January 4, 2021

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, 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 National Coordinator Rucker:

The Medical Group Management Association (MGMA) is pleased to submit the following response to the Office of the National Coordinator for Health Information Technology (ONC) interim final rule (IFR) *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 Medical Group Management Association (MGMA) is the premier association for professionals who lead medical practices. Since 1926, through data, people, insights and advocacy, MGMA empowers medical group practices to innovate and create meaningful change in healthcare. With a membership of more than 58,000 medical practice administrators, executives and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures and specialties that deliver almost half of the healthcare in the United States.

This IFR recognizes the impact that the COVID-19 national pandemic has had on the physician practice community and we appreciate the extended compliance date. Below we have provided comments on the April 5, 2021 date identified in the IFR as well as offered recommendations on the enforcement of information blocking, educational opportunities, and suggested topics for additional ONC guidance.

Summary of Comments

- MGMA recommends the compliance date for the information blocking requirements be established as a minimum of 180 days after the public health emergency (PHE) has been lifted by the HHS Secretary.
- On the issue of enforcement of information blocking, MGMA urges ONC to focus on supplying physician practices with technical advice and leveraging corrective action plans as opposed to imposing civil monetary penalties.
- ONC should engage in an aggressive effort to educate physician practices on the provisions of the information blocking regulation, compliance obligations, and documentation requirements.
- ONC should take advantage of the additional time and disseminate comprehensive “real-world” guidance on the information blocking regulation and physician practice compliance requirements.

Compliance Date Extension

Many government initiatives have had to be postponed or delayed due to the COVID-19 national pandemic. This catastrophic event has significantly impacted physician practice revenues, staff resources, and their ability to focus on issues not directly related to the delivery of patient care. While we appreciate ONC extending the compliance deadline to April 5, 2021, we assert that this extension is insufficient.

We recommend the compliance date be established as a minimum of 180 days after the public health emergency (PHE) has been lifted by the HHS Secretary. While there are promising new advances in vaccines to combat COVID-19, it is highly likely that the nation will be continuing to battle the pandemic well after the April 5, 2021 information blocking compliance date. Linking the compliance date with the lifting of the PHE will avoid the situation where the compliance date arrives, and practices are unable to appropriately respond due to their continued focus on the pandemic.

Enforcement Approach

The information blocking requirements, including the eight exception categories, are extremely complex. While physician practices may have in place general policies that seek to identify potential blocking situations and address them, due to their focus on addressing the needs of their patients and staff during the COVID-19 national pandemic, few have or will have in the near future comprehensive policies in place that address each provision of the regulation.

With this in mind, we urge the agency to adopt an enforcement policy that recognizes the complexity of the regulation and the need for additional ONC guidance and instruction. Rather than seeking to impose civil monetary penalties on physician practices deemed to have blocked information, ONC should adopt an enforcement approach to focuses on:

- Educating the physician practice on why they were deemed to have blocked patient data;
- Instructing the physician practice on the actions they should have taken to permit the patient information to flow; and
- If appropriate, require the physician practice to enter into a corrective action plan (CAP).

An information blocking corrective action plan would a step-by-step process for a physician practice to achieve targeted outcomes for resolution of identified errors that led to the finding of information blocking. The plan would: (i) identify the most cost-effective actions that a practice could implement in order to correct an error; (ii) develop and implement a plan of action to improve processes or methods so that outcomes resolve the issues that led to the blocking; (iii) achieve measureable improvement; and (iv) eliminate policies that led to information being blocked.

Implementing these CAPs would permit ONC to monitor and asses the ongoing actions of the physician practice and ensure that appropriate steps were taken to address the issues that led to the complaint. Beyond being a punitive measure, CAPs would also be an important policy tool for ONC. Release of deidentified CAPs would assist others physician practices adopt appropriate policies and procedures to prevent information blocking. A focus on improvement, not penalties will promote overall industry compliance.

Further, we recommend ONC engage in an educational campaign with the following components:

- In concert with the Office for Civil Rights (OCR) and patient advocacy organizations, inform patients of their rights under HIPAA and the information blocking rule to access their health information.
- In concert with OCR and professional societies like MGMA, inform physician practices of their rights and responsibilities under the information blocking regulation. This campaign

could emphasize, for example, that practices are encouraged to provide patients the information they request as quickly as possible and in the format that best meets the needs of the patient. This campaign could also focus on the role of the practice's EHR vendor and the role of the Health Information Exchange (HIE) entity that a practice may interact with. It will be critical for practice's to also understand how a vendor or HIE could contribute to information blocking and what steps the practice can take should they encounter blocking from these entities.

- In concert with professional societies like MGMA, educate physician practices on the eight exceptions to information blocking and what documentation is required to support a practice's determination that one of the exceptions applies to a particular situation. ONC should augment this education with model documentation templates for each of the eight exception categories.
- In concert with professional societies like MGMA, develop and disseminate physician practice model policies and procedures that address information blocking.
- In concert with professional societies like MGMA, inform physician practices of the types of information blocking occurrences that have been reported to the agency. This information, deidentified in terms of the actors, would be extremely helpful to the industry in better understanding the policies, procedures, and conduct that led to the information blocking. This transparency will be critical if physician practices are to modify policies and procedures.
- In concert with professional societies like MGMA, update physician practices with deidentified examples of enforcement actions, including CAPs. Learning about the failures in policies and procedures that led to the information blocking from peers will be very helpful. As well, understanding the required actions included in CAPs will guide practices in the development of appropriate policies and procedures.
- In developing educational materials, we urge you to take advantage of the multiple methods of reaching the provider community. These include webinars, podcasts, one-pager information pieces focused on specific topics, infographics that can be emailed, and interactive web-based toolkits that can be updated as necessary.

The Challenge of Multiple State and Federal Records Release Requirements

Physician practices face overlapping state and federal requirements for sharing health information with patients. Since 2003, practices and other covered entities have been subject to the requirements of the HIPAA Privacy Rule. This rule permits practices to respond to a patient's request for information within 30 days and allows for an additional 30 days once the practice has informed the patient of this necessity. Although by law practices are permitted to respond any time within these 30 days, typically practices seek to provide the patient their requested information as quickly as possible.

While the goal is to produce the information for the patient as quickly as possible, there are multiple reasons why a practice may require additional time to produce a medical record for a patient:

- Protected Health Information (PHI) maintained in multiple facilities. Physician practices may have multiple facilities, each potentially maintaining separate medical records for a patient. Compiling the full record set from these various facilities will require considerable staff time and coordination.
- PHI maintained in multiple systems and in multiple formats. In many physician practices, PHI is maintained electronically in multiple systems. While the bulk of the PHI could be housed in the main EHR, other parts of the record could be in other clinical or administrative systems. For example, if the practice conducts clinical trials, it may capture and store the clinical data associated with the trial in a separate file from the traditional

medical record. A practice may have PHI contained in a system designed to benchmark non-deidentified quality data, while others may have electronic data stored in systems that are strictly performing revenue cycle functions. Additional time would be required by staff to compile the complete designated record set to fulfill a patient request.

Even if a practice has migrated to an EHR, it is likely that they have not scanned in every patient record. Many EHRs, for example, contain only the last few years of patient records. Older paper records are typically kept either in a designated area of the practice or stored offsite. However, these older records would be considered part of the designated record set and would need to be included in a complete medical record as requested by a patient. Assembling these records would require considerable staff time.

- Form and format. Patients have the right to request the practice provide the designated record set in a specific form and format and the practice must agree if it is reasonable. For example, the patient may request their designated record set be provided to them in PDF and stored on a USB "thumb" drive. With the record potentially being in multiple formats (i.e., PDF, Excel, images, paper), it could take staff additional time to convert these multiple formats into the one requested by the patient.
- Physician review of the record. Current HIPAA regulations permit the clinician to review the medical record prior to it being provided to the patient. Clinicians have the right to redact portions of the record should they believe disclosure of that information could be harmful to either the patient or another individual. This process requires sufficient time to both compile the complete record and have the appropriate review take place.

While some individual access requests should be relatively easy to fulfill, the HIPAA Privacy Rule recognizes that there may be other circumstances where additional time and effort is necessary to locate and format the requested PHI. The Privacy Rule is intended to set the outer time limit for providing access, not indicate the desired or best result. In cases where PHI is required for clinical purposes (i.e., referrals, coordination of care, transfer of care), physician practices make every effort to expedite the retrieval of that information and provide it as quickly as possible to the patient or other care setting (often the same day it is requested, if that is feasible). However, in the majority of instances, the patient does not require their designated record set immediately and waiting even the full 30 days does not prove a hardship on the patient.

The recently released Office for Civil Rights Notice of Proposed Rulemaking *Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement* (RIN 0945-AA00) proposes to shorten covered entities' required response time to no later than 15 calendar days (from the current 30 days) with the opportunity for an extension of no more than 15 calendar days (from the current 30-day extension). Adding to the complexity, many states have implemented specific timeframes for when physician practices must provide patients their health information.

We also note that the Centers for Medicare & Medicaid Services Merit-based Incentive Payment System's Promoting Interoperability component has established its own maximum response time. Eligible clinicians are required to upload a subset of the patient's health information to an online portal within 4 business days.

While ONC stipulates in the information blocking regulation that the designated data set must be shared with the patient without "unreasonable" delay, the agency has not identified specific timeframes. Thus "unreasonable" is left up to interpretation by the physician practice, the patient, and ultimately ONC. We assert that it would be fair for the physician practice to establish that a "reasonable" timeframe for releasing the information to the patient would be that which conforms to current applicable state law and federal HIPAA regulations (whichever is more stringent).

Additional Guidance

We appreciate the recent publication of a limited number of frequently asked questions (FAQs) on information blocking compiled on the ONC website addressing topics such as "Actors," "Electronic Health Information," "Interference," "Enforcement," and "Reporting Claims of Information Blocking." While these are helpful in clarifying some questions, there remains a significant number of topics that ONC should address in the FAQs. In particular, we urge the agency to focus the development of guidance on critical "real-world" operational issues that physician practices will need to leverage as they develop and implement appropriate policies and procedures.

We recommend ONC develop guidance to address the following policy areas:

- Physician practices being subject to the information blocking regulation even if they do not use any certified technology.
- The timing of when a physician practice is required to give the patient their requested information requirements under HIPAA-when must a practice get information to the patient to avoid being an "information blocker."
- The timing issue of when a physician practice is required to give the patient a test result (i.e., a lab result or radiologic image) prior to having the clinician develop the "interpretation."
- The timing of supplying patients their requested health information via online patient portals or via APIs-will the timing for making information available to the patient be different than with these modes compared with other types of communication options.
- The issue of releasing clinical notes to the patient. For example, will clinical notes be included in API access and/or the online patient portal as of the date requested by the patient? How should the physician practice handle, for example, behavioral health notes? Should they be made available to the patient with the same expedited timing? Will there be any accommodation for the fact that the physician may not have sufficient time to review the notes for any potential threats to the patient or other individual (as they are permitted to do under HIPAA).
- The ability of the physician practice to engage with the patient to define (and provide) the specific information they are seeking.
- The capability of an EHR to appropriately segregate sensitive data from other portions of the record and the impact on information blocking.
- The intersection of HIPAA 42 CFR Part 2 rules regarding substance abuse data and information blocking.
- The agency's expectation of a physician practice's information blocking compliance framework. Will a physician practice be encouraged to leverage other government-developed compliance frameworks, such as the one created by the Office of the Inspector General (a resource that includes seven separate program compliance elements with over 400 individual compliance program metrics).
- The physician practice selection, implementation, and documentation of compliance metrics. Examples of these metrics should be provided.
- The scope of use of the Infeasibility Exception for COVID-19 or other emergency reasons. At issue is whether this exception allows prioritization of some information sharing use cases over others during PHEs.
- Definitions for information blocking terms. For example, how a physician practice is to determine (and document) whether an action that blocks information is "reasonable" and the factors ONC will rely upon to determine that an action is "unreasonable."
- Physician use of professional judgement when determining if a delay in communicating information to the patient is appropriate. It will be important to understand how professional judgement will be applied, for example, to the Harm Exception, especially in

light of this right of the physician to use their professional judgement being reiterated in the recent OCR NPRM modifying HIPAA.

- Issues related to minors and access to health information. A minor's portals would most likely be established by their parents who then would have access to office notes, labs, and other potentially sensitive information. As EHRs typically do not segment information based on who is accessing the patient's portal guidance is necessary to address access issues. Would one or more of the exceptions apply in the case of a minor and if so, what would constitute appropriate documentation on the part of the physician practice.
- Release of psychotherapy notes that meet the established HIPAA definition. Would the Privacy Exception be invoked to support the physician practice should they not release those records? The intersection of HIPAA and the information blocking regulations in this area should be addressed.
- Details on how physician practices should handle situations where certain sensitive health data fall under different federal or state regulations. Segmentation of sensitive data is a critical issue and practices will need explicit guidance to assist with compliance.
- Issues related to the level and nature of the authorization the physician practice can/must require from the patient prior to release of data.
- Situations where multiple actors are involved in an information blocking action (i.e., physician practice and EHR vendor). What role would a Business Associate Agreement play in these situations and what would be the documentation requirements.
- Clarification on how these new information blocking requirements will be integrated with the changes to HIPAA requirements released recently by OCR.
- How exceptions will work with entity's that (a) have facilities in several states, (b) see patients from several states, and (c) use telehealth services that involve vendors, patients and providers in multiple states.
- What happens when a patient "opts out" of interoperability. For example, what does the physician practice do if the patient has decided they do not wish their information to be shared with the local HIE? Even more complex is the situation where the patient agrees to participate with the local HIE but for only certain portions of their data.
- Clarification for how physician practices must document their rationale for using the sub-exceptions identified in the ONC final rule.
- The potentially conflicting requirements that physician practices give patients the opportunity to consent to share information, while at the same time practices are prohibited from encouraging patients not to share their information.
- The general issue of how physician practices can avoid oversharing patient health information and satisfy privacy-protective pre-conditions established by HIPAA.
- What a physician practice must provide to the patient in terms of an opportunity to consent/provide authorization to share their health information. Guidance on how to provide a meaningful opportunity to provide a required consent or authorization, and whether different expectations should arise in the context of a consent versus a HIPAA authorization.
- Multiple case examples for each of the eight exceptions-with specific facts, recommended actions on the part of the actor, and samples of the type of documentation required to support a successful application of the exception.

Conclusion

In conclusion, MGMA believes the information blocking regulation has the potential of assisting in health information exchange by discouraging actors from preventing patient data from being accessed or transmitted. However, meeting these complex and confusing information blocking regulatory mandates will require physician practices to overcome numerous technical, legal, and

logistical hurdles-a daunting task even in the best of times. The COVID-19 national pandemic has presented historic challenges for the entire healthcare sector. Physician practices are fighting to simply keep their doors open and their staff and patients safe. Diverting scarce resources away from patient care to focus on meeting a new set of regulatory requirements at this time would be counterproductive.

In recognition of the unique environment created by COVID-19, we strongly urge ONC to push back the information blocking compliance date and link it to the end of the PHE. We also call on the agency to leverage this additional time and educate physician practices on these new requirements and issue comprehensive guidance to assist practices in their compliance efforts. We look forward to continuing to work with ONC to facilitate the physician practice transition to effective and efficient health IT and ensure that the promise of improving the nation's healthcare system through technology becomes a reality. Should you have any questions regarding these comments, please contact Robert Tennant, Director, Health Information Technology Policy, at 202.293.3450 or rtennant@mgma.org.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs