AMERICAN OSTEOPATHIC ASSOCIATION

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October 4, 2024

Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
U.S. 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 Proposed Rule (RIN 0955-AA06)

Dear Assistant Secretary Tripathi,

On behalf of the American Osteopathic Association (AOA) and the more than 197,000 osteopathic physicians (DOs) and osteopathic medical students we represent, thank you for the opportunity to submit comments on the Office of the National Coordinator for Health IT/ Assistant Secretary for Technology Policy (ONC/ASTP) Health Data, Technology, and Interoperability Proposed Rule. This rule is another important step forward in fostering improved data sharing across our healthcare system, promoting care coordination for physicians across settings and specialties, and ensuring that data is exchanged in a manner that protects the patient-physician relationship. Our feedback on several elements of this rule is outlined below.

Health IT Certification Program Updates

The AOA strongly supports ONC/ASTP's proposal to incorporate new criteria into the certification program that will improve the information available to physicians at the point of care for clinical decision making, improve prior authorization processes, and ease administrative burdens. To ensure true interoperability across payer and provider health IT, it is essential that ONC/ASTP align certification program criteria with CMS requirements adopted under the 2024 Promoting Interoperability and Improving Prior Authorization Processes Rule and the 2020 Interoperability and Patient Access Rule.

While aligning requirements for adopting standards for certified health IT will drive broader and more seamless data exchange, providers will continue to face administrative burden and financial strain associated to when (1) developers pass costs of complying with new requirements to the physicians who purchase certified health IT, and (2) when there are inconsistencies in API requirements and implementation guides across payer IT and certified health IT adopted by providers. We elaborate on these issues below and urge ONC/ASTP to consider refinements as it moves forward with these policies. We also encourage ONC/ASTP to work with other federal agencies to support secure and effective data exchange, through promotion of unified standards, across technologies that store or generate health data but may not be certified health IT.

Real-Time Prescription Benefit Criterion

The AOA supports ONC/ASTP's proposal to establish a real-time prescription benefit (RTPB) standard based on the National Council for Prescription Drug Programs (NCPDP) RTPB standard version 13 and incorporate this certification criterion into the Base EHR definition. We believe that policies should empower physicians when

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partnering with their patients to deliver care that best meets their needs, and establishing a RTPB standard will support broader adoption of real-time benefit tools. The availability of RTPB allows physicians to view information about patients' plan benefits, coverage, costs, and prior authorization requirements at the point of care, within the prescribing workflow. We agree with ONC/ASTP that low adoption of RTPB tools is partially due to "fragmented availability and implementation of tools across EHR vendors," and this new certification criterion will help to address this issue.

The prior authorization process is complementary to the prescribing workflow. Within a single workflow, physicians should be able to begin the prescribing process, view formulary information (including drug tiers), review cost and coverage information, view prior authorization requirements, and submit prior authorizations. The AOA believes the combined proposals for RTPB standards and adoption of patient, provider, and payer Application Programming Interfaces (APIs) will help streamline the prescribing and prior authorization process and reduce administrative burden.

Patient, Provider, and Payer APIs

Patient Access API
The AOA applauds ONC/ASTP's proposal to establish a patient access API certification criterion to enable patients to access their health and administrative information using health applications of their choice. The proposal to adopt a patient access API would include payer drug formulary details and patient coverage, claims, and clinical information. The AOA supports patients' right to access their health information, and we appreciate ONC/ASTP's continued efforts to empower patients as owners of their health data.

Under this new certification criterion, ONC/ASTP proposes that health IT must allow patients to incorporate their data into apps or systems of their choice with minimal effort. While we support greater patient access to their health information, we have previously raised concern that patients are often unaware of how their health information is used when it is downloaded to third-party applications. To ensure appropriate privacy protections for patients' sensitive health data, ONC/ASTP should establish additional requirements for developers certifying to this criterion that ensure transparency to patients on potential privacy concerns when their data is exported. We also urge ONC/ASTP to work with other federal agencies with jurisdiction over regulation of consumer applications not subject to HIPAA, such as FTC, to prevent inappropriate disclosure of patient data downloaded to third-party applications.

Provider API
ONC/ASTP is proposing to adopt a provider API to support provider access to patients' claims and encounter data held by payers. This would include information about the patient's encounters, providers, organizations, locations, dates of service, diagnoses, procedures and observations, and prior authorizations. The AOA agrees with ONC/ASTP that this policy has the potential to allow providers to have improved access to patient information and histories, enabling them to have a more complete picture of the patient's care across settings. This information will support care delivery, improve care coordination, and potentially aid in avoiding duplicative services. The AOA has long advocated for improved data sharing to support clinical decision making. The provider API certification criteria will drive data sharing that enables physicians to have complete patient records and more detailed information at the point of care.

Payer-to-Payer API
ONC/ASTP is proposing to adopt a payer API to support the electronic exchange of patient information between payer systems when a patient changes insurance plans. The new criterion is intended to support the availability of certified health IT that can enable payers to meet CMS requirements under the Promoting Interoperability and Improving Prior Authorization Processes Rule to implement and maintain payer and provider APIs. ONC/ASTP indicates in the

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proposal that this API is intended to improve coordination of care and reduce administrative burden when a patient transitions from one payer to another.

The AOA is supportive of this proposal to improve data exchange and transition of coverage for patients. However, we are concerned about the potential for unintended consequences that could harm the delivery of care or create greater burden. When plans gain access to patients' complete data from previous payers, there are no guardrails in place to prevent inappropriate use of the data. This includes warehousing data and using it for the creation of internal resources, which can be used for development of UM criteria or other coverage policies, auditing providers using historical data from across patients, creating limitations on access, or potentially applying data in discriminatory ways. While we recognize that this issue is beyond ONC/ASTP's authority, we urge the office to work with CMS to develop strict guardrails to prevent the potential misuse of data by plans.

Prior Authorization API

ONC/ASTP is proposing to adopt a prior authorization API to support electronic prior authorization for providers and payers. For providers, this would allow physicians to request coverage information and initiate a prior authorization request within certified health IT. Payers that utilize the certified health IT, as proposed, would have the ability to accept prior authorization requests from providers, send requested coverage information, and send prior authorization decisions.

Physicians need accurate and useful prior authorization information to treat their patients in a timely manner. A 2023 physician survey revealed that one in three physicians report that the prior authorization requirement information provided in their electronic health record or electronic prescribing system is "rarely or never" accurate[1]. The majority of physicians surveyed reported a high or extremely high burden associated with prior authorization in their practices for all major health plans. Inaccurate and unusable prior authorization information, and the inability to complete PAs within a physician's workflow, can lead to delays in care and negative health outcomes for patients.

While ensuring that certified health IT supports electronic prior authorization processes to be completed more efficiently, it will not eliminate the burden associated with PA. The AOA is supportive of finalizing provisions that build capabilities to address the administrative burden and information inaccuracies physicians face when navigating prior authorization. However, as the ONC/ASTP makes clear in the proposal, health plans are not obligated to use certified health IT. MIPS-eligible physicians will be required to support electronic prior authorization under the Centers for Medicare & Medicaid Services (CMS) Promoting Interoperability and Improving Prior Authorization rule, which was finalized in January 2024. Under this rule, payers will be required to implement and maintain a Prior Authorization API, but they are not required to use standardized APIs. If payers are not required to utilize the same standards as physicians and health IT developers, these tools intended to improve interoperability may have limited utility until the requirements are aligned. We strongly urge ONC to work with CMS to ensure that health plans subject to the rule must use certified APIs.

We are also concerned about the financial risk for physicians if this proposal is finalized without requirements for payers to comply with aligned standards. Adopting certified health IT places a substantial cost burden on many small and independent practices. As health IT developers must comply with new capabilities under the certification program, these costs are passed down onto the purchasers/users of certified health IT. Compounding these costs, CMS is imposing requirements on physicians participating in the Merit-Based Incentive Payment System (MIPS) to engage in

[1] American Medical Association. 2023 AMA prior authorization physician survey. Available here.

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electronic prior authorization while not requiring plans to comply with standardized APIs. If full interoperability is not achieved with payers, while physicians must absorb the cost of these new technical requirements, this will result in practices experiencing additional administrative burden while being saddled with new, unnecessary costs. We urge ONC/ASTP to work with CMS to require plans to comply with the standardized Prior Authorization API to ensure the adoption and use of the Prior Authorization API meets its full potential.

Provider Directory API

ONC/ASTP is proposing that certified Health IT Modules must support the ability to publish information about providers in a payer's network to help patients understand which physicians, pharmacies, and facilities are covered by their insurance plan. This information also helps physicians with making referrals, enabling them to ensure that their patients can see specialists and other providers covered by their health plan. The AOA strongly supports adopting technical standards to enable real-time, standardized exchanges of directory information.

Information Blocking Enhancements- Exceptions

As physicians who partner with our patients to develop care plans, being able to utilize interoperable health IT to understand patients' medical histories and deliver the highest quality of care is deeply important to us. For this reason, we supported the interoperability provisions of the 21st Century Cures Act in 2015, and ONC/ASTP's efforts to implement the information blocking provisions to ensure that patients are the true owners of their data and that physicians have the information they need to deliver the highest quality care.

Patients' perceived privacy and whether they have established a relationship with their provider often influences whether they choose to seek out care, as patients rely on physicians to safeguard their information. This is especially true in cases where patients are concerned about particularly sensitive information, such as information about reproductive and sexual health, mental health, and substance use. Trust is earned, and physicians work hard to build relationships with their patients.

The AOA applauds ONC/ASTP's proposed revisions to the exceptions to the information blocking definition. The possibility of information being disclosed in a manner that would be against our patients' wishes, restrict their care, or cause other harm is deeply concerning to us. The AOA strongly opposes government interventions that hinder the practice of medicine and delivery of evidence-based care, and that place our patients at risk for adverse outcomes. As an increasing number of states consider policies that mandate disclosures of certain health information, particularly that of reproductive health information, it is essential that policies are enacted to protect patients and ensure that physicians are not penalized for delivering evidence-based care. Please find our comments on several of ONC/ASTP's proposals related to information blocking exceptions below.

Protecting Care Access Exception

ONC/ASTP proposes a new exception to what would constitute information blocking in instances where an actor chooses not to share EHI because they believe in good faith that sharing such information "could risk exposing a patient, provider, or facilitator of lawful reproductive health care to potential legal action based on what care was sought, obtained, provided, facilitated, or (specific to the patient protection condition) is often sought, obtained, or medically indicated for the patient's health condition(s) or history." This proposal comes in light of the Supreme Court's decision in *Dobbs* v. *Jackson Women's Health Organization.* Since this decision, several states have considered and even enacted further restrictions on reproductive health care, and several state courts have ruled that

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privacy protections do not extend to abortion[2], potentially exposing patients and physicians to prosecution.[3] This exception would allow an actor not to disclose EHI when it believes that doing so would reduce potential exposure to legal action related to reproductive health care.

The patient-physician relationship is a fundamental aspect of osteopathic care, due in large part to a partnership that is created between the physician and patient which relies heavily on communication and trust. Statutorily required medical practices and prohibitions of care delivery prevent patients from being involved in making medical decisions or receiving the care they require. The AOA firmly opposes interference in the physician patient relationship, and appreciates ONC/ASTP's efforts to ensure that physicians will not be subject to information blocking penalties if they refrain from sharing information in an effort to protect themselves or their patients from legal action when rendering necessary care.

Requestor Preferences Exception

The newly proposed requestor preferences exception to information blocking would ensure that actors do not implicate the information blocking definition when honoring a patient's preferences "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." This is important when a patient is receiving particularly serious care. The AOA believes that patients are the true owners of their medical data; however, there are instances when sensitive data (such as abnormal results for a life-threatening condition) needs to be interpreted by a physician before it is presented to the patient. These conversations are especially sensitive, and it can be harmful to the patient to receive detailed results before a physician has had the opportunity to interpret the information and work with the patient on a care plan based on their established patient-physician relationship.

This new exception will ensure that actors do not implicate information blocking when information is withheld based on patient preferences on timing or scope of information to be shared. We believe that this change is important to protect the patient-physician relationship. That said, for this exception to be meaningful, ONC/ASTP must ensure that (1) health IT is capable of segmenting information in a manner that providers can comply and delay sharing of specific information with patients, and (2) the health IT must be capable of receiving and registering patient preferences. We appreciate this effort by ONC/ASTP and urge the office to make the above refinements.

Privacy Exception—Individual's Request Not to Share EHI

ONC/ASTP proposes to revise this sub-exception of information blocking requirements by removing the existing limitation, which applies the exception only to individual-requested restrictions on EHI sharing that are permitted by other applicable law. Under this proposal, the language "unless otherwise required by law" under § 171.202(e)-Sub-Exception would be removed so that the sub-exception would extend to "an actor's practice of implementing restrictions the individual has requested. even when the actor may have concern that another law or instrument could attempt to compel the actor to fulfill access, exchange, or use of EHI contrary to the individual's expressed wishes."

ONC/ASTP is proposing this change in light of the Supreme Court decision in *Dobbs* v. *Jackson Women's Health Organization* recognizing that actors may choose not to restrict sharing of information under current regulation "due

[2] New York Times. Tracking Abortion Bans Across the Country. September 25, 2024. Available here.
[3] Brookings Institution. The criminalization of abortion and surveillance of women in a post-Dobbs world. April 18, 2024. Available here.

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to uncertainty about whether the actor is aware of and can account for any and all laws that might override the individual's requested restrictions." We believe that this change will ensure that physicians who do not share EHI out of a good faith effort to fulfill patients' wishes are not subject to penalties under information blocking rules. The AOA urges ONC/ASTP to finalize this proposal.

Conclusion

The AOA is pleased to have the opportunity to comment on the Health Data, Technology, and Interoperability Proposed Rule. We look forward to continuing to work with ONC/ASTP on developing final regulations. Should you have any questions regarding our comments or recommendations, please contact John-Michael Villarama, Vice President for Public Policy at jvillarama@osteopathic.org at any time should we be able to support your efforts.

Sincerely,

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