



One Prince Street
Alexandria, VA 22314-3318
☎ 703.838.0033
✉ 703.548.1890

October 4, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Micki Tripathi, PhD
Assistant Secretary
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health
Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Dear Secretary Becerra and Assistant Secretary Tripathi:

On behalf of AMGA, we appreciate the opportunity to comment on the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology's (ASTP/ONC) proposed rule **Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) [RIN 0955-AA06]**.

Founded in 1950, AMGA is a trade association leading the transformation of health care in America. Representing multispecialty medical groups and integrated systems of care, we advocate, educate, innovate, and empower our members to deliver the next level of high-performance health. AMGA is the national voice promoting awareness of our members' recognized excellence in the delivery of coordinated, high-quality, high-value care. Over 177,000 physicians practice in our member organizations, delivering care to more than one in three Americans. Our members are also leaders in value-based care delivery, focusing on improving patient outcomes while driving down overall healthcare costs.

On July 25, 2023, AMGA staff met with ONC to discuss areas of alignment, particularly in recognizing the importance of transparency and access to data among patients, providers, and payers. We continue to advocate for our shared goal of improving healthcare outcomes, facilitating data exchange, and shifting the US healthcare system towards high performance care.

AMGA is pleased to offer the comments on the HTI-2 proposed rule for your consideration.

Specifically, we are writing to express our support for the proposed Protecting Care Access and Requestor Preferences Exceptions, as well as the proposed modifications to the segmentation condition within the Infeasibility Exception. We urge ASTP/ONC to finalize these proposals.

Key Recommendations:

Prior Authorization APIs: AMGA recommends providers only be required to use certified, standards-based APIs for prior authorization if payers are required to also do so, and on the same timeline.

Immediate Resulting: AMGA supports the proposal to allow patients to request test results not be released immediately, but is concerned the implementation process is not feasible for providers.

Information Blocking: AMGA supports the proposal to allow entities to limit sharing of patient's reproductive healthcare information in certain circumstances to protect providers and patients from potential legal action and to provide an exception to federal information blocking requirements.

Prior Authorization APIs

ASTP is proposing to adopt standards and certification criteria for Prior Authorization API functionality, which would deploy FHIR-based exchange using a set of implementation guides (IGs) developed by the HL7 Da Vinci Project. These APIs are designed to allow providers to request coverage requirements, submit needed documentation for authorizations, and receive notification back from the payer on authorization status. ASTP proposes to include these functions in the Base EHR definition, which means that eligible hospitals and clinicians must implement them in order to comply with the Medicare Promoting Interoperability Program and MIPS requirements to use CEHRT, with no additional regulatory action by the Centers for Medicare & Medicaid Services (CMS).¹

However, there is no similar requirement on payers and health plans to adopt certified technology. In fact, CMS does not even require regulated plans use the Da Vinci Project implementation guides for the prior authorization APIs, but only recommends their use.² We urge ASTP and CMS to only require providers to use certified, standards-based APIs for prior authorization if payers are required to also do so, and on the same timeline. Having both parties to exchange use conformant, certified technology will increase the likelihood of success.

Immediate Resulting: Requestor Preferences Exception

AMGA supports the concept of ASTP/ONC's proposal to add a new Requestor Preferences Exception. AMGA previously raised concerns about the unintended consequences of immediately providing patients with access to the data and information at the same time as their providers.

AMGA maintains its recommendation, as detailed in our July 27, 2021 letter on "information

¹ [Calendar Year 2024 Program Requirements | CMS](#)

² <https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f>

blocking³,” of allowing providers to hold select results for 24 to 72 hours if a clinician believes providing them immediately will unduly confuse or distress a patient.

In some cases, patients may not want to receive all their healthcare information immediately and would prefer to delay delivery of lab results until they discuss them with a clinician. This exception would allow providers to honor these preferences without the risk of being considered information blockers, thereby increasing patient satisfaction with their care.

However, AMGA has two concerns about the proposal. We are concerned that the proposed exception requires requestors’ preferences to be provided in writing. Some patients may express their desire to withhold or delay data verbally, such as during a clinical visit. Accordingly, we urge ASTP/ONC to modify this proposal to allow providers to document a patient’s preferences instead of requiring them in writing. Secondly, AMGA is concerned a customized approach based on patient preferences will be administratively difficult to implement. Allowing for patient selection of the timing of test results will require customization of the electronic medical record, which will require additional programming and cost. AMGA appreciates the concept behind the proposal, but is concerned that from a practical standpoint it will not be feasible.

Infeasibility Exception:

AMGA supports the proposed modifications to the segmentation condition within the Infeasibility Exception. It is important that this condition be updated to account for the proposed Requestor Preferences and Protecting Care Access Exceptions.

Information Blocking

Given the substantial penalties for information blocking, it is critical that “actors” have clear guidelines around what constitutes information blocking. This proposed rule is a strong step towards providing clarity.

Protecting Care Access Exception

AMGA supports ASTP/ONC’s proposal to add a new Protecting Care Access Exception. The Protecting Care Access Exception proposal would allow entities to limit sharing of a patient’s reproductive healthcare information in certain circumstances. The exception would allow practices that would otherwise be considered information blocking, based on the actor’s good faith belief that sharing EHI indicating that any person(s) sought, received, provided, or facilitated the provision or receipt of lawfully provided reproductive healthcare could result in a risk of potential exposure to legal action. The exception would apply when an actor limits sharing of a patient’s electronic health information (EHI) to protect the patient from legal action or to reduce the risk of exposing others to legal action.

Providers should not be forced to navigate complicated and potentially conflicting policies around the information they must disclose about lawfully provided reproductive health care. For example, California Assembly Bill 352 (AB 352) would prevent providers from disclosing information about lawfully provided reproductive healthcare during out-of-state investigations. The proposed exemption will allow providers to comply with this bill and similar legislation in other states without worrying about violating federal information blocking requirements.

³ [AMGA July 27, 2021 letter to ONC on “information blocking”](#)

AMGA also recommends ASTP/ONC limit the burden of using the exception when acting in good faith. As currently constructed, actors must work through a range of conditions in order to satisfy the exception's requirements, creating uncertainty and documentation burden.

AMGA appreciates ASTP/ONC's continued efforts to advance interoperability, data transparency, and patient engagement, all of which are foundational to value-based care. The proposed rule aligns with these goals, particularly in providing necessary flexibility through the Protecting Care Access and Requestor Preferences Exceptions. By adopting these modifications, ASTP/ONC will enhance care coordination while ensuring compliance with both federal and state-level regulations.

We look forward to continued collaboration as these proposals are finalized, and we stand ready to assist in any future discussions aimed at achieving our shared objectives for a more integrated and patient-centric healthcare system.

Should you have questions, please do not hesitate to contact AMGA's Senior Director of Regulatory Affairs, Darryl Drevna at 703.833.0033 ext. 339 or ddrevna@amga.org.

Sincerely,

Jerry Penso, M.D., M.B.A.
President and Chief Executive Officer