October 4, 2024

Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy
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, 7th Floor
Washington, DC 20024

Re: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (RIN 0955-AA06)

Dear Assistant Secretary Tripathi:

The Medical Group Management Association (MGMA) thanks the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) for the opportunity to comment on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule. We support ASTP/ONC's efforts to remove technological roadblocks that negatively affect the ability of medical groups to transmit and receive important information.

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 medical group practices ranging from small private medical practices to large national health systems, representing more than 350,000 physicians. MGMA's diverse membership uniquely situates us to offer the following policy recommendations.

This wide-ranging proposed rule offers numerous policies which, if implemented correctly, would increase interoperability, reduce administrative burden, and avoid penalizing medical groups for commonsense practices under information blocking regulations. At the same time, we caution ASTP/ONC that there is a rapid promulgation of health information technology (IT) regulations happening that not only requires medical groups to expend substantial financial resources, but devote time to hiring/training staff, implementation, and compliance.

We offer the following comments in the spirit of supporting the office's goals of increased interoperability. ASTP/ONC should:

- **Work with the Centers of Medicare & Medicaid Services (CMS) to align all aspects of the electronic prior authorization process**. Payers must be required to utilize harmonized prior authorization technology, otherwise there would be significant gaps in regulatory requirements that would ultimately undermine the benefit of the proposed Prior Authorization APIs.

- **Implement the Prior Authorization and other API provisions with robust end-to-end testing and input from providers** to ensure the technology works efficiently without creating new barriers to interoperability.
- **Ensure that medical groups are able to access affordable certified health IT.** Developers and vendors should not be able to charge excessive prices that would prevent many practices from utilizing this important technology.
- **Move forward with certain information blocking exceptions while making modifications to avoid additional confusion and instituting barriers for practices attempting to honor patients' requests that their electronic health information (EHI) not be shared.** ASTP/ONC should develop data segmentation standards and tools within certified health IT to allow providers to comply with these information blocking exceptions.
- **Work to simplify the information blocking regulations and provide flexibilities for providers.** Significant education is needed on the complex web of information blocking definitions and exceptions to avoid unnecessarily penalizing practices due to an ever-evolving regulatory landscape.
- **Provide guidance, technical assistance, and financial resources for practices implementing the myriad technological changes in this proposed rule and others**. ASTP/ONC should consider the impact of the numerous tech-related regulations that are going into effect in the coming years; increasing compliance costs can undermine the financial viability of medical groups, especially smaller ones.
- **Finalize the revised electronic prescribing certification criterion and real-time prescription benefit criterion** to reduce administrative burden for practices and improve patient outcomes.

Patient, Provider, and Payer API

Prior Authorization API — Provider and Payer

ASTP/ONC proposes to adopt two certification criteria for providers and payers to specify requirements for certified health IT that can be used to conduct electronic prior authorization. The "Prior Authorization API - Provider" certification criterion would establish requirements for Health IT Modules that can facilitate a provider's request for information and for a prior authorization decision. The "Prior Authorization API - Payer" certification criterion would complement the provider API and allow payers to accept prior authorization requests, send request documentation and coverage information, and send prior authorization decisions.

The office's intention for these certification criteria is to support real-time access for providers to payer requirements and rules at point of service, in addition to enabling providers to request and receive authorization. The certification criteria for both APIs are based on the HL7 FHIR Da Vinci Burden Reduction IGs, which ONC is proposing to adopt. This section is meant to align with CMS-established API recommendations and requirements promulgated in the CMS Interoperability and Prior Authorization Rule (e-PA Rule) finalized earlier this year.

We commend ASTP/ONC for establishing certification criteria to facilitate electronic prior authorization. Year after year, MGMA members cite prior authorization as the number one administrative burden facing

their practices.[1] There are a multitude of challenges with the current state of prior authorization including issues submitting documentation manually via fax or through a health plan's proprietary web portal, as well as changing medical necessity requirements and appeals processes to meet each health plan's requirements. MGMA members reported numerous concerns with Medicare Advantage plans' utilization of prior authorization that lead to increased practice administration costs, disrupted practice workflows, and delays and denials of necessary medical care.[2]

MGMA supports the establishment of criteria in certified health IT to align with CMS' previously finalized rule for Medicare Advantage plans and other government payers requiring them to support electronic prior authorization. The proposed criteria are necessary for medical groups to be able to utilize certified health IT to meet MIPS reporting requirements established by the CMS e-PA Rule.

We strongly urge ASTP/ONC to work with CMS to ensure that all impacted payers under the e-PA Rule are required to utilize certified prior authorization technology that aligns with the certification standards in this proposed rule. Currently, the e-PA Rule only recommends the use of certain implementation guides for payers, while this proposal mandates certain implementation guides and requirements. Payers must be required to use the same technology to ensure actual interoperability and alleviate the significant burden of prior authorization.

Real-world, end-to-end testing is needed to ensure these systems work as intended given the myriad considerations and information that may go into a prior authorization request. ASTP/ONC should work with providers to avoid instituting technology that does help expedite the onerous prior authorization process. Once established and firmly tested, enforcement on the payer side must be robust to prevent situations where these systems are established but rarely used. Further clarity is needed regarding CMS' use of enforcement discretion for the X12 278 standard and how these proposals would interact with this policy.

ASTP/ONC and HHS should use all levers available to prevent electronic health record (EHR) vendors from charging overly excessive prices for certified health IT. Given the importance of certified health IT to physician practices, escalating costs for this technology would undermine the financial viability of many medical groups, especially those that are smaller and in rural areas. ASTP/ONC should ensure that the timelines for establishing these requirements reflect the maturity of the technology and are not implemented in a piecemeal manner without payers being included. We echo these comments for the additional APIs in this proposal that conform to CMS' e-PA Rule.

Information Blocking

Information Blocking Definition Enhancements

ASTP/ONC proposes to add a section to the information blocking regulations that would codify practices that constitute interference for the purpose of information blocking. Specifically, the proposal includes the following practices:

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[1] MGMA, 2023 Annual Regulatory Burden Report, Nov. 13, 2023, https://www.mgma.com/federal-policy-resources/mgma-annual-regulatory-burden-report-2023.
[2] MGMA, Spotlight: Prior Authorization in Medicare Advantage, May 3, 2023, https://www.mgma.com/federal-policy-resources/spotlight-prior-authorization-in-medicare-advantage.

1. Actions taken by an actor to impose delays on other persons' access, exchange, or use of EHI;
2. Non-standard implementation of health IT and other acts to limit interoperability of EHI or the manner in which EHI is accessed, exchanged, or used by other persons;
3. Improper inducements or discriminatory contract provisions; and
4. Omissions (failures to act) when action is necessary to enable or facilitate appropriate information sharing, such as where access, exchange, or use of an individual's EHI is required by law or where it is permitted by law.

While we appreciate ASTP/ONC including practices by EHR vendors, Health Information Exchanges/Networks, and others that would interfere with medical groups' ability to access important patient information, we urge the office to reconsider instituting definitions, such as the first bullet above, that are overly broad and go against exceptions in this proposed rule. Including this language adds confusion to actors covered under information blocking regulations — we recommend ASTP/ONC avoid instituting conflicting provisions in this proposal.

Protecting Care Access Exception

ASTP/ONC proposes to adopt the Protecting Care Access Exception that would except from the information blocking definition practices implemented based on an actor's good faith belief that sharing EHI indicating that any persons(s) sought, received, provided, or facilitated the provision or receipt of reproductive health care that was lawful under the circumstances in which it was provided could result in a risk of potential exposure to legal action for those persons, and that the risk could be reduced by practices likely to interfere with particular access, exchange, or use of specific EHI. An actor's practice would need to satisfy the threshold condition and at least one of the patient protection condition or care access condition in the exception.

MGMA appreciates ASTP/ONC aligning this exception with the Office of Civil Rights' (OCR) recent HIPAA rulemaking; failing to do so would have put practices in a bind in terms of complying with confusing and conflicting regulations. The office should provide additional flexibilities to practices under this exception and utilize enforcement discretion for medical groups given its complexity. Physicians should rely on their judgment and not be penalized for information blocking violations by doing so — this regulation offers much needed clarity to practices but should be further simplified.

ASTP/ONC and HHS should undertake a concerted education effort around not only this proposal but information blocking more broadly. There are numerous detailed exceptions that are difficult to understand, and the Administration is constantly adjusting, refining, and changing definitions and exceptions to the rule. Practices need transparency and resources to understand the evolving information blocking landscape. Additionally, the office needs to ensure that EHR vendors provides the full range of technological capabilities to utilize these exceptions.

Privacy Sub-exception — Individual's Request Not to Share EHI

ASTP/ONC would revise the Privacy Exception's section 171.202(e) sub-exception that applies to actors' respecting an individual's request for restriction on access, exchange, or use of their EHI. The proposal would remove the existing limitation of the sub-exception to restrictions that are permitted by other applicable law. Any practice that meets the revised requirements in 171.202(e) would simply not be

considered information blocking, regardless of whether other valid law compels the actor to disclose EHI against the individual's expressed wishes.

We appreciate ASTP/ONC's changes to this sub-exception by removing existing limitations on practices to allow providers to better honor an individual's request for restrictions without being considered information blocking. This would provide needed transparency and certainty to practices given the numerous federal/state laws and regulations at play.

Infeasibility Exception — Segmentation Condition

ASTP/ONC proposes to modify the responding to request condition of the Infeasibility Exception to allow actors a more flexible response timeframe where the reasons for infeasibility are consistent with the manner exception exhausted or infeasible under the circumstances conditions. The actor could satisfy the responding to requests condition by:

- First, initiating within 10 business days of the actor receiving request good-faith collaborative engagement with the requestor to discuss the potential infeasibility of the request as received and potentially feasible alternative ways to achieve information sharing.
- Second, where discussions and negotiations reach a result other than successful fulfillment of access, exchange, or use of EHI for the requestor, providing the requestor a written response indicating the reason for infeasibility within 10 business days of the actor's determination of infeasibility or the discontinuation of discussions (as described in proposed revised § 171.204(b)(2)(iii)).

Additionally, ASTP/ONC would amend the Infeasibility Exception to include the following:

> (2) *Segmentation.* The actor cannot fulfill the request for access, exchange, or use of electronic health information because the actor cannot unambiguously segment the requested electronic health information from electronic health information that:
>
> (i) Is not permitted by applicable law to be made available; or
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> (ii) May be withheld in accordance with § 171.201, § 171.202, or § 171.206.

We appreciate these proposed changes as they contemplate issues providers face attempting to segment data. Given the current state of data segmentation in certified health IT, it is important to avoid penalizing practices for being unable to separate data due to factors outside of their control. ASTP/ONC should allow additional flexibilities for medical groups to comprehensively address these kinds of situations.

Requestor Preferences Exception

ASTP/ONC is proposing to introduce a new "Requestor Preferences" Exception meant to offer actors certainty that, under conditions outlined in the exception, it would not be considered information blocking to honor a requestor's preference expressed or confirmed in writing for:

1. Limitations on the scope of EHI made available to the requestor;
2. The conditions under which EHI is made available to the requestor; and,
3. The timing of when EHI is made available to the requestor for access exchange, or use.

The proposed exception has four separate conditions: (a) request, (b) implementation, (c) transparency, and (d) reduction or removal. In order for an actor's practice(s) to satisfy the proposed Requestor Preferences Exception, the practice(s) would have to meet all four of the conditions at all relevant times.

While MGMA supports the intention of the Requestor Preferences Exception, we believe ASTP/ONC should go further and remove unnecessary and confusing barriers to clearly utilizing this exception. As currently constructed, physician practices attempting to honor a patient's request would face administrative and technological hurdles. The office should remove the requirement that the request to be in writing and allow for verbal communication to be sufficient to satisfy this exception. This would accurately reflect the relationship between patient and provider — ASTP/ONC should allow patients the ability to request limitations on their EHI in the manner that best suites them.

We urge the office to make sure that digital technology certified under ASTP/ONC is available to physician practices to honor patients' requests for restrictions and segmentation in a streamlined manner that fits into clinical workflows. 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 the various statutory and regulatory requirements. Standards should be developed 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.

Electronic Prescribing and Real-Time Prescription Benefit

Revised Electronic Prescribing Certification Criterion and New Real-Time Prescription Benefit Criterion

ASTP/ONC is proposing to update its version of the electronic prescribing criterion under section 170.315(b)(3); the office will incorporate National Council for Prescription Drug Programs (NCPDP) SCRIPT standard 2023011. Health IT developers may maintain the current version of the criterion — NCPDP SCRIPT standard version 2017071 — for the time period up to Dec. 31, 2027. Starting Jan. 1, 2028, a health IT developer of a certified Health IT Module must update the Module to use NCPDP SCRIPT standard version 2023011 and provide this update to customers.

ASTP/ONC is also proposing to establish a real-time prescription benefit certification criterion based on the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13. This proposal would implement section 119(b)(3) of the *Consolidated Appropriations Act, 2021*. The base EHR definition would include this certification criterion.

MGMA supports both of these proposals as they would improve the transparency of prescription drug coverage, and add numerous benefits outlined in the proposed rule: allow practices to compare the cost of a drug to that of a suitable alternative, compare prescription costs at different pharmacies, view information about out-of-pocket costs, and learn whether prior authorization is required. A well-functioning, mature, and widely adopted RTPB tool holds the promise of sharing critical clinical information with patients and physicians. ASTP/ONC should continue to work to increase the availability and functionality of this technology, and work with CMS to fully integrate prior authorization for prescription drugs.

USCDI Version 4

ASTP/ONC is proposing to update the USCDI standard by adding USCDI v4 and establishing an expiration date of Jan. 1, 2028, for USCDI v3 for purposes of the ONC Health IT Certification Program. USCDI v3 was adopted as the baseline standard beginning January 1, 2026.

As expressed in our HTI-1 Rule comments, MGMA previously agreed with requiring all CERHT 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 ASTP/ONC's proposal to adopt USCDI v4 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. ASTP/ONC should also consider the costs that quickly transitioning from v3 to v4 will have on physician practices, and utilize an appropriate timeline to avoid undercutting the benefits of USCDI.

Guidance, Training, and Resources

Given the ongoing increased regulation of health IT that is expected to continue for the foreseeable future, we caution ASTP/ONC to consider the ever-expanding requirements being place on medical groups. Many of the new proposals and rules, such as the HTI-1 Rule finalized earlier this year, are technically complex and require knowledgeable staff members to devote significant time and resources to implement. As there are wide-spread staffing shortages throughout medical practices, the rapid pace of these changes adds strain to an already stretched thin workforce.

MGMA urges ASTP/ONC to provide guidance and institute a comprehensive training regime to facilitate the adoption of these proposed rules. Grants and other funding may be required to train the appropriate staff who will be required to not only understand FHIR, but also current HIPAA requirements and other systems. Timelines for implementation must be carefully considered to avoid putting physician practices in an untenable position.

Conclusion

MGMA appreciates ASTP/ONC including numerous provisions in this proposed rule that would improve interoperability and information blocking, as well as help address longstanding prior authorization concerns, if implemented correctly. We urge the office to continue working with medical groups to ensure the proposed changes to certified health IT are cost-effective and able to function effectively. If you have any questions, please contact James Haynes, Associate Director of Government Affairs, at jhaynes@mgma.org or 202-293-3450.

Sincerely,

/s/

Anders Gilberg
Senior Vice President, Government Affairs