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September 25, 2024

Micky Tripathi, PhD, MPP
National Coordinator
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, DC 20024

Re: RIN 0955-AA06 HTI-2 NPRM

Dear Assistant Secretary Tripathi:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide feedback on the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) proposed Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) rule.

Protecting Care Access

The AMA commends ASTP/ONC for its proposals to enhance protections for individuals' health information and clarify when physicians and other actors who withhold access, exchange, or use of electronic health information (EHI) to protect patients will not be considered information blockers. The AMA has long supported EHI interoperability, particularly in physician-to-physician and physician-to-patient exchanges. However, due to changes in state and federal laws, physicians are often unsure of their obligations when these laws conflict, and they lack clarity on the extent of information blocking requirements and the penalties for noncompliance. Highly sensitive reproductive EHI is being improperly accessed, exchanged, and used by state officials and others, causing significant emotional and physical harm to patients and jeopardizing their civil liberties. Physicians are committed to protecting their patients from all forms of harm, yet the lack of clear federal policies on the intersection of reproductive health information and information blocking requirements has placed them in serious ethical dilemmas and at risk of federal penalties.

We strongly support three of ASTP/ONC's proposals which will give physicians and other actors meaningful exceptions to information blocking penalties. These exceptions can work independently or in combination depending on the situation and requested EHI. Moreover, all actors, i.e., physicians, certified health information technology (health IT) developers, and health information exchanges/networks (HIE/HIN), can now take the necessary actions to address their own, or their customer's belief that sharing EHI could expose a patient or health care provider to legal action.

1) *Protecting Care Access Exception*

ASTP/ONC proposal: *Practices that the proposed Protecting Care Access Exception would except from the information blocking definition would be those implemented 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 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.*

Recommendation: The AMA supports the new Protecting Care Access Exception and encourages ASTP/ONC to provide actors with as much flexibility as possible.

Information blocking regulations require that all EHI that can be shared under the Health Insurance Portability and Accountability Act (HIPAA) must be provided upon request, except in specific, limited circumstances (i.e., exceptions). These exceptions, while important, are narrow, complex, and require actors to meet several conditions. To effectively apply these exceptions within a health care organization, there must be close coordination between all involved parties, such as health IT vendors, HIE/HINs, compliance teams, medical-legal professionals, and administrators who develop policies and procedures. The AMA has urged ASTP/ONC to provide more guidance to ensure each participant can successfully implement these exceptions. Without this guidance, many actors are confused, hesitant to use the exceptions, and fear information blocking accusations or penalties. This has resulted in the oversharing of patients' sensitive medical information, the underuse of health IT to document medical information, and damage to the patient-physician relationship.

In the aftermath of the *Dobbs v. Jackson Women's Health Organization* decision, reproductive health data is increasingly being weaponized by state officials and others.[1] States are targeting individuals who receive or facilitate access to reproductive health care, often identifying them through medical records requests. Confusion surrounding information blocking regulations, and their exceptions, further facilitates unrestricted access to EHI. Currently, there are no exceptions specifically designed to address concerns about the legal risks (e.g., investigations, court actions, or liability) that could arise from the access, exchange, or use of specific EHI. **The AMA has been advocating for a clear, flexible information blocking exception that would allow actors to withhold reproductive health information to protect patients and physicians.**

ASTP/ONC's *Protecting Care Access Exception* proposal is a crucial step toward resolving these issues. It provides physicians with greater clarity that their decision to withhold specific EHI will not be considered information blocking. The proposal also enables health IT developers and HIE/HINs to take necessary actions based on their own or their customers' concerns that sharing specific EHI could expose physicians or individuals seeking, obtaining, providing, or facilitating reproductive care to risk. Physicians have reported that the reluctance of health IT developers and HIE/HINs to protect certain EHI significantly hampers their ability to safeguard their patients. **This reluctance is largely due to actors' fears of information blocking accusations or penalties, putting both patients and physicians at significant legal, physical, and emotional risk.** ASTP/ONC's flexibility, clarity, and education are essential for the successful use of this or any exception. Additionally, **the AMA supports the proposal to change "good faith belief" to "belief" to reduce potential misunderstandings and encourage the appropriate use of this exception.**

[1] *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022)

The AMA does not support any additional or alternative explicit requirements for the *patient protection, care access,* or *threshold* conditions. As discussed above, the need for the Protecting Care Access Exception is to provide clear, adaptable, and precise guidelines and policies. These allow all actors to withhold specific EHI without being classified as an information blocker. Any additional requirements will negate this flexibility, increase confusion, and undermine the goals of this exception.

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

ASTP/ONC proposal: *Propose to revise the sub-exception to remove the existing limitation that applies the exception only to individual requested restrictions on EHI sharing that are permitted by other applicable law.*

Recommendation: The AMA supports the revised sub-exception.

Information blocking exceptions are seen by physicians and other actors as narrow, complex, and requiring several conditions to be met, leading to confusion and hesitation to use these exceptions due to fears of information blocking accusations or penalties. Following the *Dobbs v. Jackson Women's Health Organization* decision, actors need clear guidance that using exceptions to prevent the disclosure of specific EHI will not be considered information blocking. The AMA shares ASTP/ONC's concern that actors might deny or terminate an individual's requested restrictions on sharing their EHI due to uncertainty about laws that might override these requests. Physicians are particularly concerned about the information blocking implications of honoring individual requests when facing demands for disclosure that might ultimately be enforced in court. Additionally, due to changes in state and federal laws, physicians are often unsure of their obligations when these laws conflict, as well as the extent of information blocking requirements and penalties for noncompliance.

The proposed revision to the sub-exception removes limitations based on applicable laws and will give physicians and other actors the confidence to delay the disclosure of EHI when they are aware that a court order is being contested. This allows physicians to wait and see if the order will be overturned or if it will compel them to release EHI, contrary to the individual's request for restrictions. Currently, confusion and fear about withholding EHI due to an unsettled court order are leading physicians and other actors to disclose reproductive health EHI out of fear of information blocking accusations or penalties. **Clarifying the applicability of various state laws related to information blocking will protect patients and physicians, encourage the use of health IT, and support care coordination.**

3) *Infeasibility Exception — Segmentation condition*

ASTP/ONC proposal: *Linking the Privacy Exception with the Infeasibility Exception — Propose to extend the "segmentation" condition's coverage to situations where the actor is unable to unambiguously segment EHI that could be made available, from specific EHI that the actor may choose to withhold from the individual or their representative, consistent with the Privacy sub-exception, "denial of individual access based on unreviewable grounds." This proposal would ensure that the "segmentation" condition would continue to apply in such scenarios, allowing the actor to honor the individual's request not to share the EHI and to ensure the Privacy Exception Sub-exception — Precondition not Satisfied can be utilized by all actors without fear of being an information blocker.*

Recommendation: The AMA supports the revised *Segmentation condition* sub-exception.

Physicians and other actors continue to misunderstand or are unable to utilize the Infeasibility Exception. **In the wake of the *Dobbs v. Jackson Women's Health Organization* decision, actors need clarity that use of exceptions to prevent the disclosure of specific EHI will not be considered information blocking.** As discussed above, successful application of exceptions within a health care organization requires a close coordination between the actors involved, e.g., health IT vendors and HIE/HINs, compliance teams, medical-legal professionals, and administrators who develop policies and procedures. Clarity and certainty are necessary for each participant to effectively implement exceptions.

The proposed revision to the sub-exception clarifies two important points. **First, physicians and other actors will not be considered information blockers if they are unable to segment specific EHI from medical records that an individual has requested not to share.** Data segmentation capabilities are not widely available from health IT vendors and HIE/HINs. Physicians and other actors have been concerned about facing information blocking accusations if they withhold most of a patient's medical record to protect a subset of information that cannot be redacted or segmented. **Second, the revision expands the segmentation condition to include situations where an actor is subject to one or more laws.** For example, The Office for Civil Rights (OCR) has modified its Privacy Rule to require that physicians receive an attestation that reproductive EHI will not be used for prohibited purposes. This requirement creates a precondition—the need for a valid attestation—before an actor can disclose specific EHI. Under this proposal, if a physician does not receive a valid attestation, they or their electronic health record (EHR) developer may withhold most of the medical record if prohibited from sharing specific EHI based on OCR, state, or other privacy regulations.

Accommodating Patient Preferences

Requestor Preference Exception

ASTP/ONC proposal: *Offer actors certainty that, under the conditions specified in this exception, it would not be considered "information blocking" to honor a requestor'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.*

Recommendation: The AMA supports the *Requestor Preference Exception* but has identified unintended consequences in ASTP/ONC's proposal that limits patients' preferences.

Patients and caregivers have the right to access, exchange, or use medical information, a right that the AMA strongly supports. Patients' medical records include a wide range of information, from benign details like allergies to medically complex data such as lab values, diagnostics, and imaging reports. Most patients want their information, including office notes and test results, as soon as they become available. In a survey of 8,000 patients, 95 percent preferred to receive non-normal results through their online patient portal.[2] However, in a separate survey of 1,000 patients, 65 percent preferred to speak with their physician before receiving life-changing test results, particularly those indicating a debilitating, life-limiting, or terminal illness for themselves or a family member.[3] These surveys highlight a related issue:

[2] https://www.fiercehealthcare.com/health-tech/patients-want-their-medical-test-results-immediately-even-when-its-bad-news-survey.
[3] https://www.ama-assn.org/system/files/patient-privacy-survey-results-preventing-patient-harm.pdf.

while patients are comfortable receiving non-normal or abnormal results immediately (e.g., elevated blood glucose levels), they are far more concerned about receiving life-changing results that could be misinterpreted or reveal serious, life-threatening conditions.

The AMA has received feedback from hundreds of patients and physicians about unexpected lab tests or diagnostic reports being delivered without prior physician review or lacking necessary context. Patients are receiving life-changing medical information on their phones, through text messages, or in their patient portals, often late at night, on weekends, or at times when they cannot reach their physician. This has led to unnecessary fear and mental or emotional distress.

Physicians, clinical staff, and health IT developers have identified information blocking regulations as the cause. These regulations mandate that all information be made available immediately, without explicitly considering patients' preferences for receiving non-normal versus life-changing results. Due to confusion, possible misinterpretations, and fear of being accused of information blocking or facing penalties, **health IT developers, health care administrators, and medical compliance personnel are notifying patients of test results regardless of their preferences.**

The proposed exception provides essential clarity for physicians and other actors. Actors will not be considered information blockers if a patient requests only specific lab tests or reports and/or expresses concerns about when or where the results are made available. For example, physicians and other actors would not be considered an information blocker when honoring a patient's request to delay release of concerning test results until their physician has a chance to review. Similarly, actors who honor a patient's request not to receive certain results or reports through an EHR portal or application (app) alerts would not be considered information blockers. **This clarity will protect physicians, EHR developers, and HIE/HINs actors from information blocking penalties when honoring patient requests. The AMA strongly supports clarity in these situations.**

However, the AMA has identified three concerning aspects of ASTP/ONC's proposal. First, honoring a patient's request to delay or limit the release of results or reports is only possible if the technical capability exists. In other words, a patient would need to electronically select which lab test results they want delayed within their EHR portal or medical record app. If the EHR lacks this technical capability, the request cannot be fulfilled. The AMA has raised this issue multiple times. While we support ASTP/ONC's proposed exception, **we urge ASTP/ONC to establish a certification criterion that would require health IT developers to provide the technical capability to delay certain medical information, allow patients to control alerts for new results or reports, and specify where medical information is made available. To this day, ASTP/ONC has neglected to include these certification requirements.** Without the necessary technical capability, patients' preferences cannot be fully honored, and those who fear receiving life-changing information may still experience harm.

Second, a strong patient-physician relationship is essential. Patients trust their physicians, who have unique insights into their patients' expressed needs and desires. Many important discussions occur, and while most are documented, some remain verbal. Additionally, many physicians work in settings where patients may be incapacitated, such as in emergency departments or during anesthesia, and where patients might have limited English proficiency or literacy skills.

ASTP/ONC proposes a *request* condition where, for this exception to apply, patients must express their preferences in writing. ASTP/ONC states that this requirement is intended to prevent inappropriate use of the exception or retroactive attempts to "justify" an actor's decision to meet their patient's preferences. **However, requiring patients to express their preferences in writing may undermine the flexibility**

and responsiveness that are crucial to the physician-patient relationship. In many cases, patients may not have the capacity or resources to provide written consent, especially in urgent or sensitive situations. Verbal communication often serves as the most immediate and effective means of conveying preferences, particularly in environments where patients are vulnerable or when language barriers exist. By insisting on written documentation, ASTP/ONC's proposal risks alienating those very patients it aims to protect, potentially leading to unmet needs and compromised care.

The AMA does not support the *request* condition as proposed and strongly urges ASTP/ONC to remove the requirement that patients express their preferences in writing, and instead allow patients to do so in a way that accommodates their cultural and situational needs. Physicians should be trusted to use their professional judgment, verbal communications, and patient relationships to accommodate preferences. If ASTP/ONC is concerned about potential abuse of this exception, the agency already has joint authority with the Office of the Inspector General to investigate information blocking allegations and impose civil monetary penalties or other sanctions. This provides enough of a disincentive to prevent actors from misusing the *Requestor Preference Exception*. Requiring written documentation as part of the *request* condition undermines the goal of the *Requestor Preference Exception*, which is to reduce ambiguity around information blocking by actors.

Third, the AMA has concerns regarding the proposed addition verbiage "without any improper encouragement or inducement by the actor" which seems to have ambiguous and subjective phrasing. Specifically, this could be interpreted as precluding proactive requests for patient preferences via routine forms and questions when patients check in. This would be a drastic difference from current ASTP/ONC's policy and how it was communicated in February 2022. Furthermore, this exception would become impractical for physicians who interpret diagnostic imaging or tests, as these professionals typically do not engage directly with patients. Instead, they rely on contextual information gathered from records and documents like orders, referrals, and patient-completed check-in forms. **We urge ASTP/ONC to clarify that dedicated questions on patient forms and during patients'/caregivers' digital check-in processes would not be considered "improper encouragement or inducement."**

<u>Leveraging Technology to Improve Prior Authorization and Benefit Transparency</u>

The AMA applauds ASTP/ONC's proposal to update certification criteria and require vendors to support standardized electronic capabilities and functionalities for prior authorization (PA). Currently, PA is a largely opaque, manual, time-consuming process. The 2023 AMA PA physician survey shows that this process continues to be a heavy burden on physicians: practices complete an average of 43 PAs per week, per physician, with this weekly workload consuming 12 hours of physician and staff time.[4] Given these statistics, it is no surprise that 95 percent of physicians report that PA increases burnout, which is a major concern given the looming physician workforce shortage. Even more troubling are the dangers that PA can pose for patient health. An overwhelming majority (94 percent) of surveyed physicians reported that PA delays patient care, which leads to treatment abandonment and negative clinical outcomes. Alarmingly, nearly one-quarter (24 percent) of physicians reported that PA has led to a serious adverse event (e.g., hospitalization, permanent disability, or even death) for a patient in their care. By ensuring consistency across systems and automating the PA process, this proposed rule represents a significant step forward in achieving real-time communication between providers and payers to streamline systems towards better interoperability—and, most importantly, ensure timely patient care.

[4] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

Adding a certification criterion regarding provider PA application programming interfaces (APIs) will also help physicians meet regulatory requirements. The Centers for Medicare & Medicaid Services (CMS) Prior Authorization and Interoperability Rule requires that Merit-based Incentive Payment System (MIPS) eligible clinicians attest to completing at least one electronic PA for a medical item or service utilizing an API. Having vendors support the same implementation guides cited in the CMS rule will help physicians comply with this requirement.

The AMA supports ASTP/ONC in adding two new payer and physician API requirements into the base EHR definition. For physicians to realize the benefits of electronic PA, their EHR developers must provide and support this technology as part of their base product offering. However, for each end of the electronic PA exchange to function successfully, e.g., payer APIs connecting to EHR developer APIs, **payers must be required to use certified electronic PA technology**. Absent this "technology handshake," physicians cannot be guaranteed their EHRs will communicate with payers in a standardized and effective way. **The AMA encourages ASTP/ONC to collaborate with CMS and require that impacted payers, such as Medicare Advantage Organizations, adopt and use certified payer APIs as a condition of their participation in CMS programs.** Adding this requirement will only further incentivize payers to implement the Health Level Seven International (HL7®) implementation guides as they are currently only recommended by the CMS rule, not required.

While the AMA is supportive of the PA API certification criterion, several questions remain. We are unclear on the interplay between the use of the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard and the HIPAA-mandated X12 278, particularly since CMS has announced that it will be using enforcement discretion for the X12 278 standard for covered entities that implement an all-FHIR-based PA API. If certified provider health IT vendors only need to support FHIR-based APIs, it is unclear how these systems will successfully interact with health plans that continue to still use the X12 278 standard. This situation could force physician practices to employ costly intermediaries, as well as open the door for translation errors between the FHIR and X12 standards. In addition, we are concerned that CMS' enforcement discretion can be revoked at any time, leaving physicians who use certified PA APIs that only support FHIR in the lurch if they are suddenly required to use the X12 278 standard transaction. **We urge ASTP/ONC to clarify how CMS' enforcement discretion interfaces with the PA API certification criterion, as well as how physicians utilizing certified APIs can be sure that they will be able to communicate with all health plans—some of which may still be relying on the X12 278 standard. ASTP/ONC should provide additional context beyond simply stating that nothing it its proposal "*would alter requirements for covered entities to use adopted HIPAA transaction standards.*"**

Finally, the AMA supports the addition of electronic prescribing and real-time prescription benefit (RTPB) technology into the base EHR definition, as well as certification criteria requiring support of the National Council for Prescription Drug Programs (NCPDP) electronic PA and RTPB standards. Increasing physician access to these high-value functionalities will address well-known transparency issues and administrative burdens related to drug prescribing and PA. In the 2023 AMA PA physician survey, a majority of physicians (63 percent) reported that it is difficult to determine whether a prescription medication requires PA; moreover, nearly one in three (29 percent) physicians report that the PA requirement information provided in their EHR/e-prescribing system is rarely or never accurate.[5] This lack of prescription formulary transparency at the point of prescribing leads to hassles for both physicians and pharmacists, as patients too often face unpleasant surprises at the pharmacy counter when their medication requires PA, is not covered by their plan, or comes with a high co-pay. More concerningly,

[5] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

patients facing these challenges may completely abandon treatment, leading to medication adherence issues and worsening health outcomes. Requiring certified vendors to support standard RTPB technology will enable informed conversations between physicians and patients during medication selection and prevent many of the problems cited above. We also agree that vendors should be required to support NCPDP electronic PA standard transactions, as many physicians currently do not have access to this technology: only 23 percent of surveyed physicians reported that their EHR system offers electronic PA for prescription medications.[6] Requiring certified EHRs to support these critical functionalities will improve the transparency and efficiency of prescription drug prescribing and PA and benefit both physicians and patients. **For these reasons, we encourage ASTP/ONC to collaborate with CMS to require all government-regulated prescription drug plans—not just Part D plans—to support NCPDP electronic PA and RTPB standard transactions.**

Protect Physicians from Unreasonable Fees

As discussed above, the AMA largely supports ASTP/ONC's proposals to certify APIs that facilitate the exchange of medical information between patients, physicians, and payers. Establishing a process to evaluate and test APIs will create standard APIs, promoting end-to-end interoperability between EHRs and payer systems, reducing PA burdens. As such, **the AMA encourages ASTP/ONC to collaborate with CMS and require that impacted payers, such as Medicare Advantage Organizations, adopt and use certified payer APIs as a condition of their participation in CMS programs.**

However, physicians shoulder the brunt of health IT costs. Even with ASTP/ONC's API proposals, the AMA anticipates that health IT developers seeking voluntary certification will impose substantial fees for APIs. With each federally mandated transition to a new EHR version, such as the certified EHR technology (CEHRT) requirements for MIPS participation, certified health IT developers find ways to incrementally charge physicians for each update, upgrade, and enhancement. While physicians understand the necessity for health IT developers to maintain profitability, the unexpected fees have become excessive. For example, system upgrades or overhauls can range from $10,000 to $50,000 or more, depending on the complexity. Customizations and additional features may further increase costs, potentially reaching $100,000 or higher. Training clinical staff on new EHR features and maintaining the EHR system will incur additional fees. For small, solo, or rural practices, even a few thousand dollars in unexpected costs can be a significant financial burden.[7,8,9]

The AMA acknowledges ASTP/ONC's hesitation to directly regulate health IT and EHR costs, as costs can vary depending on the product type, installation method, and practice size. However, the burden of PA affects hundreds of thousands of physicians and millions of patients annually. CMS has indicated it will require physicians to use certified electronic PA (ePA) API technology. Since CMS is reluctant to mandate that impacted payers adopt certified ePA API technology, the AMA anticipates that physicians will once again be forced to upgrade, purchase, and use new EHR features without guarantees that payers will support standardized APIs—leading to additional EHR cost. **Given that many physician practices contract with multiple payers, the resulting EHR developer fees will compound and become excessive.**

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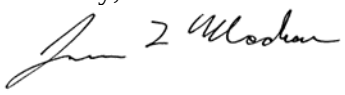
[6] Ibid.
[7] https://education.ncgmedical.com/blog/how-to-keep-costs-down-in-an-ehr-implementation.
[8] https://www.tempdev.com/blog/2021/08/15/ehr-implementation-cost-breakdown/.
[9] https://www.medicaladvantage.com/blog/ehr-cost-of-implementation/.

The AMA strongly urges ASTP/ONC to identify and leverage policies that mitigate certified health IT developer fees. ASTP/ONC could utilize a combination of its information blocking fee limitations and Condition and Maintenance of Certification requirements. For example, the AMA is concerned that health IT actors' ePA API fees will reflect rent-seeking, opportunistic, or exclusionary practices. Given payers' widescale use of PA, and physicians' desire to reduce PA burdens, it is likely ePA API price gouging will be widespread and prolific. Physicians need clear mechanisms to report bad actors. **Therefore, ASTP/ONC should add a dedicated section within its information blocking reporting portal specifically for issues related to actor API fees.** Additionally, many payers are likely considered HIE/HIN actors under the information blocking definition. Based on our members' experiences, PA practices often interfere with, prevent, or materially discourage the access, exchange, or use of EHI. For example, payers restrict physicians and patients from accessing PA-related administrative and clinical information. **We are concerned that CMS' payer API requirements—which are not certified or standardized—may create financial incentives for payers to charge physicians fees to connect to their API systems. This concern underscores the need to capture specific complaints about actor API fees.**

ASTP/ONC should instruct its ONC-Authorized Certification Bodies (ONC-ACBs) to investigate any health IT developer accused of information blocking related to API fees. According to the Condition and Maintenance of Certification requirements, a certified API developer must publish all terms and conditions for its certified API technology, including any fees, restrictions, limitations, obligations, registration processes, or similar charges. These fees must be clearly described in detailed, plain language, and include all material information. ASTP/ONC should assess whether the fees charged by the API developer align with the published rates. If an information blocking accusation triggers an ONC-ACB investigation, it is likely that a significant fee discrepancy will be uncovered. **ASTP/ONC should utilize all available disincentives, including the suspension, decertification, and banning certification of health IT products.**

Thank you for the opportunity to provide feedback. Additional comments can be found in the **attached appendix**. If you have any questions, please do not hesitate to contact Matt Reid, Sr. Strategic Health Policy Consultant at matt.reid@ama-assn.org.

Sincerely,



James L. Madara, MD

Appendix

Proposal	AMA Support as Proposed, Support with Modification, or Oppose	Comments
ASTP/ONC Health IT Certification Program Updates		
ASTP/ONC is proposing to update certification requirements to meet the United States Core Data for Interoperability Version 4 (USCDI v4).	Support with modification	The AMA supports requiring USCDI v4 as part of certification. V4 includes several new data elements that will benefit physician practice and patient care. To maximize the benefit of these data elements, they need to be associated with widely used and trusted vocabulary standards. The AMA has identified two gaps that, if resolved, would further strengthen the USCDI. Clinical Tests The AMA submitted comments during the open comment periods in 2023 and 2024 requesting that the Current Procedural Terminology (CPT) code set be added to the applicable vocabulary standards for Clinical Tests – Clinical Tests, but this request has not yet been accepted. The CPT code set contains numerous codes for non-imaging and non-laboratory clinical tests including, but not limited to electroencephalography (EEG), echocardiography (EKG), cardiovascular and exercise stress tests, pulmonary function tests, electromyography (EMG), electroretinography (ERG), audiologic function tests, evoked potential tests, intraocular pressure measurement, visual acuity and function tests, allergy challenge tests, fetal monitoring, and sleep studies. In 2022, the CPT code set was added to ONC's Interoperability Standards Advisory (ISA) vocabulary list for Representing Non-Imaging and Non-Laboratory Clinical Tests. **We request that the CPT code set be added to USCDI V4.** Diagnostic Imaging Test The AMA submitted comments during the open comment periods in 2023 and 2024 requesting that the CPT code set be added to the applicable vocabulary standards for Diagnostic Imaging – Diagnostic Imaging Test, but this request has not yet been accepted. The CPT code set contains a comprehensive and regularly curated

		list of several hundred diagnostic and interventional radiology procedures. In 2019, the CPT code set was added to ONC's ISA vocabulary list for Representing Imaging Diagnostics, Interventions and Procedures. **We request that the CPT code set be added to USCDI V4.**
ASTP/ONC is proposing to require the use of SMART App Launch 2.2 capabilities. health IT modules must support the following: • Support for the ability for patients to authorize an application to receive their EHI based on individual FHIR resource-level and individual sub-resource-level scopes. • Support for the ability for patients to authorize an application to receive their EHI based on individual sub-resource-level scopes when corresponding resource-level scopes are requested.	Support with modification	The AMA supports patients' use of any application (app) of their choosing to access, exchange, and use their EHI. However, the AMA has repeatedly urged ASTP/ONC to include a requirement that certified health IT modules should seek an attestation from app developers and to provide the attestation information to patients and physicians. To help provide a minimal amount of transparency to patients about how a health app will use their health information, **ASTP/ONC should implement a basic privacy framework requiring certified health IT developer application programing interfaces (APIs) to check an app's "yes/no" attestation to: (1) Industry-recognized development guidance (2) Transparency statements and best practices (3) A model notice to patients.** This would not regulate apps and does not extend beyond ASTP/ONC's authority. Requiring certified health IT's API to check for an app developer attestation would not be a significant burden on electronic health record (EHR) developers. Likewise, apps would not be prevented from connecting to an EHR even if they attest "no" to the three attestations. Accordingly, ASTP/ONC's Decision Support Interventions transparency requirements utilize the same concept the AMA is proposing—requiring a certified health IT developer to request information from a third party and make that information available to users.
ASTP/ONC is proposing new imaging link requirements for § 170.315(b)(1), (e)(1), (g)(9), and (10) certification criteria.	Support	

ASTP/ONC is proposing a revised clinical information reconciliation and incorporation criterion that would promote new capabilities that would benefit physicians by reducing the burden of reconciliation and incorporation in clinical workflows.	Support	The AMA supports health IT's ability to automatically reconcile and incorporate specific medical information from transition of care or referral summaries.
ASTP/ONC is proposing to incorporate the NCPDP SCRIPT standard version 2023011 in an updated version of the electronic prescribing certification criteria.	Support	The AMA supports the proposal to incorporate the NCPDP SCRIPT standard version 2023011 in an updated version of the electronic prescribing certification criteria. The AMA appreciates ASTP/ONC's proposal to align the updated e-prescribing standard implementation date with the January 1, 2028, implementation deadline for Part D plan sponsors, and therefore the AMA supports ASTP/ONC's proposed January 1, 2028, certification criterion effective date as this will improve the functionality and overall interoperability of physicians' e-prescribing systems. Regarding specific updates to the transactions included in §170.315(b)(3)(ii), the AMA supports ASTP/ONC's proposal to remove certain transactions from the certification criteria, while also requiring inclusion of other "new and updated" elements in the NCPDP SCRIPT standard version 2023011. In particular, the AMA supports the following proposals: • Revise the name used for the NewRx transaction to "New Prescription (NewRx)" to align with the updated terminology used by NCPDP within the SCRIPT standard. • Remove the request and receive medication history transactions (i.e., RxHistoryRequest, RxHistoryResponse) as a requirement for the "electronic prescribing" certification criterion. • Remove the following transactions, currently identified as "optional," from the "electronic prescribing criterion" in

		§ 170.315(b)(3)(ii)(B)(1) – (8) (i.e., NewRxRequest, NewRxResponseDenied; RxFillIndicatorChange; GetMessage; Resupply; DrugAdministration; RxTransferRequest, RxTransferResponse, and RxTransferConfirm; Recertification; REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse). We note that the RxTransfer transactions are not used by physicians; rather these transactions are used to transfer prescriptions between pharmacies. **While the AMA acknowledges that relatively few developers have elected to certify the optional transactions proposed for removal, we caution ASTP/ONC against assuming that these optional transactions lack utility solely based on vendor adoption rates.** The fact that NCPDP developed these transactions indicates that there was recognition of unmet business needs and agreement across stakeholder groups to pursue this standards development work. Rather than suggesting low interest or value, the minimal adoption of these transactions can more likely be attributed to vendors building systems to only meet the minimum technical certification requirements to control costs and reduce development workloads. In addition, vendors may anticipate that cost-conscious health IT end users may be unwilling to incur additional fees for optional functionalities, despite their utility, which further disincentivizes vendors from including these features in their development roadmaps. **Moving forward, we strongly encourage ASTP/ONC to consider factors beyond just vendor adoption rates when assessing the value of optional transactions, such as the value of the original use cases.** *Sig segment* The AMA agrees with ASTP/ONC's assessment that communicating how a prescriber intends for

		a patient to take a medication is critical for delivering safe and effective care. Standardizing prescription directions via a codified and structured Sig field has the potential to reduce medication errors. Therefore, the AMA supports the proposal that a health IT module certified to the "electronic prescribing" criterion must enable a user to enter, receive, and transmit structured and codified prescribing instructions in accordance with the standard specified in § 170.205(b)(2) (i.e., NCPDP SCRIPT standard version 2023011). *National Drug Code (NDC)* The AMA agrees that use of FDA National Drug Code (NDC) terminology for drugs is beneficial for specific product identification in research, dispensing, and administrative workflows. We therefore support ASTP/ONC's proposal to require use of NDC in the electronic prescribing certification criterion. *RxNorm* The AMA supports the proposal to remove the existing reference to RxNorm, September 8, 2015 Release, in § 170.207(d)(3), and instead require use of at least one of the versions of the standard adopted in § 170.207(d)(1). The AMA agrees with ASTP/ONC's proposed requirement to "use progressively more recent releases of the RxNorm code set as baseline version of RxNorm" for the electronic prescribing certification criterion. *Race and ethnicity in SCRIPT* The AMA supports expanding data collection requirements across certified health IT, including options for disaggregated coding of race, ethnicity and preferred language. The capture of this information must consider the potential unintended consequences of data misuse, particularly of marginalized and minoritized individuals. All race and ethnicity information should be provided voluntarily by the patient.
ASTP/ONC is proposing to require prior authorization transactions as part of the	Support	The AMA agrees with ASTP/ONC's assessment that requiring the prior authorization transactions as part of the electronic prescribing

electronic prescribing certification criteria.		certification criteria would help advance interoperability and reduce administrative burdens associated with and related to medication prior authorization processes. The AMA agrees that requiring the NCPDP SCRIPT standard version 2023011 electronic prior authorization (ePA) transactions (i.e., PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, and PACancelResponse) would help ensure pharmacy data systems can communicate similarly across all certified health IT modules, thereby mitigating the need to build different prior authorization processes for different certified health IT systems. According to the AMA's 2023 prior authorization physician survey, only 23 percent of physicians reported that their EHR system offers ePA for prescription medications.[10] This access issue is due, in part, to the limited requirements in place for health IT developers to build out NCPDP ePA transactions. By transitioning these eight ePA transactions from optional to required, ASTP/ONC will significantly improve access to ePA systems.
ASTP/ONC is proposing to establish an RTPB certification criterion in § 170.315(b)(4) based on the NCPDP RTPB standard version 13.	Support	The AMA supports the proposal to establish an RTPB certification criterion in § 170.315(b)(4) based on the NCPDP RTPB standard version 13. The AMA agrees that utilizing the NCPDP RTPB standard version 13 as part of the RTPB certification criterion will promote wider adoption and lead to increased utilization of real-time benefit tools (RTBTs). Expanded adoption and utilization of RTBTs will improve access to patient-specific coverage and benefit information, enhance price transparency, and ideally lead to lower out-of-pocket costs for patients. Access to and utilization of RTBTs will also improve the transparency of prior authorization requirements at the point of prescribing, thereby supporting a more efficient, *prospective* ePA process.

[10] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

		As noted in this proposed rule, by January 1, 2027, Part D plan sponsors are required to implement an RTBT that conforms to the NCPDP RTPB standard version 13. To better align the ASTP/ONC's health IT certification criteria with the Centers for Medicare and Medicaid Services (CMS) requirements for Part D plan sponsors, **the AMA proposes adjusting the enforcement date for this certification criteria from January 1, 2028, to January 1, 2027.** *RTPBError Transaction* The AMA would like to note that the NCPDP RTPB standard version 13 does not contain an "RTPBError transaction." In the XML format of the NCPDP standard version 13, the transaction that allows a health plan to notify a health IT system that a system error occurred is "Error." The AMA is in alignment with NCPDP and recommends removing references to the "RTPBError transaction" because error information related to the RTPB transaction can be returned as reject codes in the "RTPBResponse transaction." The term "RTPBError transaction" appears multiple times within the proposed rule, and this recommendation applies to all references to the RTPBError transaction. *XML Format* The AMA supports the proposal in § 170.315(b)(4)(i) that a health IT module certified to the criterion must enable a user to perform the specified transactions using the XML format. The AMA agrees that only requiring use of the XML format will simplify testing for health IT developers, increase standardization, and enhance interoperability. The AMA encourages ASTP/ONC to continue to monitor ongoing syntax and format updates, as well as for further developments regarding real-time benefit transactions and the associated standards (i.e., ASTP/ONC should monitor the development of NCPDP standards written in JavaScript Object Notation (JSON) as this syntax may present enhanced interoperability capabilities in the future). Currently, the

		NCPDP RTPB standard is not available in JSON format; however, NCPDP is in the process of transitioning its standards to JSON, and these formats should be available for most NCPDP standards in the future. *RTPB Scope* The AMA supports the proposal that the scope of the RTPB certification criterion be limited to medications and vaccines covered by a pharmacy benefit; however, the AMA encourages ASTP/ONC to continue to monitor this space and to consider real-time benefit solutions for medications covered under the medical benefit in future rulemaking.
ASTP/ONC is proposing to revise § 170.207(f)(1) to include recent updates to the U.S. Office of Management and Budget's Statistical Policy.	Support	The AMA supports the adoption of newer versions of the minimum standards code sets for race and ethnicity data, including the adoption of the U.S. Office of Management and Budget's (OMB's) Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) that was revised March 29, 2024, as well as the Centers for Disease Control and Prevention (CDC) Race and Ethnicity Code Set Version 1.2. In addition, we support the expiration of the standard for the previous version of the SPD 15 on January 1, 2026. The AMA supported OMB's work to revise SPD 15, including collecting race and ethnicity information using one combined question with the instruction to select all that apply, adding "Middle Eastern or North African" as a major category, allowing more granular choices under each major category (ideally allowing local prioritization of granular categories based on the community), ensuring privacy protections particularly for small groups, and alphabetizing response options.
ASTP/ONC is proposing a revised end-user device encryption criterion that expands the information that must be protected and to advance the client/server-side security	Support	Server- and client-side encryption is vital to protect medical information. The AMA supports ASTP/ONC's efforts to strengthen the protection and security of personally identifiable information.

requirements for cryptographic modules.		
ASTP/ONC is proposing a revised encryption criterion that would protect the confidentiality and integrity of authentication credentials.	Support	
ASTP/ONC is proposing to modify current certification criteria and adopt new criteria for health IT modules supporting public health data exchange.	Support with modification	The AMA generally supports the proposals to modify current certification criteria and adopt new criteria for health IT modules supporting public health data exchange. The revisions and additions to the Certification Program's current criteria focus on the transmission or bi-directional exchange of data with public health as well as the adoption of new certification criteria related to public health. ASTP/ONC must help foster greater interoperability of public health technology and access to more actionable data by public health agencies (PHA), physicians, and other partners. In particular, the AMA supports the changes in the criteria for electronic case reporting (eCR), which alleviates the burden of case reporting on physicians through the automatic generation and transmission of case reports from EHRs to PHAs for review and action in accordance with applicable health care privacy and public health reporting laws. However, adding or revising the public health-related certification criteria is only one piece of the effort to enhance interoperability. We encourage ASTP/ONC to explore additional ways to spur the development and alignment of public health infrastructure through collaborations across the Department, including capitalizing on the Centers for Disease Control and Prevention's (CDC's) Data Modernization Initiative (DMI). CDC's DMI is an opportunity to provide funding for the adoption and use of public health-related technology and improve public health data exchange. The AMA supports positive financial incentives for physician practices to adopt and upgrade technology and

		the functionalities required for public health reporting and help ensure bidirectional information sharing. We advocate for incentives for physicians to upgrade their EHR and other health IT systems to support eCR as well as incentives to submit case reports that are timely and complete. The AMA works from the perspective that financial incentives are most effective when framed as a positive stimulus, as opposed to a penalty. Moreover, the AMA recognizes the need for increased federal, state, and local funding to modernize our nation's public health data systems to improve the quality and timeliness of data. Positive financial incentives for physician practices should be coordinated with other financial investments in public health data systems for PHAs at the federal, state, and local levels. HHS should build on the use of ASTP/ONC health IT-certified technology by combining the use of certified technology with CDC's DMI to provide financial incentives for physicians as well as PHAs at the federal, state, and local levels. Since the COVID-19 Pandemic, the CDC has provided grants to PHAs as they modernize their data systems, offering direct support for new technology and adoption of data standards. Such programs could be expanded to include positive financial incentives for physician practices and PHAs that adopt and use certified technology as well as ASTP/ONC's new and revised criteria, amplifying the benefits of adherence to ASTP/ONC-certified standards for broader public health data sharing. We agree that the proposed updates to the certification criteria have a wide range of benefits for physicians, public health practitioners, and the patient populations they serve by helping remove long-standing barriers to public health data interoperability. However, positive financial incentives are needed for physicians and PHAs to fully adopt ASTP/ONC certified health IT and enable broader public health data sharing. CDC's DMI can be the

		vehicle to provide these incentives, and it is imperative that ASTP/ONC collaborate with CDC to leverage DMI to improve public health response capabilities and the nation's healthcare system, enabling better-informed decision making, more comprehensive data analytics, and faster, more coordinated responses to public health threats and emergencies.
ASTP/ONC is proposing a requirement that health IT modules must meet multi-factor authentication requirements.	Support	The AMA supports certified multi-factor health IT requirements and agrees with ASTP/ONC that this update is in line with industry information security best practice and is necessary to better protect electronic health information.
ASTP/ONC is proposing new prescription drug monitoring program (PDMP) certification requirements related to query, receive, validate, parse, and filter.	Support with modification	The AMA agrees that PDMP standards are currently not sufficiently mature or widely adopted to require a particular standard for certification. Given this, a solution-agnostic approach—which leverages existing state PDMP technology rather than forcing physicians and health IT developers to prematurely convert to untested standards—is more practical. We support functional requirements for access controls including access roles and audit logs within this new criterion. We support requirements to enable a user to query a PDMP, including bi-directional interstate exchange, to receive PDMP data in an interoperable manner. However, we have concerns with law enforcement accessing sensitive PDMP data without a warrant and oppose health plan access. We urge ASTP/ONC to monitor these trends and take necessary measures to protect PDMP data. We have concerns with the proposal to enable both passive and active bi-directional query of a PDMP, including an interstate exchange query, and send an acknowledgement message in response to receipt of data after a query is performed. In 2022, there were over 1.4 billion PDMP queries. Alert fatigue is a major cause of physician burnout, and too many PDMP alerts will lead to declined physician use—negating the value of the PDMP. ASTP/ONC's policies

		must make clear the intent of this requirement would not be to clog physicians' inboxes or add administrative burdens. At the very least, users should have the option to enable/disable passive and active PDMP queries on demand. We support requirements to enable a user to receive, validate, parse, and filter electronic PDMP information, as this would integrate PDMP functionalities within physicians' clinical workflow and EHR/e-prescribing systems and reduce the administrative burdens associated with accessing PDMPs via portals. We have concerns with requirements to demonstrate the ability to detect valid and invalid electronic controlled substance medication prescription received. The responsibility for determining whether a prescription for a controlled substance is valid is the responsibility of the pharmacist. This should not be delegated to the PDMP. We urge ASTP/ONC to clarify if this is not its intent. We have similar concerns with ASTP/ONC's proposal to identify valid electronic controlled substance medication prescription received and to process the data elements. While ensuring a prescription has all the legal elements of a valid prescription, e.g., name, address, etc., would be beneficial, we do not support enabling or delegating the legitimacy of a prescription to a PDMP, as that is the responsibility of the pharmacist. **Furthermore, the ultimate prescribing decision should be by the physician, who reviews the PDMP information but should not be prevented from prescribing a controlled substance by a PDMP.** We support requirements to enable access roles for clinicians and pharmacists and to enable a user to customize additional roles for any delegate or surrogate under applicable law.
ASTP/ONC is proposing revisions for patient and user access to information through certified APIs using consumer apps.	Support with modification	The AMA supports patients' use of any app of their choosing to access, exchange, and use their EHI. However, the AMA has repeatedly urged ASTP/ONC to include a requirement on certified health IT APIs to require an attestation

		from app developers and to provide the attestation information to patients and physicians. To help provide a minimal amount of transparency to patients about how a health app will use their health information, **ASTP/ONC should implement a basic privacy framework requiring certified health IT developer APIs to check an app's "yes/no" attestation to: (1 Industry-recognized development guidance (2 Transparency statements and best practices (3 A model notice to patients.** This would not regulate apps and does not extend beyond ASTP/ONC's authority. Requiring certified health IT's API to check for an app developer attestation would not be a significant burden on EHR developers. Likewise, apps would not be prevented from connecting to an EHR even if they attest "no" to the three attestations. Accordingly, ASTP/ONC's Decision Support Interventions transparency requirements utilize the same concept the AMA is proposing—requiring a certified health IT developer to request information from a third party and make that information available to users.
ASTP/ONC is proposing adding a certification criterion requiring support of provider prior authorization APIs.	Support with modification	The AMA supports ASTP/ONC adding a certification criterion requiring support of provider prior authorization APIs. Today, prior authorization is an extremely burdensome, manual process that relies on phone calls and faxing. Requiring certified health IT systems to support prior authorization technology that integrates with a practice's EHR workflow has the potential to reduce the amount of time physicians and their staff spend completing prior authorizations, as well as minimize processing time and care delays. In addition, adding this certification criterion will support physicians meeting the new MIPS Promoting Interoperability electronic prior authorization measure. **However, as noted below, the AMA urges ASTP/ONC to work with CMS and create a parallel requirement that impacted payers use certified prior authorization APIs. As**

		stated in our cover letter, we also request clarification on the interplay between the FHIR-based API and the HIPAA-mandated X12 278 standard and whether vendors will be required to support both standards for certification purposes.
ASTP/ONC is proposing the addition of criteria to the base EHR definition. The proposal includes adding a provider access API, prior authorization API, NCPDP electronic prescribing standards, and RTPB to the base EHR.	Support with modification	The AMA supports ASTP/ONC in adding two new payer and physician API requirements, as well as electronic prescribing and RTPB requirements, into the base EHR definition. For physicians to realize the full benefits of ePA, electronic prescribing, and RTPB, their EHR developers must provide and support ePA, electronic prescribing, and RTPB technology as part of their base product offering. However, for each end of the ePA, electronic prescribing, and RTPB exchange to function successfully, e.g., payer APIs connecting to EHR developer APIs, payers must be required to use certified health IT technology that supports ePA, electronic prescribing, and RTPB functionality. Absent this "technology handshake," physicians cannot be guaranteed their EHRs will communicate with payers in a standardized and effective way. **The AMA encourages ASTP/ONC to collaborate with CMS and require that impacted payers, such as Medicare Advantage Organizations, adopt and use certified payer APIs as a condition of their participation in CMS programs.**
ASTP/ONC is proposing to allow the use of "relied upon software" to demonstrate compliance with the single prior authorization certification criterion.	Support	The AMA supports this proposal as it will likely lead to cost savings and efficiencies. It eliminates the need for developers to build solutions from the ground up, streamlining the implementation process.
ASTP/ONC is proposing support for the Da Vinci Documentation Templates and Rules (DTR). Implementation Guide. The proposal includes the option to support Light or Full DTR functionalities for certification.	Support with modification	The AMA supports adopting DTR for certification purposes, **but we recommend that developers be required to implement Full DTR capabilities.** Full DTR has more potential for automation and improved performance since it can be preprocessed in the background. While Light DTR is ripe for widespread adoption, we are concerned that allowing developers to choose between Light or Full will create an inconsistent end user experience for providers.

		Full DTR also has the added benefit of an internal form-filling function and dynamic registration. Full DTR's enhanced functionality will offer a superior user experience for physicians and their staff, thus encouraging increased adoption of prior authorization APIs.
ASTP/ONC is proposing that requirements applicable to Coverage Requirements Discovery (CRD) clients for the additional data retrieval be treated as SHALL instead of SHOULD	Support	For a Clinical Decision Support (CDS) Server to fully determine coverage requirements, it is critical to implement a prefetch query functionality. This will reduce the need for manual intervention by the provider. So long as the information gathered is not beyond the scope of the hook invocation, the AMA supports the change from SHOULD to SHALL related to the additional data retrieval requirements in CRD.
ASTP/ONC is proposing support for CDS Hooks. Specifically, requiring *Order Sign*, *Patient View*, and *Appointment Book* will facilitate streamlining the prior authorization workflow.	Support with modification	The AMA supports the need to leverage CDS Hooks. The AMA supports requiring the implementation of CDS Hooks that 1) can be seamlessly integrated within the EHR workflow and 2) do **not** increase burden (e.g., alert fatigue) or impinge on patient privacy or physician autonomy. These include *Order Sign*, *Patient View*, and *Appointment Book*. Further, the AMA recommends that ASTP/ONC require developers to support the CDS implementation best practices (https://cds-hooks.org/best-practices/), which contain several critical recommendations related to security for CDS clients and servers.
ASTP/ONC is proposing certified health IT requirements for subscriptions.	Support with modification	The AMA has long advocated the need for a subscription capability. We, however, recommend that ASTP/ONC standardize the requirement to HL7 FHIR R4B to ensure consistency across different systems and leverage enhanced backport for security reasons.
ASTP/ONC is proposing updated to its Insights Condition and Maintenance of Certification Requirements.	Support	The AMA supports the continued implementation and refinement of the Insights Condition and the benefits that the measures reported can provide to the broader health IT community as well as other federal agencies. We applaud ASTP/ONC for the updates in this proposal that call for requiring health IT developers to include health care provider identifiers for the providers included in the data submitted in response to the measures. We agree that such a step will enable more granular analysis and utility of the submitted Insights

		measures. In addition, this fuller data will enable richer comparisons of measures across developers, creating greater value from the measures. As we have commented previously, the AMA sees a significant opportunity for CMS to use the Insights Condition measures to improve the efficiency and accuracy of CEHRT evaluations across the physician community and **replace or augment attestations from Medicare Shared Savings Program (MSSP) participating physicians regarding the use of CEHRT as part of CMS Merit-based Incentive Payment System (MIPS) Promoting Interoperability (PI) performance category requirements**. Using Insights Condition data is the most effective path forward for advancing CEHRT adoption and interoperability, while not requiring individual physicians to take time away from delivering care to report duplicative interoperability information to CMS. The Insights Conditions can and should play a major role in helping CMS evaluate CEHRT adoption and use and serve as a preferred alternative to extending MIPS PI reporting to ACO participants. **The AMA urges ASTP/ONC to work with CMS to leverage its more informative, timely data on CEHRT adoption, use, and interoperability while reducing physician burden and encouraging participation in the MSSP.** The AMA stands ready to assist ASTP/ONC and CMS in these efforts. We also encourage ASTP/ONC to work closely with developers as well as the AMA and the Federation of Medicine to promote the benefits of physician reporting of Insights Condition data to their certified health IT developer. **We also support the proposal to require certified health IT developers to provide health care provider identifiers (e.g., National Provider Identifier (NPI), CMS Certification Number (CCN), or other type of unique national identifier) for physicians and other providers included in the data**

		submitted. The AMA agrees that detailed information regarding physicians and other providers that are represented in the data would also help further interpret the results of the data received and allow ASTP/ONC and CMS to assess whether the data is nationally representative. This will also allow ASTP/ONC to report results indicating whether, and how, the data are skewed and develop future refinements that could ensure the data provides the comprehensive picture of certified health IT interoperability and data exchange across the nation. **To be clear, the use of NPI should be limited and only used to supplement CEHRT reporting as a replacement for physician PI reporting.** In addition, we agree with ASTP/ONC that it **should not limit reporting for the Insights Condition to data that only relates to those "clinicians" participating in CMS programs**. A more complete picture of certified health IT use across the entire physician and provider landscape will be more compelling information. Moreover, we urge ONC to conduct **a pilot program with certified health IT developers to determine how a developer could extend the reporting of health care provider identifier information so that it can be correlated with responses to specific Insights Condition measures**. Taking such a step could help fully replace the burden of physician PI CEHRT reporting and assist ASTP/ONC and CMS answer questions around the specific levels of data exchange across different kinds of physicians and regions.

ASTP/ONC Information Blocking Enhancements		
ASTP/ONC is proposing to codify certain practices that constitute interference for the purposes of information blocking: • 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; • Improper inducements or discriminatory contract provisions; and • Failures to publish (or make available for publication) technical information.	Support	The AMA has urged ASTP/ONC to consider policies that would prevent EHR developers, HIE/HINs, and other actors from blocking physicians, clinicians, and patients from receiving medical information. These new policies will help address the AMA's concerns and will restrict all actors from using financial, legal, or technical information exchange roadblocks. We support ASTP/ONC codifying several of these practices so that EHR developers, HIE/HINs, and other actors are explicitly restricted from preventing patients and physicians from accessing medical information.
ASTP/ONC is proposing to codify certain practices that constitute interference for the purposes of information blocking: • Actions taken by an actor to impose delays on other persons' access, exchange, or use of EHI.	Oppose	ASTP/ONC has made two opposing proposals in its HTI-2 rule. On one hand, ASTP/ONC recognizes the need to provide clarity to actors who withhold EHI when honoring a patient's preference. As discussed in this letter, the AMA supports the *Requestor Preference Exception.* On the other hand, ASTP/ONC is proposing to double down on the very same policy that necessitated clarifying *Requestor Preference Exception* in the first place. ASTP/ONC states that "actors have indicated they are uncertain of the scenarios when honoring an individual's request for delay of EHI would not be information blocking." ASTP/ONC goes on to state "the *Requestor Preference Exception* would address actors' concerns by providing certainty…". ASTP/ONC, through its own admission, recognizes physicians and other actors fear being an information blocker when withholding EHI. Yet, ASTP/ONC is stating that

		withholding EHI is information blocking and is making it seem as though there are no situations when it would not be information blocking. The AMA consistently highlights to ASTP/ONC that conflicting policies and guidance create confusion, resulting in inconsistent interpretation—making compliance extremely difficult, if not impossible. Codifying this practice will untimely undermine the goals of horning patient's preferences. There are several instances where a patient may not or could not document their preference to delay EHI. Patients may not always be able to provide written consent to delay EHI due to lack of capacity, resources, or the urgency of their situation. In these cases, verbal communication is often the quickest and most effective way to express their preferences, especially for vulnerable patients or those with language barriers. Without written documentation, physicians,' EHR developers,' and health care facilities' compliance personnel might misinterpret ASTP/ONC policy, potentially overlooking the patient's wishes. Moreover, **171.104(a)(1) "Delay on new access"** is particularly non-additive to current compliance knowledge. These scenarios are highly unlikely to be known/viewed as unreasonable by providers. Often the proposed (a)(1) interference type may be necessary for a physician to review, oversee, and/or validate the accuracy of the EHI (for example, review of EHI outputs from medical devices such as many current AI/ML for which human expert review of the data is a necessary component of safe and effective on-label use). By codifying this practice as information blocking, OIG and other agencies will infer that withholding EHI should always be considered information blocking, further sowing uncertainty and confusion given the contradiction between these two proposals. **The AMA strongly urges ASTP/ONC to withdraw its proposal to codify that actions taken by an actor to impose delays on other persons'**

		access, exchange, or use of EHI <u>will constitute interference</u> for the purposes of information blocking. The AMA suggests ASTP/ONC reframe its proposal and make clear there are certain conditions, such as honoring a patient's preferences, where an actor's actions will not constitute interference. Lastly, regarding **171.104(a)(8) "Medical images,"** the scenario described in the interference example of 171.104(a)(8) is misunderstanding the root cause(s) of disc-based exchange, and so misses an opportunity to address the network/information technology side of this issue. Radiology provider-actors do not *choose* physical media for data sharing—they do so because they are forced to use physical media by their current technological circumstances. **Rather than focusing on provider-actors, as ASTP/ONC does in 171.104(a)(8), it would be more helpful for the agency to provide compliance information to developers/networks that facilitate electronic exchange of images.**
ASTP/ONC is proposing several updates to its ONC-Authorized Certification Bodies (ACB) surveillance and maintenance of certification policies. ASTP/ONC is proposing that the impacted health IT developer must notify all its affected customers of its suspended, terminated, or banned certification.	Support with modification	The AMA strongly supports ASTP/ONC's desire to utilize certification suspension, termination, or banning when a health IT developer is no longer conforming to ASTP/ONC's surveillance and maintenance of certification policies. However, while ASTP/ONC proposes that the impacted health IT developer must alert its affected customers, neither ASTP/ONC nor ONC-ACBs are required to alert any federal agency that requires use certified health IT modules for successful participation in its programs, e.g., CMS' Quality Payment Program (QPP). For example, if a physician's EHR is decertified midway through a MIPS PI participation period, and CMS is unaware hundreds or thousands of its MIPS eligible clinicians are suddenly using uncertified health IT, CMS will be unable to respond or protect the impacted eligible clinicians. Eligible clinicians may submit hardship exceptions to CMS for issues related to EHR issues, but only during a narrow window and only if they themselves are aware of the

		circumstances of decertification. This creates a gap in communication and puts physicians' success in MIPS at risk. CMS must be provided with immediate notice if a certified health IT module's certification is in jeopardy and impacting QPP eligible clinicians. **The AMA urges ASTP/ONC and its ONC-ACBs to establish protocols and policies that would 1) communicate to all applicable federal agencies when health IT's certification is in jeopardy, and 2) ensure all impacted eligible clinicians are protected from health IT's certification being suspended, terminated, or banned.**