC) on its interim final rule with comment period (IFC) (RIN 0955-AA02), 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."

The AMA greatly appreciates ONC's effort to provide regulatory relief and flexibilities to support our health care system in response to the national threat of the COVID-19 pandemic. 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. **The AMA strongly encourages ONC to extend physician information blocking applicability dates to at least the end of 2021, or as long as the COVID-19 pandemic continues to impact physicians' ability to implement and comply with the information blocking requirements.**

The AMA 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.[1] We also agree with ONC that the public health emergency (PHE) has substantiated the importance of these goals. However, any applicability date prior to the end of the PHE is simply not feasible to an already over-burdened clinical workforce. The economic impact of COVID-19 on health care continues to reveal itself through reductions in patient volume and revenue and in higher practice costs. A nationwide survey of 3,500 physicians between July and August showed an average *drop* in practice revenue of 32 percent with an average *increase* in personal protective equipment (PPE) spending of 57 percent.[2] 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—any new regulatory and implementation requirements for physicians cannot begin until the pandemic is under control.**

[1] https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf.
[2] https://www.ama-assn.org/practice-management/sustainability/covid-19-physician-practice-financial-impact-survey-results.

While we understand ONC's view 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 their staff to prepare for additional health data requests and make sure they are not inadvertently blocking information. For example, while we appreciate ONC creating eight information blocking categories, each exception is overly complex, riddled with subjective terminology, and demands policy and procedure documentation above and beyond practicality. Physicians will be required to navigate dozens of exceptions, sub-exceptions, and conditions to justify their actions as medical professionals. The burden of proof is unreasonable and the need to demonstrate that a physician's exception policy is sufficiently tailored to meet ONC requirements is likely to create a costly compliance burden. We also fear rushing to comply with the regulations by early spring may result in physicians misinterpreting or overutilizing information blocking exceptions. **More time and education are needed to ensure physicians understand the requirements and to ensure that exceptions are not used unnecessarily or incorrectly.**

Furthermore, ONC downplays the cost and resources required to implement a regulatory compliance framework within a medical practice. Neither ONC's 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. ONC has yet to release or clarify compliance program guidance. At a high-level, a compliance framework guides an entity's development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. For instance, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) Compliance Program Guide for Individual and Small Group Physician Practices is likely one example of an information blocking compliance framework. The OIG's resource includes seven separate program compliance elements with over 400 individual compliance program metrics.[3] The OIG states that "using them all or even a large number of these is impractical" and that "one size truly does not fit all." Additionally, we are hearing from our members that a cottage industry of experts who sell "packaged" compliance plans at exorbitant prices has emerged.

The lack of clarity from ONC—and the Final Rule's complexity—will put physicians in an unworkable situation where they must either digest, interpret, and implement a federal guidance document on their own or pay thousands of dollars in consultants' fees. For the foreseeable future, physicians will continue to struggle with the impact of the pandemic on their practices. They are seeing substantially fewer patients and have significant costs associated with providing a safe environment to see patients. We do not expect medical practices to be where they were financially before the pandemic by early next spring. Physicians should never be put in an untenable position compromising patient care for the sake of administrative compliance requirements. **The AMA strongly encourages ONC to consider what is best for patient care, physician practice sustainability, and the resilience of the nation's health care system. Additional time for physician compliance is needed, and ONC must prioritize the development of comprehensive guidance on implementation and compliance with these regulations.**

Finally, ONC bases its urgency for an early spring deadline on findings from a 2015 Health Information Blocking Report to Congress where ONC "concluded that information blocking is a serious problem and recommended that Congress prohibit information blocking and provide penalties and enforcement mechanisms to deter these harmful practices." Most information blocking practices are a result of actions taken by health information technology (health IT) vendors and large organizations, yet ONC's Final Rule paints all "Actors" with a broad brushstroke. ONC's report largely identified technical, financial,

[3] https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf.

and contractual methods used by health IT developers and vendors as the main cause of information blocking. It also recognized issues with large organizations exercising control over information as a business interest. Yet, when it came to physicians and their medical practices, the report found physician confusion with Health Insurance Portability and Accountability Act (HIPAA) requirements as the main culprit. Unfortunately, ONC's rules subject physicians and their medical practices to the same powerful and complex regulations as EHR vendors and large health care organizations. Research has shown that physicians overwhelmingly want to share information.[4] Yet, they are limited by their EHR vendors and are caught between organizations' competing business practices. **To address the vast majority of information blocking practices while reducing the stress on the provider community, the AMA recommends that ONC extend the *health care provider* actor compliance timeline while continuing to encourage health IT organizations' information blocking compliance.**

The AMA greatly appreciates the provided extensions and flexibilities within the IFC as well as the opportunity to further comment on the IFC. We hope 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, please feel free to contact Matt Reid, Senior Health IT Consultant, Federal Affairs, at matt.reid@ama-assn.org.

Sincerely,

James L. Madara, MD

[4] Over 85 percent of physicians view sharing electronic protected health information (ePHI) as important and that it improves efficiency and quality in health care. https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/medical-cybersecurity-findings.pdf