June 20, 2023

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street SW
Washington, DC 20201

Re: RIN: 0955-AA03, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Dear Dr. Tripathi:

On behalf of our member medical group practices, the Medical Group Management Association (MGMA) thanks you for the opportunity to provide comments on the Office of the National Coordinator for Health Information Technology's (ONC's) Notice of Proposed Rule Making on Certification Program Updates, Algorithm Transparency, and Information Sharing ("proposed rule").

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 medical groups in which more than 350,000 physicians practice. These groups range from small private practices in rural areas to large regional and national health systems, and cover the full spectrum of physician specialties and organizational forms, making MGMA well-positioned to offer the following feedback.

While many aspects of the proposed rule make appropriate updates to important ONC-administered health information technology (IT) programs, we offer the following comments to highlight areas significant to medical groups. MGMA supports ONC's efforts to promote interoperability and transparency in the electronic sharing of health information. We have long advocated for patient safety and the adoption of safe, effective, and affordable health IT to improve administrative processes and reduce practice costs.

We hope the agency will work in collaboration with medical groups of all sizes to ensure that the proposed changes to information blocking regulations, ONC certification criteria, decision support interventions, and more function properly as to ensure there are no unintended consequences. Adding unnecessary administrative and financial burdens to practices will only hinder necessary efforts to facilitate the efficient sharing of electronic health information (EHI).

Key Comment and Recommendations

- **Move forward with the information blocking definitional changes.** MGMA supports efforts to provide clarity and guidance regarding the information blocking definitions for providers given

their regulatory complexity. Updating the definition of "offering health IT" to appropriately distinguish in certain situations between health IT developers and providers is a welcomed development.

- **Institute proposed information blocking exceptions with certain parameters.** MGMA supports of ONC's efforts to clarify and add certain exceptions to the information blocking regulations. We urge ONC to implement these in a way that mitigates regulatory burden while ensuring continuity of care.
- **Adopt the United States Core Data for Interoperability (USCDI) v3 data set.** MGMA supports USCDI v3 and recommends ONC provide medical groups and other stakeholders with the appropriate resources and training to collect this data set.
- **Develop a standardized patient requested restriction criterion that works for patients and providers**. MGMA supports patients' right to privacy and their ability to request restrictions to their sensitive personal health records, as trust between a patient and provider is paramount. ONC's proposal to add a patient requested restriction criterion is a great step towards achieving a streamlined electronic process. Standards need to be developed and evaluated in real-world scenarios to encourage widespread adoption and ensure that the technology is mature and functions without negative consequences and undue burden.
- **Collaborate with federal agencies and stakeholders to make information about predictive decision support interventions easily accessible and understandable to promote transparency in certified health information technology.** We agree with ONC's efforts to promote transparency in decision support intervention technology and urge the agency to work with stakeholders to improve the effectiveness and trustworthiness of these tools.
- **Alleviate prior authorization burden by rulemaking in the future on a real-time prescription benefit tool**. MGMA supports the adoption in future rulemaking of the National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit (RTPB) standard as part of a real-time prescription benefit criterion. If implemented correctly, this criterion would reduce prior authorization burden by checking requirements at the point of prescribing.

New and Revised Standards and Certification Criteria

Adoption of USCDI v3

The USCDI establishes the minimum set of data classes required for health information exchange nationwide and includes data elements and vocabulary standards. ONC proposes to move from USCDI v1 to USCDI v3. USCDI v3 is a larger data set that includes elements related to social determinants of health (SDOH), health insurance information, and clinical tests.

MGMA previously agreed with requiring all certified electronic health records (EHRs) to support USCDI v1 in the 21st Century Cures Act Final Rule, and we agree with utilizing a predictable, transparent, and collaborative process to updating the data set. While we support ONC's proposal to adopt USCDI v3 to improve standardization, providers need resources, training, and proper support to allow them to understand the changes and efficiently capture this information. Certified health IT end-users must establish workflows to collect and share this data in a way that is efficient while respecting individuals' privacy. We joined the Health IT End-Users Alliance Consensus Equity Statement detailing principles to

ensure these goals are met specific to SDOH data elements.[1] We urge ONC to institute the proper infrastructure to support the implementation of these efforts.

Patient Requested Restrictions Criteria

ONC proposes to add a new certification criterion, an addition to the Privacy and Security Certification Framework under the Program, and a revision to an existing criterion to implement patient requested information privacy restrictions. Health IT developers will be required to enable patients to request a restriction on USCDI data elements, as well as to allow providers (or any other user) to flag whether any data element should be restricted from use or disclosure. The agency's proposal does not specify a standard that health IT developers must follow when developing these capabilities but believes that individuals should have a reasonable opportunity and the technical capability to make informed decisions about their electronic health information.

MGMA agrees with the impetus for ONC's proposed criterion that individuals should be able to express their preferences and make informed decisions flagging sensitive health information. Certified health IT products should offer straightforward methods for patients to access their EHI and request restrictions. Similarly, medical groups need these tools to support patient requests and navigate a myriad of statutory and regulatory requirements. The technology ultimately adopted should not be overly complicated nor cost prohibitive.

ONC should develop standards for data segmentation to ensure uniformity and functionality given the current landscape of health IT products and their limited ability to segment data. Potential operational challenges should be addressed at the outset to avoid any detrimental downstream effects to patient and provider functionality and coordination of care — ONC should incorporate provider feedback when designing standards focusing on ease of use and scenarios where incomplete medical records may impact care. Practices with less resources, solo practitioners, and smaller medical groups will need support to facilitate these processes — EHR vendors need to provide this functionality without unreasonable costs. Education and guidance from ONC to both patients and providers would help ensure compliance.

Decision Support Interventions

ONC is proposing to include new requirements into the health IT certification program for health IT modules that support artificial intelligence (AI) and machine learning (ML) technology. The agency plans to rename the "clinical service decision" criterion to "decision support intervention" (DSI), and to define predictive DSI as "intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."

The agency's rationale is to allow users of certified health IT to review model design and evaluation, and determine whether a model works for them while improving transparency and trustworthiness in the program. The proposals will require health IT modules certified to the DSI criterion to enable users to review information about source attributes relevant to health equity and other purposes. Developers will be required to engage in intervention risk management practices for predictive DSI, and make summary

[1]Health IT End-Users Alliance, Consensus Statement on Data to Support Equity, https://hitenduser.org/wp-content/uploads/2023/05/ADV_HIT_for-AT_5.10.23-v2.pdf.

information regarding these practices publicly available. Trustworthy or high quality predictive DSIs will be categorized as Fair, Appropriate, Valid, Effective, and Safe (FAVES).

A March 30, 2023, MGMA poll found that 10% of medical groups use AI tools on a regular basis.[2] A strong majority of medical group leaders who do not use AI tools stated that they were unlikely to add AI until they see more evidence of their efficacy. While AI and predictive DSI can be powerful tools, transparency and proper risk management are vital to combat negative practice and patient outcomes — MGMA supports ONC's efforts to facilitate better understanding of these rapidly developing technologies.

Federal agencies should work in concert with stakeholders to understand predicative DSI, enhance ONC's proposals, avoid instituting stifling requirements, and allow end-users to access DSI source attributes in a functional and nonburdensome manner. Greater transparency about the datasets used to train predictive DSI would avoid embedding bias in the system and help improve efficiency. We should distinguish between providers developing DSI systems internally and EHR vendors offering DSI services through certified health IT products. This distinction is important as providers have greater understanding and experience with self-developed DSI tools they use internally and should not be subject to the same requirements as vendors offering DSI tools in certified health IT products for commercial use. ONC made a similar distinction in the information blocking definitions. In addition to collaborating with stakeholders to improve transparency requirements, MGMA asks for continued education and guidance from the agency.

Insights Condition and Maintenance of Certification Requirements

ONC proposes to institute the new "Insights Condition" as required under the *21st Century Cures Act*. This EHR reporting program will include measures across four topic areas related to interoperability which health IT developers would respond to in the reporting criteria. Developers of certified health IT would be expected to report on a measure if the developer has: at least 50 hospital users or 500 clinician users across their certified health IT products; any applicable health IT modules certified to a criterion associated with a given measure; and any user of the applicable criterion/criteria associated with the measure.

MGMA supports the goals of this condition to provide transparent reporting that will address information gaps in the health IT marketplace, provide insights on the use of specific certified health IT functionalities, and provide information about end-users' experience with certified health IT. We believe reporting on these measures will improve end-users understanding of certified health IT products and improve interoperability. It is important to account for how EHR vendors reporting will impact medical groups as vendors may need to interface with end-users to obtain reporting data for some measures. We urge ONC to review how this interaction may increase providers' regulatory burden and ensure providers are not subject to unnecessary additional reporting requirements.

Information Blocking

ONC proposed updates to the definition section of the information blocking regulations, as well as to individual exceptions. MGMA recognizes the importance of limiting information blocking and

[2] MGMA Stat, Medical groups moving cautiously as powerful general AI tools emerge, Mar. 30, 2023, https://www.mgma.com/data/data-stories/medical-groups-moving-cautiously-as-powerful-gener.

appreciates these clarifications to a complex series of regulatory requirements that medical groups must navigate. In addition to the comments below on specific proposals, we ask ONC to continue to define the underlying principles of information blocking and clarify ambiguities in the text that persist to this day.[3] The agency should provide further education on best practices, use-case examples, training, and guidance to medical groups on compliance**.** Aligning HIPAA rules, 42 CFR Part 2 requirements, and other state and federal laws with information blocking regulations is vital so that medical groups can focus on providing high-quality care in a private and secure manner.

Definitional Changes

The proposed rule narrows the definition under "Health IT Developer of Certified Health IT" of what it means to "offer health IT." The new definition would explicitly exclude beneficial and necessary activities from providing, supplying, or otherwise making available certified health IT under any arrangement or terms. Specifically, two activities would not fall under offering health IT:

- (1) encouraging beneficial arrangements under which providers in need can receive subsides for the cost of obtaining, maintaining, or upgrading certified health IT; or
- (2) to give health care providers (and others) who use certified health IT concrete certainty that implementing certain health IT features and functionalities, as well as engaging in certain practices that are common and beneficial in an EHR-enabled environment will not be considered an offering of certified health IT (regardless of who developed that health IT).

ONC received public feedback after the 21st Century Cures Act Final Rule detailing concerns that healthcare providers and entities might stop subsidizing providers who cannot afford certified health IT. While providers are already actors under information blocking regulations, the potential to offer subsides to other providers may be curtailed if they are to potentially be regulated as a health IT developer of certified health IT and subject to regulations under 45 CFR part 171, a heightened knowledge standard ("knew or should have known that such practice is likely to interfere"), and potential fines. Additionally, ONC proposes to modify the "health IT developer of certified health IT" definition so that it is clear that providers who self-develop certified health IT would continue to be excluded from this definition contingent they supply the self-developed certified IT to others under the arrangement excluded from the "offer health IT" definition.

MGMA supports ONC's updates to these definitions — these commonsense changes will help facilitate donors, large health systems, and others to assist less-resourced providers in promoting interoperability. Without such clarifications, as evidenced by the feedback ONC has received, these arrangements may have ceased to exist given the increased reporting requirements and penalties. We appreciate ONC's willingness to incorporate provider feedback to remove unnecessary compliance barriers and hope it will continue to act collaboratively to ensure medical groups are not penalized while trying to comply with complex regulations. ONC should continue to incorporate provider feedback to reflect the multitude of provider arrangements.

Updates to Information Blocking Exceptions

Manner Exception

[3] *See* MGMA and partner organizations request additional clarity and guidance surrounding information blocking regulations, Aug. 2022, https://www.mgma.com/advocacy/advocacy-statements-letters/advocacy-letters/august-18,-2022-mgma-and-partner-organizations-req.

ONC proposes to include in the Manner Exception an additional exception for Qualified Health Information Networks (QHINs), participants, and subparticipants participating in Trusted Exchange Framework and Common Agreement (TEFCA). The proposed TEFCA condition would allow actors who offer to fulfill a request for EHI access, exchange, or use for any purpose permitted under the Common Agreement and Framework Agreement(s) from any other QHIN, participant, or subparticipant, to not be required to offer the EHI in any alternative manner; any fees charged by the action related to fulfilling the request are not required to satisfy the exception in section 1771.302; and any license of interoperability elements granted by the actor in relation to fulfilling the request is not request to satisfy the exception in section 171.303.

MGMA has been supportive of ONC establishing TEFCA as an on-ramp to nationwide electronic health information sharing. The agency should encourage voluntary participation as it continues to develop the program. Adding this manner exception incentivizes participation in TEFCA and could reduce administrative burden for providers. ONC should work with stakeholders to eliminate any gaps or perverse incentives that may force providers to use TEFCA when there may exist easier alternative methods of data exchange.

We want to reiterate that the inclusion of this exception for TEFCA demonstrates that there may be conflicting and confusing mandates under different federal programs, making compliance with information blocking regulations more difficult. We urge ONC to continue to review how all federal and state laws, regulations, and programs interact to relieve the unnecessary burden of varying requirements that may not align — harmony is essential to avoid unintended consequences and promote compliance.

Infeasibility exception – uncontrollable events

ONC proposes to amend the uncontrollable events condition of the infeasibility exception to the information blocking regulations. Specifically, the proposed rule would replace the word "due to" with "because of" in the uncontrollable events condition. The agency states that this change will make clear that the actor attempting to use the uncontrollable events exception would have to demonstrate a causal connection between the uncontrollable events and not providing access, exchange, or use of EHI. MGMA appreciates the increased transparency on how the uncontrollable event condition operates which will allow providers to clearly understand the requirements under this exception.

Infeasibility exception – third party seeking modification use

ONC proposes to add a new condition to the infeasibility exception, "third party seeking modification use." This exception would apply in response to a "request is to enable use of EHI in order to modify EHI (including but not limited to creation and deletion functionality), provided the request is not from a health care provider requesting such use from an actor that is its business associate." This would not be available to a provider when the requesting actor is a business associate (directly, or through another business associate of the provider).

MGMA appreciates that this proposal would reduce administrative burden and increase efficiency by allowing a provider to deny a request for modification without having to fulfil the requirements of another infeasibility exception like Preventing Harm. Providers and patients must be able to trust that their EHR records are accurate and not subject to modifications that may raise treatment and security concerns. ONC should consider how this condition impacts care coordination between providers not in business associate agreements. There are situations where clinicians not subject to a business association agreement may need to modify a patient's EHR; we hope ONC balances this exception to allow for beneficial sharing of EHI and allow modifications where appropriate. More guidance is needed from ONC detailing how this

exception will work in practice and how providers will comply with it while minimizing administrative burden.

Manner Exception Exhausted

ONC proposes to add a new "manner exception exhausted" condition to the "infeasible under the circumstances" exception. The manner exception exhausted would apply and an actor would be considered unable to fulfil the request if the following three conditions are met:

- (i) The actor could not reach agreement with a requestor in accordance with § 171.301(a) *manner requested* condition (as we have proposed it in this proposed rule) or was technically unable to fulfill a request for electronic health information in the manner requested;
- (ii) The actor offered all alternative manners in accordance with § 171.301(b) *alternative manner* condition (as we have proposed it in this proposed rule) for the electronic health information requested but could not reach agreement with the requestor; and
- (iii) The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.

We appreciate ONC including this exception and ask for further guidance to explain the terminology in the exception. Examples of similarly situated entities and use-case scenarios would be helpful to better understand its parameters.

Health IT Capabilities for Data Segmentation and User/Patient Access – Request for Information.

MGMA appreciates ONC's attempts to promote the development of data segmentation technology and improve the availability of solutions to support healthcare providers' efforts to honor patient requests. This request for information parallels ONC's proposal regarding a patient restriction request criterion, and we echo our earlier comments here. Health IT products vary significantly in their ability to segment patient data in the current environment, and many do not possess the ability to segment data efficiently. As ONC continues to develop data segmentation standards, we hope the agency will incorporate stakeholder feedback while undergoing real-world testing, so the technology works to ably allow for data segmentation.

Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities – Request for Information

ONC intends to establish in future rulemaking a real-time prescription benefit health IT certification criterion within its health IT certification program. This criterion would certify health IT so that a provider is able to view in the electronic prescribing workflow at the point of care for patient-specific benefit, estimated cost information, and viable alternatives. Additionally, ONC is considering adopting the National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit (RTPB) standard as part of this certification criterion. ONC contemplates that the RTPB would facilitate key real-time prescription benefit capabilities that may include medication history, eligibility checks, and electronic prior authorization.

Recently, MGMA submitted comments in response to CMS' notice of proposed rulemaking regarding changes in Medicare Part C & Part D.[4] We supported CMS' proposal to require Part D plan sponsors to comply with NCPDP to allow practices to check prior authorization requirements at the point of prescribing. We reiterate that support here — a well-functioning, mature, and widely adopted RTPB tool holds the promise of sharing critical clinical information with patients and physicians. If implemented correctly, enabling physicians to check prior authorization requirements at the point of prescribing would reduce a time and resource consuming process that can delay care. The IT infrastructure must be in place to ensure that the RTPB functions correctly and does not add administrative hurdles related to the sharing of incomplete or incorrect information and avoids other potential pitfalls. We support ONC instituting a RTPB criterion that would facilitate electronic prior authorization to reduce what MGMA members consistently rank as their most onerous regulatory burden.[5]

Conclusion

MGMA supports ONC's aims to advance interoperability, improve transparency, and support the access, exchange, and use of EHI. If done appropriately, medical groups will see reduced administrative burden and benefit from effectively sharing clinical data among care settings, improving their ability to offer high-quality care. We appreciate clarifications regarding the information blocking regulations and hope ONC will continue to simplify these requirements and harmonize them with other federal and state laws. MGMA urges ONC to collaborate with medical groups and other stakeholders to effectively implement many of the changes in this proposed rule. If you have any questions about the above recommendations, please contact James Haynes at jhaynes@mgma.org or 202-293-3450.

Sincerely,

/s/

Anders Gilberg
Senior Vice President, Government Affairs

[4] MGMA comments on Medicare Part C and Part D Proposed Rule, Feb. 10, 2023, https://www.mgma.com/getmedia/a100cb7d-8ae0-4926-83bc-b84f72931ea1/02-10-2023_MGMA-Part-C-D-Proposed-Rule-FINAL.pdf.aspx?ext=.pdf.

[5] MGMA Annual Regulatory Burden Report, Oct. 2022, https://www.mgma.com/getmedia/4bfd2489-6099-49e5-837f-f787d6d0a30f/2022-MGMA-Regulatory-Burden-Report-FINAL.pdf.aspx?ext=.pdf.