James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

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Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for
Health Information Technology
Mary E. Switzer Building
330 C Street, SW, 7th Floor
Washington, DC 20024

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule

Dear National Coordinator Tripathi:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments on the Office of the National Coordinator for Health Information Technology's (ONC) notice of proposed rulemaking (NPRM): *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1).*

The AMA supports many of ONC's proposals to advance certified health information technology's (health IT) ability to meet the needs of patients and physicians. The AMA has long advocated that health IT, e.g., electronic health record systems (EHR), function as a tool to serve the clinical care team, patients, and their caregivers. The increased use of augmented intelligence (AI) in health care makes this more evident. However, EHRs can get in the way of patient care. Research shows that EHRs create new or exacerbate physician burden and have become a pronounced contributor to burnout.[1] Moreover, EHRs lack the necessary functionally to support patients' expressed preferences for the access, exchange, or use of their electronic health information (EHI). ONC should use its Certification Program to address these issues. **At the same time, ONC must ensure that its policies do not exaggerate EHR fees charged to physicians or cause "bottlenecks" that prevent physicians from receiving new EHR technology or meet federal reporting program requirements.**

The following outlines our principal recommendations on this proposed rule:

- The AMA strongly agrees that transparency is a prerequisite for trustworthy AI.
- The AMA encourages ONC to strengthen its "plain language" requirements for AI transparency.
- The AMA urges ONC to ensure EHR developers do not use technical, financial, or contractual levers to influence or steer physicians' use of AI in EHRs.
- EHR developers should be prohibited from shifting AI risk and liability to patients and clinicians.
- Patients and physicians need insight whether their data will be used to develop and/or train AI tools.
- Educational materials are needed to help physicians interpret and act on information provided by AI and EHR developers.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10134123/.

- EHRs must enable a physician to support their patients' requests to restrict the use or disclosure of sensitive personal health information.
- The AMA strongly urges ONC to require that EHR developers give patients control over when, where, and how they receive diagnostic reports.
- The AMA supports ONC's Insights Conditions requirements to help users and others better evaluate EHRs.
- The AMA encourages ONC to require EHRs to document a consumer application's intended use of patient data.
- Physicians should no longer shoulder the cost and burden to measure EHR interoperability to meet Centers for Medicare & Medicaid Services (CMS) EHR Program requirements.
- The AMA strongly urges ONC to develop an information blocking exception so physicians can protect patients' sensitive personal health information.

In the next section, we provide feedback on specific ONC health IT policy proposals. For comments on the technology sections of the NPRM, including the provisions related to additional EHR certification criteria and response to the requests for information (RFIs) included in the rule, please see the **Appendix**.

Improving Health IT Certification and Information Sharing: Response to Health IT Policy Proposals

Decision Support Interventions and Predictive Models

The AMA applauds ONC's efforts towards addressing the complexities surrounding transparency of rapidly evolving AI tools in health care. ONC's use of its Health IT Certification Program to surface information about AI development, training, risk, and fairness is likely the federal government's first major effort to establish regulatory guardrails on AI transparency. We support ONC's vision to promote greater trust in decision support interventions (DSI) and predictive models through the ONC Health IT Certification Program. While AI is a term often used to represent a broad category of technology, we believe the concept of AI aligns with ONC's DSI definition such that AI are "algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis." Therefore, **ONC's efforts are necessary to achieve the shared goals of the AMA and the Administration in improving algorithm transparency. We agree that transparency is a non-negotiable prerequisite for trustworthy AI.** [2]

The physician community has identified aspects of AI that, together, help define the contours of trustworthy AI. This includes AI that:

- is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
- is transparent;
- conforms to leading standards for reproducibility;
- identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and

[2] See ONC RIN 0955-AA03 where ONC references the history of federal guidance and action documents to include OMB Memorandum for the Heads of Executive Departments and Agencies on Guidance for Regulation of Artificial Intelligence Applications (Nov 2020); E.O. 13960 Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government (Dec 2020); GAO published report titled Artificial Intelligence: An Accountability Framework for Federal Agencies and Other Entities (June 2021); Biden-Harris Admin. Principles for Enhancing Competition and Tech Platform Accountability (Sept 2022); Biden-Harris Admin. Blueprint for an AI Bill of Rights (Oct 2022).

- safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.[3]

While we recognize ONC's regulatory oversight is limited to certified health IT, requiring EHR developers to serve as a "conduit" to promote trustworthy AI is appropriate and aligns with ONC's congressionally mandated Strategic Plan to "enhance the use of health information technology in improving the quality of health care," to "reduce health disparities," and "foster the public understanding of health information technology."[4] The use of AI in health care is expanding—impacting health care quality, equity, data privacy, and security. We support policies that enhance DSI transparency, elevate DSI risk management and governance, and advance health equity by addressing bias and health disparities propagated by DSI models. **Robust policies are needed to ensure health care AI is user centric, high-quality, and clinically valuable.** As such, **the AMA is a strong proponent for federal oversight to ensure AI is trustworthy—which may require using regulatory levers from multiple agencies in new ways.**

The AMA also appreciates ONC's efforts to make information about EHR-enabled or -interfaced DSI available to an end user in plain language. It is likely many physicians will engage with AI while using their EHR. Physicians, for better or worse, spend hours each day in their EHR and are likely accustomed to finding and using information to inform their decisions. **Providing physicians insight into DSI tools through their EHR leverages the health IT ecosystem they are already familiar with.** To be clear, we support ONC's proposals that information must be available to users via direct display, drill down, or link out from a health IT module. **In no way should ONC's DSI transparency requirements be interpreted as requiring health IT modules to alert physicians using "pop-ups" or other methods that would interfere with their workflow.**

We recognize that ONC's DSI transparency and risk management efforts may not ensure information is uniform or consistent, and that the utility of the information may not always be user centric. While this may ultimately become the goal, **we believe that surfacing information about DSI tools is the first step in providing physicians meaningful knowledge about the trustworthiness of AI in health care.** Moreover, making it evident that a DSI developer refuses to provide source attribute information, provides low-quality information, or declines to assist EHR developers in developing a risk management program itself can send a signal to a physician, medical practice, or health system about the trustworthiness of a DSI tool. **Given the impact AI will have on health care, and the lack of willingness many AI developers have in being transparent, the AMA believes there is a strong need to pull or surface information through novel means.**

Patients too are expressing their desire to ensure AI provides equitable care. In December 2022, the Pew Charitable Trusts surveyed over 11,000 individuals and explored public views on the use of AI in health care. While over half of the survey respondents believed AI could reduce bias in health care, nearly 60 percent said it could make the patient-provider relationship worse. Six-in-ten U.S. adults say they would feel *uncomfortable* if their own health care provider relied on artificial intelligence. **Three-quarters of Americans said their greatest concern is that health care providers will move too fast implementing AI in health care before fully understanding the risks for patients.**[5] The AMA recognizes there is a need for industry-defined guardrails to help instill trust and promote adoption. Yet, without increasing DSI transparency and protecting patients and physicians from algorithm failures, we could experience a counter-evolutionary overreaction to AI usage—where physicians choose "algorithmic abstinence" due to a lack of information and trust. While we support many of ONC's DSI proposals, there are important considerations that may arise as a by-product.

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[3] https://www.ama-assn.org/system/files/2019-01/augmented-intelligence-policy-report.pdf.
[4] https://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf.
[5] https://www.pewresearch.org/science/2023/02/22/60-of-americans-would-be-uncomfortable-with-provider-relying-on-ai-in-their-own-health-care/.

Federal Coordination and Shared Definitions

The AMA agrees that the approach ONC is taking to update the existing clinical decision support (CDS) certification criterion reflects contemporary and emerging functions, uses, and data elements. The use of AI has gone through a hyper speed transformation and the changes brought about by the new DSI distinction are warranted. **We urge ONC to consider how new CDS nomenclature will be interpreted across federal agencies and the need for education to avoid undue confusion among varying audiences.** For example, the AMA believes the more appropriate term when referring to AI is "augmented intelligence." Augmented intelligence reflects the enhanced capabilities of human clinical decision making when coupled with computational methods and systems. As noted in this proposed rule, DSI tools are not inherently created to replace, but rather, to support end users. The AMA agrees that AI-based tools are best suited to augment the skills and judgment of a physician and should not serve as a replacement. While the AMA does not support the use of these tools to completely replace the valuable knowledge and judgment of our skilled clinicians, we do recognize the valuable role they can play to provide insight and information about patients, their conditions, and potential treatments. **Achieving this value proposition will require continued private-public partnerships in support of regulation, implementation, transparency, and education.**

In that vein, the AMA strongly urges ONC to continue to partner with other federal agencies and medical professionals and societies to establish shared definitions concerning AI solutions. We are encouraged that ONC's proposals leverage existing regulatory efforts aimed at establishing guidelines to promote good health outcomes with these tools. We also appreciate ONC's recognition of the AMA's Artificial Intelligence Taxonomy and its role to advance a common understanding of health care AI.[6]

Updated Source Attributes Requirements for Greater Performance Transparency

AMA supports ONC's proposed DSI source attributes to drive consistency in evaluating DSI quality and whether its recommendations are fair, appropriate, valid, effective, and safe (FAVES). We strongly agree that physicians should be able to understand what data were used to train the predictive DSI; how the predictive DSI should be used, updated, and maintained; and how the predictive DSI performs using validity and fairness metrics in testing and local data. **We also encourage ONC to strengthen its requirements that health IT modules provide FAVES information in a "plain language description" to physician users.** For example, ONC should consider requiring that health IT developers involve practicing physicians that are unaffiliated with the health IT developers to assist in reviewing the understandability of source attributes.

Organizational Transparency in the form of Predictive DSI requirements for Health IT Modules and Developers of Certified Health IT

AMA supports ONC's proposals requiring that developers of certified health IT employ or engage in intervention risk management practices, i.e., activities related to "risk analysis," "risk mitigation," and "governance." **ONC should explicitly require that a developer's mitigation practice must:**

- identify and take steps to address bias and avoid introducing or exacerbating health care disparities including when testing or deploying new DSI tools on vulnerable populations;
- safeguard patients' and other individuals' privacy interests and preserve the security and integrity of personal information; and
- create a full feedback loop to provide front-line users DSI tools with a straightforward method to report any egregious problems that they encounter when the tool is deployed in a real-world setting.

[6] https://www.ama-assn.org/system/files/cpt-appendix-s.pdf.

Oversight and regulation of health care AI systems must be based on the risk of harm and benefit to patients and account for a host of factors. **We urge ONC to expand its risk analysis requirements to include intended and reasonably expected DSI use(s), DSI evidence of safety, DSI efficacy, DSI level of automation, and conditions of DSI deployment.**

We reemphasize our support for ONC working with other federal agencies grappling with AI issues that fall under their individual jurisdictions. We believe ONC's approach will help lay the foundations for enhanced federal AI transparency and move the needle closer towards establishing necessary assurances for greater trust in AI use.

Physician Concerns and Strategies to Address

The AMA recognizes the significant opportunity for transformation and improvements to health care through AI. Still, we stress our cautiously optimistic approach due to the uncertainty around elements such as liability for poor patient outcomes resulting from use of poorly performing AI. The National Academy of Medicine (NAM) highlights the real risk of increasing current inequities and distrust if AI tools are developed and deployed without thoughtful preemptive planning, self-governance, trust-building, transparency, appropriate levels of automation and augmentation, and regulatory oversight.[7] Given the number of stakeholders and policymakers involved in the evolution of AI in health care, **it is essential that we not only adopt a base level of policy to guide our engagement, but continue to refine our existing policies to ensure that the perspective of physicians in various practice settings informs AI oversight.**

While not contemplated by ONC, **we stress that clinical AI should be independently validated, deployment conditions well-specified, and that physicians have the information needed to understand the clinical limitations, risks, and liability—particularly if systems are fully autonomous, unlocked, or utilize unsupervised learning.**

We also have concerns that health IT module developers and developers of certified health IT may use ONC's certification requirements on DSI transparency to artificially inflate EHR costs, increase monthly/yearly service fees, attempt to renegotiate user contracts, shift liability or risk, or utilize additional unreasonable tactics to pressure physicians using DSI. ONC has implemented several certified health IT developer controls through its Conditions and Maintenance of Certification requirements, e.g., real-world testing, assurances, communications, and fee limitations. **We urge ONC to consider additional ways to use these requirements to ensure EHR developers do not unduly place downward technical, financial, or contractual pressure on their customers to influence or steer DSI use.**

Accountability Considerations for Certified Predictive DSI

We are sensitive to the reality that if finalized as proposed, once developers of certified health IT demonstrate that they have satisfied their DSI transparency requirements, this may inherently shift risk to physicians. In other words, the logic may follow that once an algorithmic-based tool reflects certain performance levels, physicians should be able to rely on the information provided by the tool. However, while we encourage embracing the use of quality AI tools, **we strongly stress that we are not supportive of shifting risk and liability to patients and clinicians where they are not able to fully understand nor mitigate the risks posed by use of an AI-enabled tool**.

[7] Matheny, M., S. Thadaney Israni, M. Ahmed, and D. Whicher, Editors. 2019. Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril. NAM Special Publication. Washington, DC: National Academy of Medicine, p. 235.

Even if developers provide high levels of transparency around these algorithmic technologies, for certain technologies utilizing machine learning, there will always be a level of uncertainty around how the algorithm is actually learning and functioning. True augmented intelligence and machine learning tools are not necessarily predictable to humans and possess a certain level of autonomy. With these technologies, it may not be clear to a physician when outputs are incorrect or when human intervention is necessary. In these cases, the physician is arguably the least well situated to understand when something is wrong and to intervene. **Instead, the developer of the tool should bear the responsibility of ensuring optimal performance of the tool they developed and should bear the brunt of the liability when errors occur.**

Ensuring levels of transparency appropriate to help a physician evaluate the quality and appropriateness of an AI-enabled tool should not shield a physician from liability resulting from inappropriate tool selection or use of a tool in an unintended manner. However, transparency mandates alone are not enough to confer liability to a physician for failure of the tool itself to perform as marketed and intended. **ONC should be aware that DSI and EHR developers may use this transparency mandate to shift liability for poorly performing tools. ONC should take steps, including working with other federal agencies, particularly across the U.S. Department of Health and Human Services (HHS), to ensure that accountability for the performance of the tool rests with the appropriate parties.**

Furthermore, **we urge ONC to reconcile the fact that physicians are not going to know, and should not be expected to predict, an unanticipated poor outcome of a DSI, regardless of whether it satisfies criteria that should indicate otherwise.** NAM frames this concern well, stating that:

> **"**[t]he notion of "explainability" is not well defined. Humans may be in a poor position to comprehend the explanations of AI recommendations or actions. While requiring explainability may not always be compatible with maximizing capacity and performance, the proposed form of enabling better transparency, might at least begin to enable effective oversight."[8]

Ethical, Legal, and Social Implications of Data Collection

The AMA stresses that data privacy is highly relevant to AI development, implementation, and use. We are deeply invested in ensuring individual patient rights and protections from discrimination remain intact, that these assurances are guaranteed, and that the responsibility falls with the data holders.[9] AI development, training, and use requires assembling large collections of health data. Patients are increasingly aware their data can be used against them or their family. While DSI developers may create legal arrangements, e.g., business associate agreements, that bring them under the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, **the "black box" nature of AI makes a DSI tool's use and repurposing of data opaque.**

In a 2022 survey of 1000 patients, **92 percent of patients consider data privacy a right. Nearly 75 percent of people expressed concern about protecting the privacy of their health data.** While patients are most comfortable with their physician or hospital having access to their data, **patients are least comfortable with social media sites, employers and big technology companies receiving access to their health data.[10]** Given that many DSI tools are being developed by large technology companies, ONC's efforts to surface data privacy and security risk mitigation practices are vital to meet the needs of patients and physicians. In fact, research also

[8] Id.
[9] https://www.ama-assn.org/system/files/2020-05/privacy-principles.pdf
[10] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.

shows that **94 percent of patients believe that companies that collect, store, analyze or use health data should be held accountable by the law.**[11]

To enhance ONC's Intervention Risk Management Requirements, and promote good data privacy practices, the **AMA urges ONC to require that certified health IT developers provide physicians and patients information whether their data will be used to develop and/or train DSIs.**

Call for Educational Campaign for Physicians, Health Care Providers, and Patients

As AI-enabled tools are rapidly coming to market, groups with varying levels of understanding of AI will need education on AI's impact on the practice of medicine. Competency training to enhance confidence in utilizing DSI tools, and an understanding as to how DSI decisions or recommendations are made, will be critical. **ONC's efforts to promote trustworthy AI through transparency will help establish a basis for this education.** ONC's proposal that information about predictive DSI is made available to their customers and presented in plain language is particularly relevant in this regard. **Moreover, ONC should coordinate with public and private AI experts and develop educational materials to help physicians interpret and act on the source attribute information provided by DSI developers and health IT developers.**

ONC notes that "[p]hysicians are likely essential to the overall process of ensuring predictive DSIs are FAVES and for determining how these predictive DSIs can be best used in their settings and for their patients."[12] We would agree, with the caveat that as the state of technology constantly evolves, it would be a stretch to suggest that physicians will always have sufficient information to make that determination. We appreciate and agree with ONC that, while some aspects of predictive DSI should be familiar to physicians, some competencies may be novel and challenging. Understanding how these tools are implemented in everyday practice will undoubtedly be a shift for many and will require time and deliberate thought in execution on a large scale. As a thought leader in the possibilities of AI in medicine, **the AMA recognizes the opportunity to collaborate with the federal government on this endeavor and to explore how we can best prepare physicians for the transformative change AI presents.** The AMA has created an abundance of educational resources and continues to strategize on the best ways to present this complex information to physicians and how to implement these tools in their practice.

The AMA is committed to encouraging education for patients, physicians, medical students, and other health care professionals to promote a greater understanding of the promise and limitations of AI in health care. In addition, the AMA is focused on addressing other legal implications of AI, such as issues of liability, intellectual property, and appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI. We look forward to continuing to be a collaborative partner with the federal government as the future of medicine continues to be shaped by these technological advances.

Patient Requested Restrictions Certification Criterion

Expanding the access to health information is essential to support patient-centered clinical care. The AMA is a strong advocate for patient access to their medical records. Empowering patients and including them as a partner in care decisions has been shown to improve the patient-physician relationship and improve outcomes. Our ability to collect and track health and wellness data has benefited a growing population of users across the United States. Physicians and care teams can more closely monitor known conditions, identify early signs of diseases, and

[11] Id.
[12] See ONC RIN 0955-AA03.

proactively engage with patients. Likewise, patients are better enabled to manage their own care and make informed decisions.

However, as more data are collected and exchanged, there is a lack of meaningful controls for patients to express their preferences and direct the access, exchange, or use of their personal health information. For years, the AMA has called on policymakers and health IT developers to expeditiously work to create technology and policies that allow for "equitable interoperability"—that is, information exchange that empowers and does not disadvantage individuals. Further, the AMA agrees with ONC that, with the addition of new data elements in the U.S. Core Data for Interoperability (USCDI), there is a heightened need for data privacy due to the potential for bias or stigmatized care. **It is essential that we protect sensitive personal health information—as both a foundation for health equity but also to mitigate the risk of negative impacts to individuals resulting from the disclosure of their information.**

The ability for an individual to manage their data at a granular level, e.g., controlling elements of their record such as specific lab values, can be a powerful mechanism to protect their medical information. Allowing some, but not all, of their information to be accessible or transmitted to another entity can give patients the confidence to continue to share personal information with their physician. In a 2022 survey of 1000 patients, **92 percent of patients believe that privacy is a right and nearly 75 percent of patients are concerned about protecting the privacy of their health data. Almost 80 percent of patients want to be able to "opt-out" of sharing some or all of their health data. Over one-half of surveyed patients stated that they are very or extremely concerned about negative repercussions related to insurance coverage, employment or opportunities for health care resulting from access to their health data.**[13]

Yet, lacking adequate tools for granular segmentation of sensitive data, health care organizations resort to imprecise automated or manual processes to withhold sharing for broad patient populations. This can result in care inequities and the potential for information blocking. Lacking trust in data protection, patients with stigmatized conditions will be less likely to consent to having their data shared. As sensitive conditions are more prevalent in historically minoritized and marginalized populations, this can contribute to health disparities. **The AMA seeks to advance an interoperable ecosystem with an eye toward ameliorating disparities using granular data segmentation—in other words, preserving trust while sharing data.**

Patients have the right to withhold specific sensitive data, due to state and/or federal law. In other instances, a patient's living situation, culture or values, relationships, or other expressed needs may warrant a clinician withholding health information. The HIPAA Privacy Rule provides individuals with several rights. This includes the right to request restrictions on certain uses and disclosures of health information and the right to agree or object to certain disclosures. While these rights are not new, the ability to meet patients' data sharing preferences has been largely managed by "humans in the middle." That is, records requests have often been reviewed and considered by medical office staff. Sharing information with an outside entity would require information management professionals to manually collate and redact information, based on patient preference, law, or office policy.

This humanistic approach, while slow, has served as a pragmatic process to meet individuals' data sharing preferences. The use of EHRs, health information exchanges (HIE), and clinical and administrative demands by payers—coupled with federal information blocking regulations—is propelling the sharing of information beyond what can be reasonably managed by humans. As a result, patients' sharing preferences have been removed from the equation. **Privacy-enabled technology and policies have not kept up with the volume and velocity of information sharing—putting patients and their data at risk of abuse and misuse.**

[13] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.

To help address this gap, the AMA co-founded Shift for the purpose of advancing granular data segmentation standards and implementation guidance.[14] Shift is an independent health care task force of over 250 expert stakeholders that envisions a world of safe, equitable, and patient-empowered sharing of health information. We have worked with Shift members to provide additional detailed comments on data segmentation in the appendix attached to this letter. In response to ONC's *Patient Requested Restrictions Certification Criterion*, the AMA offers the following overarching comments:

- The AMA strongly supports ONC's proposals that certified health IT must allow a user to flag data that needs to be restricted from subsequent use or disclosure and that health IT must prevent any flagged data from being included in subsequent use of disclosure for the designated restricted purposes. **At a minimum, EHRs must enable a medical practice to support their patients' requests to restrict the use or disclosure of their medical information.** As identified by ONC, and long advocated by the AMA, patients can be significantly impacted if reproductive health, behavioral health, substance use, or gender-affirming care information is inappropriately shared. **In addition to patients, medical staff should also be provided the ability to flag certain medical information—giving equitable data privacy access to patients who cannot or do not have access to online portals or other internet-enabled means.**

- The AMA is a strong advocate for patients to control where and when they view or are alerted to new medical information. The highly automated nature of information exchange—coupled with significant confusion around federal information blocking regulations—means that some information is being sent to patients without medical context or even before their physician is aware it is available. The immediate release of information is causing some patients emotional harm. In a 2022 survey, **65 percent of patients expressed concern about getting life-changing results in their patient portal without first hearing from their physician.**[15] A 2023 JAMA research article reiterated this concern. The authors state that, to mitigate patients' emotional distress, strategies could include "optimizing existing patient portal interfaces to give users control over their notification preferences related to sensitive or abnormal results or timing the release of test results during working hours."[16] **There is no denying the fact that some patients do not want to be alerted to or receive unexpected medical information before first speaking with their physician.** The AMA continues to advocate that patients need this level of control to help ameliorate instances when they are not expecting "bad news" or in instances where patients want physician review prior to seeing results themselves.

  ONC states that the proposed *Patient Requested Restrictions Certification Criterion* gives health IT developers the flexibility to implement user-enabled data flagging and restrictions via a wide range of potential means. For example, ONC identifies that "flagged data could be withheld from a summary care record, not displayed in a patient portal, or not shared via an [application programing interface] API."[17] In an accompanying RFI, ONC seeks feedback on methods to improve the availability and accessibility of solutions supporting health care providers' efforts to honor patients' expressed preferences regarding their EHI. ONC explicitly seeks feedback on granting "a patient's request to delay the release of certain EHI—such as new diagnoses or particular laboratory or imaging result(s)—to the patient or the patient's personal representative either for a particular period of time or until a particular event, such as communication between the patient and a clinician or patient educator, has occurred."[18]

[14] https://www.drummondgroup.com/shift/.
[15] https://www.ama-assn.org/system/files/patient-privacy-survey-results-preventing-patient-harm.pdf.
[16] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2802672.
[17] See ONC RIN 0955-AA03.
[18] Id.

While the AMA appreciates ONC's RFI, without enacting near-term policies, EHR developers will not have the incentive to give users control over their notification preferences nor will physicians be able to honor patients' expressed preferences related to sensitive, life-changing, or abnormal results. Patients who seek these controls will continue to be marginalized and harmed.

To that end, the AMA strongly urges ONC to explicitly expand and enumerate the proposed *Patient Requested Restrictions Certification Criterion* to require health IT developers to prevent flagged data from showing up in a care summary, in a patient's portal, or shared via an API. Said another way, health IT developers who meet this criterion should be required to provide patients the ability to control when and how they see medical information and when and how they are alerted to that information.

- Expanding the capabilities of certified health IT to enable control, use, and disclosure of patients' medical information—and express their preferences—is vital in a highly automated and interoperable world. The AMA appreciates the thought put into ONC's proposals. While patients, physicians, and health IT developers, are core to this mission, without a robust communication, education, and engagement effort, many entities essential to interpretating ONC's policy and implementing technology at medical practices, hospitals, and health systems will be left out.

  There continues to be confusion among health care professionals, clinical and IT staff, administrative and back-office personnel, compliance officers, consultants, attorneys, records release professionals, and technology vendors on implementing ONC's information blocking regulations. ONC-developed webinars and FAQs, while helpful, are not sufficient to clearly communicate "what can and cannot be done" to all the individuals needed to orchestrate optimal implementation of ONC's rules. **This has resulted in instances of oversharing sensitive information and confusion in complying with state and federal law.** The AMA has heard from many physicians that some health IT developers refuse to provide patients or physicians granular controls and are implementing health IT in such a way that it is nearly impossible to withhold, redact, or protect certain medical information. Confusion about information blocking is often cited. Compliance officers, administrative personnel, in-house attorneys, and policy consultants are interpreting ONC's anti-blocking regulations particularly conservatively.

  For example, ONC's guidance states that EHI does not need to be proactively pushed to patients and that "alerts" are not required for information blocking compliance. Yet, those implementing ONC's regulations at medical practices and health systems often miss these nuances. While patients and physicians are fearful of sensitive health information, e.g., reproductive health information, being used in criminal, civil, or administrative investigations, EHR developers, worried of being called an "information blocker," are not supporting physicians in protecting certain medical information—even to meet patients' preferences. **The Administration's proposed *Rule To Support Reproductive Health Care Privacy* may fall short of its desired goals if there is a lack of certified technology and if ONC neglects to adequately educate those involved in interpretating, implementing, and operationalizing its own policies.** Compliance with the information blocking regulation is overriding thoughtful compliance with other, more protective laws and rules. This concern is not novel and has been expressed by the AMA on several occasions.

  To support the Administration's goals of protecting individuals seeking reproductive health care and to promote equity by design, **the AMA calls on ONC to coordinate with agencies across HHS and develop a comprehensive "Sharing with Protections" campaign.** For example, ONC must ensure that all health care stakeholders are clearly aware of the technical capability and benefits of privacy through data segmentation, when HHS' policies permit clinicians to withhold information—particularly when it

would not be considered information blocking—and what documentation is necessary to show compliance. **ONC should leverage all communication and outreach channels available to HHS to engage with all professionals involved in health care regulatory compliance.** To be clear, EHR developers and physicians are not the only entities necessary to successfully implement federal policies. **Absent an organized communications effort by HHS, the AMA fears that the Administration's effort to support reproductive health care privacy will languish**—mired in confusion, misinterpretation, indecision, and inaction by the entire compliance community.

Insights Condition and Maintenance of Certification

ONC is proposing a new Condition and Maintenance of Certification requirement associated with its EHR Reporting Program. The "Insights Condition" would require certified health IT developers to report on four areas of interoperability, including individuals' access to EHI, public health information exchange, clinical care information exchange, and standards adoption and conformance. The proposed measure areas would use data derived from the certified health IT system itself. ONC would generate metrics using numerator/denominator calculations based on the certified health IT's supplied data points.

The AMA strongly supports ONC's proposals as far as ONC intends for the metrics to help EHR users, federal entities, and the health IT industry better evaluate the functional interoperability of EHRs. Measuring the functional interoperability of certified health IT should allow stakeholders to:

- assess an EHR's ability to facilitate users' access, exchange, or use of EHI;
- identify trends, gaps, or rate-limiting factors impacting EHI access, exchange, or use; and
- establish benchmarks for physicians and other users to better evaluate EHR performance in relation to other health IT products.

The AMA has provided detailed recommendations on ONC's EHR Reporting Program over several years. In our October 2018 comments, the AMA asked that the EHR Reporting Program be used to "1) disseminate [EHR Reporting] program information in an easily accessible, digitally consumable, and consistent manner; 2) where appropriate, utilize program information to inform ONC's Certification Program and future rulemaking", and we asked that ONC "strongly urge health IT developers to proactively improve their products' performance and functionality using information gathered in the program."[19] **ONC's proposed Insights Conditions should play a major role in identifying interoperability trends and gaps, enable the health IT industry to more quickly "course correct," and empower users to make informed health IT choices.**

Opportunities for ONC's Insights Conditions to Improve Data Use Transparency

As the industry gets closer to building longitudinal health records from a variety of disparate sources, policy makers continue to face challenges on how to best balance access with privacy. Undoubtedly, both patients and clinicians are aware of the importance of an accurate, usable, and complete medical record for care coordination. The AMA supports this goal, as well as the principle that patients should be able to easily access their medical record. We are concerned, however, about the continued lack of safeguards to ensure that patients understand what they are consenting to when they grant permission to an app to access their health information. **To help**

[19] https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FAMA-EHR-Reporting-Program-RFI-Comments-Oct-2018.pdf.

users make more informed digital health choices, the AMA strongly encourages ONC to require an app attestation as part of its EHR Reporting Program Insights Conditions requirements.

The issue of transparency is critical. Health care is built on trust and informed consent. Information flows at the speed of trust, and a loss of trust would ultimately stall information exchange. Several articles have exposed that mobile apps, Facebook, and Google are harvesting, exchanging, and selling individuals' personal information without their meaningful consent or in violation of a stated privacy policy. Additionally:

- Studies reported in the *British Medical Journal* and the *Journal of the American Medical Association* (JAMA) have demonstrated that most apps do not share privacy policies with patients.
- A study in the data science journal *Patterns* found of the five apps the authors examined, all were passing health data to a collective 32 "middleware" outfits that track users across different sites and apps. The apps were chosen due to the frequent use by patients for information and community support related to their medical conditions.
- The Federal Trade Commission (FTC) announced enforcement actions against bar GoodRx and ovulation tracking app Premom from sharing consumers' sensitive health information for advertising.
- ProPublica and NPR report that insurers gather data from unknowing patients' medical devices and apps to make coverage decisions.

The increased volume and velocity of data complicates data access, sharing rights and responsibilities—making data a tantalizing commodity while dramatically impacting patients' trust in the nation's health care system.

Patients desperately want control over their information and to make educated choices about which apps to use. In a 2022 survey of 1000 patients, respondents were unclear about laws to protect their privacy and expressed concerns about who has access to their medical records. Research shows that patients are most comfortable with their physician or hospital having access to their patients' data and least comfortable with social media sites, employers, and big technology companies receiving access. **Nine out of 10 patients want health app developers to publicize if and how their product adheres to industry standards for handling health data.** Almost 88 percent of patients believe their doctor or hospital should have the ability to review and verify the security of health apps before those apps gain access to their health data.[20] Patients and consumers clearly want transparency on how apps access, exchange, or use their medical information.

To address this, the AMA has identified an opportunity for ONC to make meaningful progress to empower patients with more information about how their apps access, exchange, or use EHI.

To help provide a minimal amount of transparency to patients about how a health app will use their health information, ONC should implement a basic privacy framework requiring certified EHR developer APIs to check an app's "yes/no" attestation to:

- (1) *Industry-recognized development guidance* (e.g., Xcertia's Privacy Guidelines/Privacy Is Good Business: a case for privacy by design in app development);
- (2) *Transparency statements and best practices* (e.g., Mobile Health App Developers: FTC Best Practices/CARIN Alliance Code of Conduct/AMA Privacy Principles); and
- (3) *A model notice to patients* (e.g., ONC's Model Privacy Notice).

This would not regulate apps and does not extend beyond ONC's authority. Requiring an EHR's API to check for an app developer attestation would not be a significant burden on EHR developers. Likewise, apps would not be

[20] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.

prevented from connecting to an EHR even if they attest "no" to the three attestations. **Accordingly, ONC's DSI transparency proposals 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.** The AMA proposed this approach in our 2019 comments on ONC's *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* proposed rule.[21]

Furthermore, this framework would complement ongoing federal activity in this space. It would serve to assist the FTC in the event of an investigation or enforcement action if the app strays from what it attests to and tells consumers.

Groups representing app developers, patients, and HHS' Healthcare Sector Coordinating Council have all recommended creating a privacy framework to accompany ONC's regulation.[22,23] Such a framework would help establish a practice of transparency as Congress works on federal privacy legislation. **The AMA strongly encourages ONC to require an app attestation as part of its EHR Reporting Program Insights Conditions requirements.**

Opportunities for ONC's Insights Conditions to Reduce Burden

Still to this day, physicians assume the burden of capturing, documenting, and reporting CMS Merit-based Incentive Payment System (MIPS) Promoting Interoperability (PI) requirements. The PI Program is designed to compel physicians to "use" their EHR and meet several MIPS interoperability requirements, including giving individuals' access to EHI, public health information reporting, and clinical care information exchange. However, MIPS is also administratively burdensome. A study of MIPS participation in 2019 showed that it cost $12,800 per physician per year, with physicians spending 53 hours per year on MIPS-related tasks—**equivalent to a full week of patient visits.** However, physician-reported PI measures are still used as a proxy for actual EHR-EHR interoperability and patient access.

Furthermore, analysis of physician PI reporting is delayed by at least 18 months, and CMS' MIPS Experience Reports can be three or more years behind. This means that federal agencies relying on physician PI reporting to gauge EHR interoperability and patient access efforts is out-of-date before it can inform policy changes. Also, physicians are incentivized to report on PI measures to score points and not get financially penalized. This data can be artificially inflated and may not accurately reflect real-world interoperability or the needs of patients and physicians. More can be done to better inform CMS and ONC policies on interoperability. Therefore, the AMA believes it is no longer appropriate for physicians to shoulder the cost and burden of data collection to measure national EHR interoperability. Rather, measurement should be equitably distributed between physicians and EHR developers.

[21] https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2019-5-31-Letter-to-Dr-Rucker-re-ONC-NPRM-Comments.pdf.
[22] https://connectedhi.com/wp-content/uploads/2022/02/CHICommentsreONCInfoBlockingRulefinal060319.pdf.
[23] https://healthsectorcouncil.org/hph-scc-cybersecurity-working-group-comments-on-hhs-onc-information-blocking-rfi/.

In our October 2018 and October 2020 comments, the AMA outlined an opportunity to utilize ONC's EHR Reporting Program as a supplement data source for PI reporting—with the goals of reducing clinician burden and monitoring real-world EHR interoperability.[24,25]

The AMA proposes that ONC coordinate with CMS and utilize EHR developer-reported Insights Conditions data and metrics to augment physicians' PI measure reporting. CMS officials have stated that PI numerator/denominator reporting is still necessary to ensure physicians are using EHRs, providing patients with their EHI, reporting to public health agencies, and exchanging information. Yet, the AMA and over 35 medical professional societies advocate that physicians should be required to only attest a "yes/no" to meeting CMS' PI measures rather than the needless hassle of capturing, analyzing, and reporting PI numerator/denominator metrics.[26] **The goals of reducing physician PI reporting burden and providing CMS and ONC insight into EHI access, exchange, or use can be jointly achieved by allowing physicians to attest to meeting PI Objectives—rather than reporting a numerator/denominator—supplemented by EHR developer-reported Insights Conditions data.** Moreover, since ONC is proposing that EHR developers report their Insights Conditions data semiannually, that is, twice a year, ONC has an opportunity to provide CMS better, more timely data about real-world EHR interoperability.

ONC seems to agree and identifies the value of Insights Conditions data to inform policymaking. ONC states that:

> *Using data gathered under this [Insights Conditions] measure, we would also be able to examine trends in the use of various mechanisms for exchange of health information over time. Monitoring the volume of exchange by various mechanisms is critical to monitoring the implementation of key ONC policies that support exchange and interoperability, including most recently TEFCA.*
>
> *Understanding varying usage of different mechanisms could better inform ONC policies because not all exchange mechanisms may adequately support true interoperability. Understanding where the market is with regards to the usage of exchange mechanisms that support interoperability (versus those that do not) is critical to informing ONC policy.*
>
> *Furthermore, examining variation in usage of exchange mechanisms can provide insights into what mechanisms may be limited to certain use cases, and whether some mechanisms implicitly or explicitly favor some parties (e.g., developer exchanges). Thus, information on exchange by mechanism will allow ONC to better target its support for interoperable exchange.*
>
> *Furthermore, these data can be used by ONC to assess the impacts of these various efforts, including the role certified health IT plays in supporting exchange through various mechanisms. The Program supports a number of different exchange mechanisms; understanding their uptake and use is important for informing future development and improvements.*[27]

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[24] https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FAMA-EHR-Reporting-Program-RFI-Comments-Oct-2018.pdf.

[25] https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-10-4-Letter-to-Verma-re-2021-Physician-Fee-Schedule-FINAL.pdf.

[26] https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfdr.zip%2F2023-3-2-AMA-Sign-on-Letter-to-CMS-MIPS-Value-Pathways.pdf.

[27] See ONC RIN 0955-AA03.

The AMA strongly urges ONC to work with CMS and leverage its Insights Conditions requirements to better assess the impacts of each agencies' various efforts, support EHR interoperability, and monitor real-world EHI access, exchange, or use to inform HHS polices. The AMA stands ready to assist ONC and CMS in efforts to reduce physician burden and support interoperability.

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

The AMA appreciates ONC's attention on data segmentation and sharing based on patient preference. We emphasize that data segmentation is critical for health information exchange, regardless of where the data resides, how it is used, or with whom it is exchanged. **Patient consent and privacy, data provenance, governance, and state and federal law compliance should be inherent in technology development.** Moreover, Actors under the Information Blocking regulation lack any clear exceptions for not fulfilling requests to access, exchange, or use EHI when EHI is identified by the patient or physician as sensitive personal health care, e.g., reproductive health information or gender-affirming care. Patients may request that information is withheld, but due to the lack of EHR data segmentation, large sections of the medical record are either withheld or sensitive personal health information is released without knowledge. **This is a major gap, and the AMA urges ONC to develop a clear information blocking exception for providers in instances when requests for EHI related to sensitive personal health care are not fulfilled.**

The AMA supports ONC's efforts to develop steps to improve the availability and accessibility of solutions supporting health care providers' and other information blocking Actors' efforts to honor patients' expressed preferences regarding their EHI. We agree a more granular approach to data segmentation and consent management is applicable to many of the use cases outlined in this RFI. For example, our physician members want the ability to accommodate an individual's preferences and segment EHI about an individual's reproductive and sexual health. **We urge ONC to ensure that granular data segmentation technology is affordable and accessible to all providers, including pediatric, maternal, and women's health physicians.**

We appreciate ONC seeking feedback on use cases related to granting a patient's request to delay the release of certain EHI—such as new diagnoses or particular laboratory or imaging result(s)—to the patient or the patient's personal representative either for a particular period of time or until a particular event, such as communication between the patient and a clinician or patient educator, has occurred. Research shows that 65 percent of patients want to speak with their physician first before receiving life-changing test results.[28] Authors of a recent *JAMA* article have identified that, to mitigate patients' emotional distress, strategies could include "optimizing existing patient portal interfaces to give users control over their notification preferences related to sensitive or abnormal results or timing the release of test results during working hours."[29]

The 21st Century Cures Act directs HHS to improve patients' access to their medical records. The AMA strongly supports this and efforts like OpenNotes. However, implementation of ONC's information blocking regulations is causing patients emotional and mental harm. **There is no denying the fact that some patients do not want to be alerted to or receive unexpected medical information before first speaking with their physician.** An October 2022 *New York Times* article tells the story of an individual who suffered a pregnancy-loss. The author, Danielle Friedman, described the experience as:

> "…devastating, and the weeks after were a blur of grief, anger and physical turmoil. About a month later, on a day when I was feeling more like myself than I had in a while, I was folding clothes in my 3-year-old son's room when I received an alert from MyChart, an app that gives

[28] https://www.ama-assn.org/system/files/patient-privacy-survey-results-preventing-patient-harm.pdf.
[29] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2802672.

> patients access to their records and doctors' messages, with a new test result to view. But I was not prepared for what I saw on the screen — a fetal autopsy report." It was explained to Danielle that she had received this impersonal alert, prior to hearing it from her physician, due to requirements of ONC's information blocking regulations.[30]

The AMA and dozens of state medical societies and national medical specialty societies continue to hear from patients and physicians about the harm being caused when results that show debilitating, life-limiting or terminal illnesses are sent to patients without context. We have collected hundreds of stories from patients and physicians about serious emotional distress and ethical concerns caused by the implementation of these regulations. **ONC acknowledges there is a lack of strong data segmentation policies to support physicians in sharing information consistent with patient preferences and laws applicable to the creation, collection, access, exchange, use and disclosure of EHI.**

In 2022, patients living in California lobbied state regulators to pass SB-1419, a law where certain test results cannot be disclosed to a patient over the internet or other electronic means until a health care professional has discussed the test results with the patient.[31] **Patients were concerned about automatically receiving malignancy and HIV status information without physician context.** Additionally, OCR's proposal on the *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*[32] focuses on requiring a HIPAA covered entity to not disclose protected health information in certain circumstances, including if that information could be used in criminal, civil, or administrative investigations against any person involved in reproductive health care services. It is likely that physicians as covered entities will need health IT data segmentation capabilities, and the ability to share information consistent with patient preferences, to comply with these HIPAA provisions.

As outlined previously in our letter, the **AMA strongly supports ONC's proposed *Patient Requested Restrictions Certification Criterion.*** However, ONC is proposing that certified health IT developers would not be required to provide these capabilities until January 1, 2026, at the earliest. Absent the technical capability to comply with federal or state law and regulation or the ability to meet patients' preferences to grant a delay of EHI for a particular period of time or until a particular event, **current information blocking exceptions are woefully insufficient to accurately protect patients from the disclosure of sensitive personal health information.**

Patient-centric implementation of ONC's information blocking regulations at medical practices, health systems, and with Actors like EHR developers and HIE/HINs requires, 1) clear exceptions for when EHI can be withheld, and 2) clear guidance on interpreting these exceptions. Compliance personnel, practice administrators, attorneys, consultants, information management and IT professionals must work together to implement these polices and ensure the patient's care team have the tools to comply with the patient's wishes and federal and state law and regulation. **Unfortunately, there is widespread confusion, misinterpretation, and assumptions being made about what should and should not be done with EHI and what is and is not allowed under the information blocking regulations. This can cause information to be shared inappropriately.** OCR's forthcoming final regulation on modifications to the HIPAA Privacy Rule[33] will likely increase confusion. In instances of protecting an individual's reproductive health information or preventing a patient or caregiver from experiencing emotional harm, **the lack of technology and clear policies to support patients' requests to withhold EHI related to sensitive personal health care is inexcusable.**

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[30] https://www.nytimes.com/2022/10/03/well/live/medical-test-results-cures-act.html.
[31] https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB1419.
[32] https://www.federalregister.gov/documents/2023/04/17/2023-07517/hipaa-privacy-rule-to-support-reproductive-health-care-privacy.
[33] https://www.federalregister.gov/documents/2021/01/21/2020-27157/proposed-modifications-to-the-hipaa-privacy-rule-to-support-and-remove-barriers-to-coordinated-care.

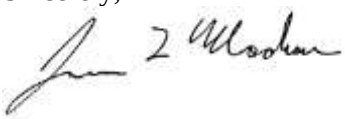
Therefore, the AMA urges ONC to take the following actions:

- finalize its proposed *Patient Requested Restrictions Certification Criterion,* giving patients, and their care team, the power to flag elements of the medical record that should be considered sensitive personal health information;
- require certified health IT developers to withhold flagged information from patient-designated disclosure, from HIE requests, third-parties, or from display or availability in the patient's portal or API; and
- create an information blocking exception, or modify an existing exception, that clearly identifies reasonable and necessary activities that do not constitute information blocking in instances of an Actor withholding the access, exchange, or use of flagged sensitive personal health information.

The AMA believes that this proposed rule will help to decrease EHR burdens, improve AI transparency, medical record interoperability, while helping protect an individual's privacy. Nonetheless, we reiterate the importance of ONC finalizing policies to prevent unintended harm to patients from sharing sensitive information. The AMA encourages ONC to work with stakeholders to ensure that the objectives of the proposed rule are being met. We look forward to working with ONC to fulfill these goals.

Thank you for the opportunity to provide comments on this proposal. Please contact Matt Reid, Senior Strategic Health IT Policy Consultant, at matt.reid@ama-assn.org with any questions.

Sincerely,



James L. Madara, MD

Attachment

§ 170.550 - Health IT Module Certification - Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

* * * * *

(g) *Health IT Module dependent criteria.* When certifying a Health IT Module to the ONC Certification Criteria for Health IT, an ONC-ACB must certify the Health IT Module in accordance with the certification criteria at:

* * * * *

and

* * * * *

(m) *Time-limited certification and certification status for certain ONC Certification Criteria for Health IT.* An ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for:

* * * * *

Preamble FR Citation: 88 FR 23759 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.

Public Comment Field: ONC proposes to establish dates by which an existing version of a certification criterion is no longer applicable because a new or revised version of that criterion is adopted. In addition, ONC proposes to establish applicable timelines, including expiration dates, for the adoption of standards when a new or revised version of the standard is adopted for the same purpose. Under this proposal, a developer of certified health IT would not be required to provide technology updates for certification criteria or standards to a user, e.g., physician, who declined such updates. If such an update is not provided, the health IT module would no longer be certified. ONC proposes that to "provide" the product means that the developer must do more than make the product available and there must be demonstrable progress toward implementation in real-world settings.

The AMA supports ONC's proposal to discontinue year-themed editions. However, many physicians may not understand the implications of declining an update. Our understanding is that declining an update would result in a "decertified" EHR and therefore the physician would not be able to participate in federal EHR programs, e.g., CMS' MIPS Program. We are concerned that shifting the responsibility to the physician, rather than requiring explicit use of a specific certified edition as ONC and CMS have required for years, will disadvantage physicians. The AMA is aware that many EHR developers charge physicians for "upgrades" and software updates to support new certified editions. While largely unreasonable, these fees often signify a required change in EHR versions to support federal reporting requirements. Leaving it up to the EHR developer to "provide" ongoing certified EHRs to physicians will likely result in the EHR developer charging physicians for updates without sufficiently communicating why the update is necessary. This could result in physicians choosing to decline the update as a reasonable attempt to save money without realizing this action would decertify their EHR and prevent them from successfully participating in MIPS. As such, **the AMA strongly urges, as part of ONC's proposed definition of "provide", to include a**

§ 170.550 - Health IT Module Certification - Related to "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"

requirement that certified health IT developers use written and verbal communication methods to adequately inform physicians as to what a "provided product" means and what declining the product means for the health IT's certification status and the physician's ability to participate in federal reporting programs. The certified health IT developer should also be required to document its written and verbal communications, their customer's response, and provide that documentation to ONC and its customer.

§ 170.213 - The United States Core Data for Interoperability Standard (USCDI) v3

The USCDI standard is currently cross-referenced to § 170.213 in certain certification criteria, each of which could currently be certified using either USCDI v1 or USCDI v2 because USCDI v2 is approved for SVAP. With our proposal to add the USCDI v3 in § 170.213, these criteria may also be certified using USCDI v3. We propose to continue allowing USCDI v1 or USCDI v2 under SVAP, and to also allow USCDI v3 through December 31, 2024. We propose to allow only USCDI v3 after this date for the criteria using USCDI. The criteria cross-referencing to USCDI § 170.213 are as follows:

- "Care coordination - Transitions of care - Create" (§ 170.315(b)(1)(iii)(A)(*1*));
- "Care coordination - Clinical information reconciliation and incorporation - Reconciliation" (§ 170.315(b)(2)(iii)(D)(*1)* through (*3*));
- "Patient engagement - View, download, and transmit to 3rd party - View" (§ 170.315(e)(1)(i)(A)(*1*));
- "Design and performance - Consolidated CDA creation performance" (§ 170.315(g)(6)(i)(A));
- "Design and performance - Application access – all data request – Functional requirements" (§ 170.315(g)(9)(i)(A)(*1*)); and
- "Design and performance - Standardized API for patient and population services – Data response" (§ 170.315(g)(10)(i)(A) and (B)).

§ 170.213 United States Core Data for Interoperability.

The Secretary adopts the following versions of the United States Core Data for Interoperability standard:

(a) *Standard*. United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2025.

(b) *Standard*. United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (incorporated by reference, see § 170.299).

Preamble FR Citation: 88 FR 23762 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23884 for estimates related to this proposal.

§ 170.213 - The United States Core Data for Interoperability Standard (USCDI) v3

Public Comment Field: The AMA supports ONC's USCDI efforts to promote the establishment and use of interoperable data sets of EHI for interoperable data exchange as well as to follow a predictable, transparent, and collaborative process to expand future versions of the USCDI. We support additions to the USCDI Version 3 (USCDI v3), which focuses on promoting equity, reducing disparities, and supporting public health data interoperability. Overall, USCDI v3 builds on USCDI v2, and adds 24 data elements across six of its data classes.

However, USCDI v3 includes many data elements often considered sensitive, such as social determinants of health, sexual orientation, and gender identity. As noted throughout our public comments, sharing of such data without guardrails can pose significant patient safety issues for some individuals. There have been misunderstandings and misuse of current USCDI versions whereby Actors have required sharing of all data elements even when not needed. **The AMA recommends that ONC move forward with the granular data segmentation policy changes included in our comments concurrently with adopting USCDI v3. In many instances, it will be inappropriate to share all USCDI v3 elements unless granular segmentation is enabled to protect privacy related to sensitive data elements, in accordance with patient preference, state and federal law and regulation.** Moreover, the AMA recommends that ONC redouble its educational campaign around USCDI. We want to ensure that the community is educated that USCDI is the standard for data required to be accessible through certified health IT for numerous certification criteria and that adoption of a new USCDI version does not indicate required sharing of such data, especially if a patient requests to restrict sharing of such data.

§ 170.207 - "Minimum Standards" Code Sets Updates

We propose to adopt newer versions of the following minimum standards code sets:

(a)* * *

(1) *Standard*. IHTSDO SNOMED CT®, U.S. Edition, March 2022 Release (incorporated by reference, see § 170.299).

* * * * *

(c)* * *

(1) *Standard*. Logical Observation Identifiers Names and Codes (LOINC®) Database Version 2.72, February 16, 2022, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference, see § 170.299).

* * * * *

(d)* * *

(1) *Standard*. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, July 5, 2022 Full Monthly Release (incorporated by reference, see § 170.299).

* * *

(4) *Standard.* The code set specified at 45 CFR 162.1002(b)(2).

* * * * *

(e)* * *

(1) *Standard*. HL7 Standard Code Set CVX - Vaccines Administered, updates through June 15, 2022 (incorporated by reference, see § 170.299).

(2) *Standard*. National Drug Code Directory (NDC) - Vaccine NDC Linker, updates through July 19, 2022 (incorporated by reference, see § 170.299).

* * * * *

(f)* * *

(3) *Standard*. CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021) (incorporated by reference, see § 170.299).

* * * * *

(m)* * *

(1)* * *

(2) *Standard*. The Unified Code of Units of Measure, Revision 2.1, November 21, 2017 (incorporated by reference, see § 170.299).

(n)* * *

(1) *Standard.* Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see § 170.299), up until the adoption of this standard expires January 1, 2026, attributed as follows:

(i) Male. M; (ii) Female. F; (iii) Unknown. nullFlavor UNK.

§ 170.207 - "Minimum Standards" Code Sets Updates

(2) *Standard.* Sex must be coded in accordance with, at a minimum, the version of SNOMED CT ® codes specified in § 170.207(a)(1).

(3) *Standard.* Sex for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC ® codes specified in § 170.207(c)(1).

(o) *Sexual orientation and gender information*--(1) *Standard*. Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED-CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see § 170.299), up until the adoption of this standard expires on January 1, 2026, for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

(i) *Lesbian, gay or homosexual.* 38628009

(ii) *Straight or heterosexual.* 20430005

(iii) *Bisexual.* 42035005

(iv) *Something else, please describe.* nullFlavor OTH

(v) *Don't know.* nullFlavor UNK

(vi) *Choose not to disclose.* nullFlavor ASKU

(2) *Standard*. Gender identity must be coded in accordance with, at a minimum, the version of SNOMED-CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), up until the adoption of this standard expires January 1, 2026, for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

(i) *Male.* 446151000124109

(ii) *Female.* 446141000124107

(iii) *Female-to-Male (FTM)/Transgender Male/Trans Man.* 407377005

(iv) *Male-to-Female (MTF)/Transgender Female/Trans Woman.* 407376001

(v) *Genderqueer, neither exclusively male nor female.* 446131000124102

(vi) *Additional gender category or other, please specify.* nullFlavor OTH

(vii) *Choose not to disclose.* nullFlavor ASKU

(3) *Standard*. Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in § 170.207(a)(1).

(4) *Standard.* Pronouns must be coded in accordance with, at a minimum, the version of LOINC codes specified in 170.207(c)(1).

(p)* * *

(1) *Financial resource strain.* Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC ® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC ® code 76513-1 and LOINC ® answer list ID LL3266-5.

(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® code 63504-5 and

LOINC® answer list ID LL1069-5.

(3) *Stress.* Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3.

(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL361-7), 44255-8 (with LOINC® answer list ID LL361-7), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

(5) *Physical activity.* Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2).

(6) *Alcohol use.* Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

(7) *Social connection and isolation.* Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76511-5 (with LOINC answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: Intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) of this section and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)).

* * * * *

(r)* * *

(2) *Standard*. Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, October 29, 2021 (incorporated by reference, see § 170.299).

(s)* * *

(2) *Standard*. Public Health Data Standards Consortium Source of Payment Typology Code Set Version 9.2 (December 2020) (incorporated by reference, see § 170.299).

§ 170.207 - "Minimum Standards" Code Sets Updates

Preamble FR Citation: 88 FR 23768 **Specific questions in preamble?** No

Regulatory Impact Analysis: Please see 88 FR 23880 for estimates related to this proposal.

Public Comment Field: The AMA recommends ONC add "Target of perceived adverse discrimination and persecution" among the minimum standards.

The Office of Management and Budget (OMB) recently proposed updates to race and ethnicity statistical standards. One of the main considerations driving the proposed updates was the increasing number of uncategorized responses due to respondents not feeling represented by the categories provided or being forced to choose only one category. ONC's code set update should include granular categories and the ability to select more than one category.

ONC should also consider adding a category of Middle Eastern or North African, with more granular categories provided. Similarly, the OMB proposed updates collapse race and ethnicity into a single question. We recommend ONC begin preparing for this technical shift, while upholding the current standards, to avoid unnecessary delays. Further, ONC should consider offering gay and lesbian as separate answer choices.

§ 170.315(f)(5) - Electronic Case Reporting

Included in Base EHR Definition? No

(5) *Transmission to public health agencies – electronic case reporting.* (i) Enable a user to create an electronic case report for transmission meeting the requirements described in paragraphs (f)(5)(i)(A) through (C) of this section for the time period up to and including December 31, 2024; or meet the requirements described in paragraph (f)(5)(ii) of this section.

(A) Consume and maintain a table of trigger codes to determine which encounters may be reportable.

(B) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.

(C) Create a case report for electronic transmission based on a matched trigger from paragraph (f)(5)(i)(B) of this section and including at a minimum:

(1) The data classes expressed in the standards in § 170.213.

(2) Encounter diagnoses information formatted according to the standard specified in § 170.207(i) or the version of the standard specified in § 170.207(a)(1).

(3) The provider's name, office contact information, and reason for visit.

(4) An identifier representing the row and version of the trigger table that triggered the case report.

(ii) Enable a user to create a case report for electronic transmission in accordance with the following:

(A) Consume and process electronic case reporting trigger codes and parameters and identify a reportable patient visit or encounter based on a match from the Reportable Conditions Trigger Code value set in § 170.205(t)(4) received from the eRSD profiles as specified in the HL7 FHIR eCR IG in § 170.205(t)(1).

(B) Create a case report consistent with at least one of the following standards:

§ 170.315(f)(5) - Electronic Case Reporting

(1) The eICR profile of the HL7 FHIR eCR IG in § 170.205(t)(1), or

(2) The eICR profile of the HL7 CDA eICR IG § 170.205(t)(2).

(C) Receive, consume, and process a case report response that is formatted to either the reportability response profile of the HL7 FHIR eCR IG in § 170.205(t)(1) or the HL7 CDA RR IG in § 170.205(t)(3).

(D) Transmit a case report electronically to a system capable of receiving an electronic case report.

* * * * *

Preamble FR Citation: 88 FR 23769 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23886 for estimates related to this proposal.

Public Comment Field: The AMA supports ONC's plan towards greater standardization and specification of electronic case reporting (eCR), and the move from functional requirements to standards-based requirements to improve consistency of implementations and interoperability over time. We recognize public health surveillance as a core public health function that is essential to inform decision making, identify underlying causes and etiologies, and respond to acute, chronic, and emerging health threats while acknowledging the important role that physicians play in public health surveillance through reporting diseases and conditions to public health authorities.

The AMA also supports the Centers for Disease Control and Prevention's (CDC) Data Modernization Initiative (DMI)[1], including eCR, as it helps alleviate the burden of case reporting on physicians through the automatic generation and transmission of case reports from EHRs to public health agencies for review and action in accordance with applicable health care privacy and public health reporting laws. Support for DMI accompanies 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 incentives could assist physicians in upgrading their EHR systems to support eCR. Federal coordination and funding will also support the modernization and standardization of public health surveillance systems used by CDC and state and local health departments. Overall, the AMA supports data standardization that provides for minimum national standards, while preserving the ability of states and other entities to exceed national standards based on local needs and/or the presence of unexpected urgent situations.

[1] https://www.cdc.gov/surveillance/data-modernization/index.html

§ 170.315(b)(11) – Decision Support Interventions (DSI)

Included in Base EHR Definition? Yes

(11) *Decision support interventions*--(i) *Decision support intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.

(ii) *Decision support configuration.* (A) Enable interventions and reference resources specified in paragraphs (b)(11)(iii) and (iv) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) Enable interventions:

(1) Based on the following data expressed in the standards in § 170.213, at a minimum:

(i) Problems;

(ii) Medications;

(iii) Allergies and Intolerances;

(iv) At least one demographic specified in paragraph (a)(5)(i) of this section;

(v) Laboratory;

(vi) Vital Signs;

(vii) Unique Device Identifier(s) for a Patient's Implantable Device(s).; and

(viii) Procedures.

(*2*) When a patient's medications, allergies and intolerance, and problems are incorporated from a transition of care or referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

(C) Enable end users to provide electronic feedback based on information displayed through the intervention and make available such feedback data for export, in a computable format, including but not limited to the intervention, action taken, user feedback provided (if applicable), user, date, and location.

(iii) *Evidence-based decision support interventions.* Enable a limited set of identified users to select (i.e., activate) electronic decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on any of the data referenced in paragraphs (b)(11)(ii)(B)(*1*)(*i*) through (*vii*) of this section.

(iv) *Linked referential DSI.* (A) Identify for a user diagnostic and therapeutic reference information in accordance with at least one of the following standards and implementation specifications:

(1) The standard and implementation specifications specified in § 170.204(b)(3).

(2) The standard and implementation specifications specified in § 170.204(b)(4).

(B) For paragraph (b)(11)(iv)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (b)(11)(ii)(B)(*1*)(*i*), (*ii*), and (*iv*) of this section.

(v) *Predictive decision support interventions attestation.* Health IT developers must make one of the following attestations:

(A) Yes – the Health IT Module enables or interfaces with one or more predictive decision support

interventions as defined in § 170.102 based on any of the data expressed in the standards in § 170.213.

(B) No – the Health IT Module does not enable or interface with one or more predictive decision support interventions as defined in § 170.102 based on any of the data expressed in the standards in § 170.213.

(vi) *Source attributes.* Enable a user to review a plain language description of source attribute information as indicated and at a minimum via direct display, drill down, or link out from a Health IT Module:

(A) For evidence-based decision support interventions under paragraph (b)(11)(iii) of this section:

(1) Bibliographic citation of the intervention (clinical research or guideline);

(2) Developer of the intervention (translation from clinical research or guideline);

(3) Funding source of the intervention development technical implementation; and

(4) Release and, if applicable, revision dates of the intervention or reference source;

(5) Use of the patient demographics and observations data specified in paragraph (a)(5)(i) of this section;

(6) Use of Social Determinants of Health data as expressed in the standards in § 170.213; and

(7) Use of Health Status Assessments data as expressed in the standards in § 170.213.

(B) For linked referential DSI in paragraph (b)(11)(iv) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research or guideline).

(C) For Health IT Modules that enable or interface with one or more predictive decision support interventions, as described in paragraph (b)(11)(v)(A) of this section, source attributes in paragraph (b)(11)(vi)(A) of this section and the following:

(1) Intervention details:

(i) Output of the intervention;

(ii) Intended use of the intervention;

(iii) Cautioned out-of-scope use of the intervention;

(*2*) Intervention development:

(i) Input features of the intervention including description of training and test data;

(ii) Process used to ensure fairness in development of the intervention;

(iii) External validation process, if available;

(*3*) Quantitative measures of intervention performance:

(i) Validity of prediction in test data;

(ii) Fairness of prediction in test data;

(iii) Validity of prediction in external data, if available;

(iv) Fairness of prediction in external data, if available;

(v) References to evaluation of use of the model on outcomes, if available;

(*4*) Ongoing maintenance of intervention implementation and use:

(*i*) Update and continued validation or fairness assessment schedule;

§ 170.315(b)(11) – Decision Support Interventions (DSI)

(ii) Validity of prediction in local data, if available;

(iii) Fairness of prediction in local data, if available.

(D) A Health IT Module must clearly indicate when a source attribute listed in paragraphs (b)(11)(vi)(A), (B), or (C) of this section, as applicable, is not available for the user to review, including when:

(1) The source attribute includes the "if available" phrase; or

(2) The decision support intervention, enabled by or interfaced with the Health IT Module, is developed by other parties that are not developers of certified health IT.

(E) Enable a limited set of identified users to author and revise source attributes and information beyond source attributes listed in paragraphs (b)(11)(vi)(A) and (b)(11)(vi)(C) of this section, as applicable.

(vii) *Intervention Risk Management.* By December 31, 2024, a health IT developer that attests "yes," in § 170.315(b)(11)(v)(A) must:

(A) Employ or engage in the following intervention risk management practices for all predictive decision support interventions, as defined in § 170.102, that the Health IT Module enables or interfaces with:

(1) *Risk analysis*. Analyze potential risks and adverse impacts associated with a predictive decision support intervention for the following characteristics: validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy.

(2) *Risk mitigation*. Implement practices to mitigate risks, identified in accordance with § 170.315(b)(11)(vii)(A)(*1*), associated with a predictive decision support intervention; and

(3) *Governance*. Establish policies and implement controls for predictive decision support intervention governance, including how data are acquired, managed, and used in a predictive decision support intervention.

(B) Compile detailed documentation regarding the intervention risk management practices listed in paragraph (b)(11)(vii)(A) of this section and upon request from ONC, make available such detailed documentation for any predictive decision support intervention, as defined in § 170.102, that the Health IT Module enables or interfaces with.

(C) Submit summary information of the intervention risk management practices listed in paragraph (b)(11)(vii)(A) of this section to its ONC-ACB via publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

(D) Review annually and, as necessary, update documentation described in paragraphs (b)(11)(vii)(B) and (b)(11)(vii)(C) of this section.

Preamble FR Citation: 88 FR 23774 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23889 for estimates related to this proposal.

Public Comment Field: In addition to the comments the AMA made in our accompanying letter, the AMA recommends ONC consider adding "problem formulation" after *(i) Input features of the intervention including description of training and test data* but before *(ii) Process used to ensure fairness in development of the intervention* under "Intervention development." ONC should also outline more specificity in the

§ 170.315(b)(11) – Decision Support Interventions (DSI)
assessment of potential disparate impacts or opportunities to close gaps between groups. For example, ONC could further specify “Intended use of the intervention” and “Input features of the intervention including description of training and test data” with “Explicit mention of specific populations.”

§170.315(a)(5) Patient Demographics and Observations Certification Criterion

Included in Base EHR Definition? Yes

(a)* * *

(5) Patient demographics and observations. (i) Enable a user to record, change, and access patient demographic and observations data including race, ethnicity, preferred language, sex, sex for clinical use, sexual orientation, gender identity, name to use, pronouns, and date of birth.

(A)* * *

(*1*) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify race.

(*2*) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify ethnicity.

* * * * *

(C) *Sex.* Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1) for the time period up to and including December 31, 2025; or § 170.207(n)(2).

(D) *Sexual orientation.* Enable sexual orientation to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(1) for the time period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify sexual orientation.

(E) *Gender identity.* Enable gender identity to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(2) for the time period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify gender identity.

(F) *Sex for Clinical Use.* Enable a patient's sex for clinical use to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(3). Conformance with this paragraph is required by January 1, 2026.

(G) *Name to Use.* Enable a patient's preferred name to use to be recorded. Conformance with this paragraph is required by January 1, 2026.

(H) *Pronouns.* Enable a patient's preferred pronouns to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(4). Conformance with this paragraph is required by January 1, 2026.

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Preamble FR Citation: 88 FR 23819 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23895 for estimates related to this proposal.

Public Comment Field: The AMA supports the voluntary inclusion of a patient's biological sex, current gender identity, sexual orientation, preferred gender pronoun(s), preferred name, and sex specific anatomy in medical documentation and in a culturally sensitive and voluntary manner. An individual's genotypic sex, phenotypic sex, sexual orientation, gender, and gender identity are not always aligned or indicative of the other, and that gender for many individuals may differ from the sex assigned at birth. Further, sexual orientation, sex, and gender identity are not binary. Terms such as "clinical sex" or "sex for clinical use" could be used against gender minority people. Any term, no matter how well intended or stated, can be

§170.315(a)(5) Patient Demographics and Observations Certification Criterion

misused**,** or used for harm.

Terms "biological sex," "sex for clinical use," or "clinical sex" do not account for an individual's organs that may need to be monitored, such as for prostate, cervical or breast cancer, and the physician or medical team must still account for organs and hormonal levels with or without hormonal treatments. Many transgender men, whose doctors are not informed, may misunderstand, asking or advising about birth control options. It could be implied that they are being treated as if they are "male for clinical purposes," and physicians may not consider that they may have a cervix, uterus, ovaries, and fallopian tubes and could become pregnant.

As such, the AMA does not support ONC's proposal use of "sex for clinical use" and recommends the use of "sex assigned at birth."

§ 170.315(d)(14) - Patient Requested Restrictions Certification Criterion

Included in Base EHR Definition? No

(d)* * *

(14) Patient requested restrictions.

(i) For any data expressed in the standards in § 170.213, enable a user to flag whether such data needs to be restricted from being subsequently used or disclosed as set forth in 45 CFR § 164.522; and

(ii) Prevent any data flagged pursuant to paragraph (d)(14)(i) of this section from being included in a use or disclosure.

Preamble FR Citation: 88 FR 23821 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23898 for estimates related to this proposal.

Public Comment Field: The AMA supports ONC's belief that individuals should be provided a reasonable opportunity and technical capability to make informed decisions about the collection, use, and disclosure of their EHI. Through the AMA Privacy Principles, we are working to ensure that as health information is shared—particularly outside of the health care system—patients have meaningful controls over and a clear understanding of how their data is being used and with whom it is being shared. Above all, patients must feel confident that their health information will remain private. Preserving patient trust is critical.

The AMA supports the addition of a new *Patient Requested Restrictions Certification Criterion* to ensure that individuals are provided a reasonable opportunity and technical capability to make informed decisions about the collection, use, and disclosure of their EHI. To that end, the AMA encourages the incentivization of standards-based technology to promote interoperability. Although some stakeholders may assert that a standards-agnostic approach would lead the private sector to come to consensus on their own, we would advise that this has not proven successful in the past.

However, given the immaturity of the current standards, the AMA strongly supports federally-funded connectathons and other policy-driven approaches intended to stimulate the developer community to

implement toward a particular use case with the purpose of advancing standards development. Even under the best circumstances, patients and most physicians are not able to drive standards and technology development.

Ultimately, the AMA recommends leveraging the HL7 Data Segmentation for Privacy (DS4P) Fast Healthcare Interoperability Resources (FHIR) Implementation Guide (IG) in a stepwise maturity model. With the appropriate federal support and funding, DS4P FHIR shows the most promise within the next several years.

There are challenges associated with the other alternatives ONC proposed in the Regulation. The Healthcare Classification System (HCS) Security Label Vocabulary is a high-level standard that provides a complex layout of a health care classification. The AMA would therefore not recommend this standard as the basis for interoperability. The HL7 Clinical Document Architecture (CDA) DS4P IG and the HL7 FHIR DS4P IG are instantiations of HCS with specific guidance on technical implementation that would be suitable for vendors. While CDA is still a common means of data sharing in this country, FHIR is more flexible and the FHIR DS4P IG provides the most recent and complete security labels and tags as well as being actively piloted across several domains.

Segmentation tagging standards and terminology hierarchies are only pieces of the larger workflow. An individuals' ability to exert preferences on data sharing involves several other requirements, including:

- Patient consent standards and implementation profiles, i.e., an indication of the desire to request restrictions.
- A policy adhering to those restrictions.
- The technical ability to restrict disclosures based on those consent rules, leveraging security labels.

Work on a consent framework is underway. The IHE Privacy Consent on FHIR, Stewards of Change Institute, and others are developing FHIR consent tools and consent management platforms.

The AMA supports a maturity model with a limited set of codes. We recommend starting with a minimum viable code set covering the most common use cases to encourage health IT developer implementation of DS4P FHIR—incrementally adding to the code sets as the industry moves forward and the bar is raised.

It is important to note some possible unintended consequences surrounding the implementation of data segmentation standards, including:

- It is almost impossible to guarantee that data will be completely segmented from all areas of the record and completely impossible to avoid inference. Specifically, data may already have been shared with downstream systems. Patients need to be informed and understand that data may leak into other areas of the chart; they also need to understand the clinical risks of not fully sharing their health information with physicians or other health care providers. **ONC should work with stakeholders to define clear and reasonable expectations as well implementation guidance such as informed consent.**
- Reference implementations are needed to demonstrate granular segmentation standards built on existing consent management platform technology. These implementations must ensure

§ 170.315(d)(14) - Patient Requested Restrictions Certification Criterion

additional burden is not placed on physicians, providers, or health systems to indicate patient data sharing choices. Optimal solutions should address prospective data as well as the ability to redact and withdraw information. **This is especially important when jurisdictional laws or person-centered circumstances change and where not having the ability to withdraw consent and redact data may cause patient harm.**

The AMA has heard from health IT developers that implementing granular segmentation of data would be at a significant cost. However, we strongly believe that the cost of not moving forward with policy-driven adoption of data segmentation will increase disparities, medical mistrust, and decrease quality of care. ONC has implemented policy related to other areas of patient concern, such as information blocking, where there is less data supporting the association with trust and quality of care. We are concerned that certified health IT developers will attempt to pass these costs on to their physician customers. **As stated previously in this letter, ONC should consider leveraging its Conditions and Maintenance of Certification requirements to curb unreasonable health IT developer fees.**

Laboratory Data Interoperability Request for Information

We seek public comment generally on any topics identified for the Consolidated Appropriations Act, 2023, Section 2213(b) study on the use of standards for electronic ordering and reporting of laboratory test results, such as the use of health IT standards by clinical laboratories, use of such standards by labs and their effect on the interoperability of laboratory data with public health systems, including any challenges of the types identified above. We also seek comment on whether ONC should adopt additional standards and laboratory-related certification criteria as part of the ONC Health IT Certification Program.

Preamble FR Citation: 88 FR 23847 **Specific questions in preamble?** Yes

Public Comment Field: The AMA is supportive of the work underway at ONC to examine laboratory data interoperability. We agree that the COVID-19 pandemic highlighted gaps in laboratory data exchange, particularly in reporting test results. It is imperative that our community advance standards-based exchange between ordering clinicians and laboratories' in vitro diagnostics systems and laboratory information systems, and from laboratory systems to public health agencies. **ONC's policies should also consider the needs of small, solo, and rural physician practices working on the front lines of public health and recognize their challenges in adopting and using health IT.**

The AMA encourages ONC to add a data element at the point of ordering and reporting that flags when race is included in the calculation of a laboratory result (e.g., estimated glomerular filtration rate). This would support hospital-based and independent laboratories in reassessing their use of historical race-based calculations and assist in moving to more equitable options when options exist. This would also help clinicians and patients factor race-based calculations into their shared decision-making.

The usability and standardization of laboratory report results can impact patient safety. **ONC should coordinate an effort to standardize laboratory data formats for the presentation of test results, including clearly identifiable diagnoses.**

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

We request comment from the public about specific issues related to establishing a certification criterion utilizing NCPDP RTPB standard version 12, as well as other potential actions in the Program that could support complementary and interoperable workflows. Given the statutory definition in PHSA § 3000(13) of "qualified electronic health record" as an electronic record of health-related information on an individual that includes, or is capable of including, RTBT functionality, we seek to understand whether ONC should offer or require certification of other capabilities to optimize the value of real-time prescription benefit capabilities to clinicians and patients.

Preamble FR Citation: 88 FR 23848 **Specific questions in preamble?** Yes

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

Public Comment Field: The AMA appreciates the opportunity to offer our comments regarding incorporating real-time benefit tools (RTBTs) within the ONC Health IT Certification Program (Program). The AMA strongly supports ONC's intention to adopt and reference the National Council for Prescription Drug Programs (NCPDP) real-time prescription benefit (RTPB) standard due to the increased transparency standardized RTPB will bring to both physicians and patients at the point of care regarding utilization management (e.g., prior authorization [PA]) requirements, formulary design, and patient financial responsibility. We commend ONC for recognizing the need for real-time, patient-specific prescription drug coverage information at the point of prescribing and for considering requiring adherence to the RTPB standard for ONC Program certification.

Provision of accurate, current information about a patient's prescription benefit will enable physicians and patients to evaluate drug costs and consider possible alternative therapies when selecting a medication regimen. Additionally, and equally importantly, provision of these data within the e-prescribing workflow will ensure physician awareness and completion of PA and step therapy requirements before a patient arrives at the pharmacy to pick up a prescription. In a 2021 survey, 65 percent of physicians reported that it is difficult to determine whether a prescription medication requires PA, illustrating a clear need for RTBTs.[1] Moreover, transparency of coverage restrictions in EHRs has significant potential to prevent medication nonadherence and treatment abandonment; right now, 80 percent of physicians indicate that PA can lead to treatment abandonment.[2]

If RTBTs are seamlessly integrated into the prescribing workflow, they have the potential to significantly improve patient-physician relationships. A recent study reported that 89.5 percent of patients would want their physician to use a RTBT, if it was available, to talk with them about their estimated prices for medications.[3] Having access to real-time coverage and pricing information at the point of prescribing will allow physicians to have well-informed conversations with patients about their care options, elevating the likelihood of improved care outcomes and stronger patient-physician relationships.

NCPDP has been developing an electronic RTPB standard since 2014, and the AMA has actively participated in the RTPB standard's development since its inception. The AMA has previously urged both ONC and CMS to ensure that updated SCRIPT and RTPB standards are widely available in the EHR developer market prior to placing any requirements on physicians for adoption (e.g., ONC EHR certification or CMS PI measures), and the AMA appreciates ONC considering adherence to the NCPDP RTPB standard for ONC Program certification. The AMA supports ONC utilizing the NCPDP RTPB standard for RTBT functionality certification with **two important caveats that will ensure that physicians experience the full value of this technology:**

- **Pharmacy benefit managers (PBMs) must also be required to support the NCPDP RTPB standard.** This is particularly important, given current regulatory requirements: Part D plans are only required to support a single RTBT that integrates with at least one EHR product. This lack of standardization has hindered widespread adoption of RTBTs, as proprietary tools with inconsistent availability of prescription drug coverage data across all patients and plans discourage utilization. **While the AMA generally supports inclusion of the NCPDP RTPB standard in future ONC certification, we stress the need for a concurrent update to the Part D program to require use of the NCPDP RTPB standard by prescription drug plans.**

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

- **Prior to requiring RTBT certification under the ONC Program, EHR developer and any intermediaries must test RTBTs with real-world physicians, other clinicians, and pharmacies.** Again, the AMA strongly believes that RTBTs could be a major "game-changer" in improving drug pricing transparency, informing therapy selection in alignment with patient cost concerns, and reducing administrative burdens associated with prescription rework. **However, poor initial experiences with RTBTs—whether it be through clunky user interfaces or inaccurate, unreliable information—will serve as a major disincentive to physician adoption of RTBTs. Because there will only be one chance to make a positive first impression on physicians, it is critical that EHR and RTBT vendors sufficiently test their products in real-world practice settings prior to widespread deployment.**

Included below are the AMA's recommendations related to specific topics addressed in the RFI:

- **The AMA supports NCPDP's request to consider v13 of the RTPB standard rather than v12, as referenced in the RFI.**
    - We agree with NCPDP's recommendation that CMS adopt NCPDP RTPB Version 13 (vs. Version 12) due to enhancements offered in the newer version.
- **The RTPB standard's two syntax (Electronic Data Interchange [EDI] & Extensible Markup Language [XML]) format presents potential challenges that must be considered when establishing Program certification requirements.**
    - The NCPDP RTPB standard supports both XML and EDI to allow flexibility; however, the AMA continues to be concerned that translating from one syntax to the other may present information exchange challenges. Given the RTPB standard's limited real-world testing, it is difficult to predict the impact any syntax translation challenges will have on interoperability.
    - In response to ONC's question about whether the ONC Program certification criteria should require and test only the XML format or both XML and EDI formats, the AMA believes that every RTBT system should be able to communicate in both XML and EDI, whether the translation occurs through an intermediary or via the core RTBT system "speaking" both syntaxes. It is worth noting that the NCPDP RTPB standard does not require implementers to support both syntaxes and allows implementers to use intermediaries to facilitate translation. Therefore, while it is critical that any system be able to send and receive RTPB transactions in either syntax—whether or not this is through an intermediary—any ONC Program certification requirements should only require testing against one syntax. However, any RTBT system that is certified in only one format must attest that it integrates with a third-party translation system that allows the RTBT to send and respond to either XML or EDI. As discussed later, the AMA recommends that ONC also consider creating a module to support certification of intermediaries providing such translation services.
- **In an RTPB Request, NDC should be required, and RxNorm Codes should remain situational.**
    - Under the NCPDP RTPB standard, in an RTPB Request, providing an NDC is required while including RxNorm is situational. The AMA supports ONC adopting certification criteria that align with the RTPB standard's suggested requirements (i.e., NDC is required and RxNorm is situational). An NDC must be required to obtain accurate pricing information on an RTPB response. If an NDC is provided without an RxNorm code, pricing

information will still be sent by the PBM. If only an RxNorm code is provided, the plan will not be able to generate a pricing estimate if it does not process claims using RxNorm. Since RxNorm provides inconsistent value depending on the trading partners, there is no reason to elevate RxNorm from a situational to required element for certification purposes.

- **Clinical Segment, notably the requirement to include diagnosis information on an RTPB Request, should remain situational.**
    - The AMA has concerns about requiring inclusion of diagnosis information on an RTPB Request. While there are situations when including diagnosis codes in an RTPB Request may generate valuable information in the RTPB Response (e.g., indication-based formularies), the AMA does not support requiring a diagnosis on every RTPB Request. Diagnosis information usually will not impact a drug's coverage status or cost, and requiring this information will increase physician burdens due to the need to select the relevant diagnosis for the particular prescription. Additionally, patient privacy issues could be at stake if diagnoses were to be required in RTPB Requests; this is particularly true if a prescriber submits an RTPB Request with a diagnosis code, but no prescription is ultimately dispensed to the patient. The AMA supports maintaining diagnosis codes as a situational data field. We also recommend inclusion of any indications-based formulary restrictions on a particular drug in RTPB Responses, as this will alert clinicians that the diagnosis should be included in the electronic prescription.
- **Displaying Negotiated Price in an RTPB Response will offer limited value and should not be required.**
    - The AMA supports greater drug price transparency and appreciates ONC's intent to provide additional clarity regarding drug pricing by suggesting inclusion of the negotiated price in RTPB Responses. In the AMA's statement to the U.S. House of Representatives Committee on Ways & Means Subcommittee on Health on May 17, 2023, it was noted that a lack of transparency and competition in PBM markets could be driving drug prices up.[4] However, the AMA has concerns that providing negotiated price information at the point of prescribing will only negatively impact the RTBT experience for patients and physicians and do little to address the issue of rising drug costs. The goal of RTBTs, as ONC has stated, is to "enable the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identify coverage restrictions and alternatives when they exist." To achieve ONC's stated goal for RTBT, the RTPB Response does not need to include a drug's negotiated price, and the AMA has concerns that providing this information will have a detrimental rather than beneficial impact. Specifically, the additional information could confuse and distract physicians and patients, who will be reviewing the RTPB Response for the expected *out-of-pocket cost to the patient*—not the cost to the plan.
- **The Patient Segment should not be required for ONC Program Certification.**
    - The NCPDP RTPB standard does not include the same Patient Segment as the SCRIPT standard, and the AMA cautions ONC against considering elements included within one NCPDP standard as fungible with elements in another standard. The Patient Segment information that is included in the SCRIPT standard cannot be easily incorporated into the RTPB standard, as v13 of the RTPB standard does not already include this element. Since NCPDP does not have a universal patient identifier, incorporating the Patient Segment into the RTPB standard would require developing an updated version. The AMA has concerns that requiring inclusion of a Patient Segment in the RTPB standard could have a significant negative impact on RTBT interoperability and utilization, as well as delay implementation

of this technology that will support drug coverage and pricing transparency at the point of care.

- **Third-party applications and other intermediaries (e.g., translation tools) will play an important role in facilitating interoperable RTBTs, and the ONC Program certification criteria must take into account the different roles third-party entities will play in a successful RTBT process and adjust the certification criteria accordingly.**
    - RTBT at its core is an add-on service to an already implemented EHR. However, implementing an RTBT may involve multiple add-on services (e.g., an intermediary that translates an RTBT application's XML data into EDI format). In these scenarios where niche service providers are providing supplemental services to the RTBT's base application, the add-on service provider will need to certify that its technology can do what it is purporting to do. However, requiring a translation service provider to demonstrate compliance with other elements of the RTPB standard unrelated to translation would be unreasonable and deliver no value for physicians; moreover, it could result in higher costs to use that niche technology. ONC should consider a modular approach to RTBT certification, with EDI-to-XML translation existing in its own module. This would allow either a RTBT or an intermediary to certify the translation functionality.
- **An RTBT must provide real-time utilization management (e.g., PA and step therapy) information, and electronic PA (ePA) should be a required element for EHR certification.**
    - The AMA strongly supports adoption of standard prescription drug ePA technology that integrates with physicians' EHR workflow and provides a uniform user experience across PBMs. The addition of the NCPDP SCRIPT ePA transactions to the ONC Program will significantly increase physicians' access to this valuable tool, as well as support a seamless workflow from RTBT checks to ePA for those drugs that require PA. **In contrast, the AMA does not support ONC requiring formulary and benefit (F&B) for EHR certification as a tandem transaction.** As a batch (vs. real-time) standard, F&B data are frequently outdated and/or provided at too general of a level (i.e., plan vs. group) to be useful to physicians and patients. Moreover, conflicting data from F&B and RTBTs could result in physician and patient confusion. As such, we believe that ONC should not pursue certification for F&B and instead prioritize the real-time, patient-specific data offered by RTBTs for certification.
- **ONC should consider JavaScript Object Notation (JSON)-based standards for future certification requirement criteria development.**
    - At the May 2023 NCPDP Workgroup meeting in Scottsdale, Arizona, the membership voted overwhelmingly to develop future versions of the RTPB standard in JSON rather than the current XML and EDI options. In the pharmacy industry, JSON has been gaining momentum as the syntax of choice, and NCPDP's recent decision to develop future RTPB and other XML standards in JSON is another indication of the industry's commitment towards JSON. That said, the v13 RTPB standard (with both XML and EDI options) is currently the best choice for RTBT certification under the ONC Program, despite the potential translation challenges. ONC should consider JSON-based standards when developing future certification criteria, depending on industry readiness and feedback.

[1] 2021 Update: Measuring progress in improving prior authorization. Available at: https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

[2] 2022 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-

survey.pdf.

[3] Dusetzina SB, Besaw RJ, Whitmore CC, et al. Cost-related medication nonadherence and desire for medication cost information among adults aged 65 years and older in the US in 2022. *JAMA Netw Open*. 2023;6(5):e2314211. doi:10.1001/jamanetworkopen.2023.14211.

[4] See https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfcsot.zip%2F2023-5-17-WMs-Health-SubCmt-Statement-for-the-Record-on-Anticompetitive-and-Consolidated-Markets-v2.pdf.

FHIR Subscriptions Request for Information

We seek input on the maturity of the following resources that enable FHIR Subscriptions: Subscription, SubscriptionTopic and SubscriptionStatus in the FHIR Release 4 standard that is incorporated in 45 CFR 170.315(g)(10) of this proposed rule. Additionally, we seek comment on whether the FHIR Subscriptions capability aligns with the adoption of the FHIR Release 5 standard, and whether alignment with FHIR Release 5 would avoid any costly refactoring of the resources and give more time for industry to test the various features and capabilities under development.

We request comment on whether there is a need to define a minimum set of Subscription Topics that can be consistently implemented by all health IT developers of certified health IT to provide a base level expectation of behavior for clients using the services; appropriate industry led activities to maintain and keep the artifacts up to date; and comment on security, channels, payloads, and any other areas that would need to be further specified to achieve our goal of providing this capability across all certified Health IT Modules in a consistent and standardized manner using an already adopted standard.

Preamble FR Citation: 88 FR 23855 **Specific questions in preamble?** Yes

Public Comment Field: ONC seeks comment on whether there is a need to define a minimum set of Subscription Topics that can be consistently implemented by all health IT developers of certified health IT. At a minimum, FHIR Subscriptions should enable physicians to utilize subscription capabilities that support prior authorization workflows. Further, the AMA urges ONC to ensure FHIR Release 5 backports to older FHIR versions, e.g., Release 4, that are still supported by health IT developers.

Clinical Decision Support Hooks Request for Information

Given the growing use of CDS and potential for CDS to improve clinical decision making, we request comment on the scope and maturity of the FHIR CDS Hooks specification v1.0, which we are considering for future inclusion as part of the Program. Recognizing that CDS Hooks does not prescribe a default or required set of hooks for implementers, we further request comment on specific hooks that we might include in future certification criteria (the CDS Hooks specification, for example, defines a small set of hooks), as well as input on use of CDS Hooks for supporting workflow improvement and reducing health care provider burden. To the extent commenters have specific CDS Hook use cases for supporting the latter, we welcome input on this including comment on the readiness and feasibility of such use cases including, as an example, for the screening and assessing of social risk and health related social needs or history.

Preamble FR Citation: 88 FR 23855 **Specific questions in preamble?** Yes

Public Comment Field: The current feasibility of social determinants of health (SDOH) clinical decision support (CDS) Hooks appears to be limited in its focus to prompt assessments. Assessment without availability of a meaningful intervention is problematic in clinical care. Future development of CDS hooks should look toward integration with electronic health-related social needs directories and referral systems and provide a menu of options customized to the patient's context once an assessment is completed.

§ 171.204 – Infeasibility Exception

§ 171.204 Infeasibility exception - When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking?

* * * * *

(a) *** (1) *Uncontrollable events*. The actor cannot fulfill the request for access, exchange, or use of electronic health information because of a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.

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(3) *Third party seeking modification use*. The request is to enable use of EHI in order to modify EHI (including but not limited to creation and deletion functionality) provided the request is not from a health care provider requesting such use from an actor that is its business associate.

(4) *Manner exception exhausted*. The actor is unable to fulfill a request for access, exchange, or use of electronic health information because paragraphs (i), (ii), and (iii) are all true.

(i) The actor could not reach agreement with a requestor in accord ance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested;

(ii) The actor offered all alternative manners in accordance with § 171.301(b) for the electronic health information requested but could not reach agreement with the requestor; and

(iii) The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.

(5) *Infeasible under the circumstances.* (i) The actor demonstrates, prior to responding to the request pursuant to paragraph (b) of this section, through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of the following factors that led to its determination that complying with the request would be infeasible under the circumstances:

(A) The type of electronic health information and the purposes for which it may be needed;

(B) The cost to the actor of complying with the request in the manner requested;

(C) The financial and technical resources available to the actor;

(D) Whether the actor's practice is non-discriminatory and the actor provides the same access, exchange, or use of electronic health information to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship;

(E) Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged; and

(F) Why the actor was unable to provide access, exchange, or use of electronic health information consistent with the exception in § 171.301.

(ii) In determining whether the circumstances were infeasible under paragraph (a)(3)(i) of this section, it shall not be considered whether the manner requested would have:

(A) Facilitated competition with the actor.

(B) Prevented the actor from charging a fee or resulted in a reduced fee.

§ 171.204 – Infeasibility Exception

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Preamble FR Citation: 88 FR 23865 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23903 for estimates related to this proposal.

Public Comment Field: (1) *Uncontrollable events*

The AMA supports the proposed revision to replace the words "due to" with "because of." The additional clarity is helpful to Actors. Actors will need to demonstrate that the public health emergency or other disaster caused the Actor to be unable to provide access, exchange, or use of EHI.

We also encourage ONC and the Office of Inspector General (OIG) to work with CMS and across the U.S. Department of Health and Human Services (HHS) to align this exception with public health emergency (PHE) declarations. When a PHE is declared, CMS can provide flexibilities and issue waivers as needed to accommodate those impacted by an emergency or disaster. **ONC should investigate whether it could provide similar reporting flexibilities that would help minimize administrative burden and increase efficiency for Actors, particularly physicians on the front lines delivering patient care during a PHE.**

For example, rather than having ONC and OIG require an Actor to demonstrate that the public health emergency actually caused the Actor to be unable to provide access, exchange, or use of EHI for the facts and circumstances in question, **ONC and OIG should use reporting and exceptions-related flexibilities issued *during* a PHE as a demonstration of cause. During a PHE or other disaster, the focus for Actors, and specifically physicians, should be on maintaining access to care to as many people impacted by an emergency or disaster as possible.** HHS should explore every authority it has to minimize burden when applying this exception.

(3) Third party seeking modification use.

The AMA supports the proposed modifications for when an Actor can use the Third Party Seeking Modification Use Condition of the Infeasibility Exception. We agree with the steps taken to increase efficiency as well as reduce burden and uncertainty. Information exchange moves at the speed of trust, and if an Actor does not trust the information from a third party, it should not be required to accept that information into an individual's record.

However, we encourage ONC to reconsider the implications of a third party's direct modification of an individual's designated record maintained by another Actor. **ONC and OIG should consider "modification" in terms of annotation—such that the Actor that holds the original designated record can clearly see any changes made.** When an annotation occurs, the originating record holder and third party can collaborate to determine what data should remain in a patient's designated record. **Pure modification of a patient's record by a third party—with no notations about what has changed—can negatively impact care delivery.** The AMA believes that mechanisms should be in place to track who

§ 171.204 – Infeasibility Exception

made the annotation, when, why, and how. These mechanisms should create an audit trail that an Actor can use to easily determine if the new information should be a permanent piece of an individual's record.

(4) Manner exception exhausted
The AMA supports the new "manner exception exhausted" condition and how it applies where an Actor is unable to fulfill a request for access, exchange, or use of EHI despite having exhausted the Content and Manner Exception. Adding this new condition provides clarity and advances the policy goal of fostering the use of standards-based interoperability in achieving access, exchange, or use of EHI.

Many small, solo, and rural physician practices have voiced concerns about circumstances where an Actor's inability to satisfy the Manner Exception's conditions is dependent on a requestor refusing to accept access, exchange, or use in *any* manner of data exchange. If these physician practices were required to fulfill the request in any manner requested, it could require the practice to use substantial technical or financial resources as well as incur significant opportunity costs.

Overall, the new "manner exception exhausted" condition supports standards-based data exchange while minimizing the burden on Actors. In addition, **ONC could further clarify this condition by specifying that Actors are required to offer a maximum of three alternative manners for the request to meet this condition, as long as at least one of those manners used either certified technology consistent with the Content and Manner Exception or used content and transport standards consistent with that exception.** Specifying a particular number for alternative manners would be more advantageous and instructive than simply stating "all alternative manners."

§ 171.301 - Manner Exception – TEFCA Reasonable and Necessary Activities

§ 171.301 Manner exception - When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

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An actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information will not be considered information blocking when the practice follows the conditions of this section.

(a) *Manner requested*. (1) An actor must fulfill a request for electronic health information in any manner requested, unless the actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested.

(2) If an actor fulfills a request for electronic health information in any manner requested:

(i) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

(ii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

(b) *Alternative manner*. If an actor does not fulfill a request for electronic health information in any manner requested because it is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested, the actor must fulfill the request in an

alternative manner, as follows:

(1) The actor must fulfill the request without unnecessary delay in the following order of priority, starting with paragraph (b)(1)(i) of this section and only proceeding to the next consecutive paragraph if the actor is technically unable to fulfill the request in the manner identified in a paragraph.

(i) Using technology certified to standard(s) adopted in part 170 that is specified by the requestor.

(ii) Using content and transport standards specified by the requestor and published by:

(A) The Federal Government; or

(B) A standards developing organization accredited by the American National Standards Institute.

(iii) Using an alternative machine-readable format, including the means to interpret the electronic health information, agreed upon with the requestor.

(2) Any fees charged by the actor in relation to fulfilling the request are required to satisfy the exception in § 171.302.

(3) Any license of interoperability elements granted by the actor in relation to fulfilling the request is required to satisfy the exception in § 171.303.

(c) *TEFCA manner*. If an actor who is a QHIN, Participant, or Subparticipant offers to fulfill a request for EHI access, exchange, or use for any purpose permitted under the Common Agreement and Framework Agreement(s) from any other QHIN, Participant, or Subparticipant using Connectivity Services, QHIN Services, or the specified technical services in the applicable Framework Agreement available to both parties, then:

(i) The actor is not required to offer the EHI in any alternative manner;

(ii) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

(iii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

(d) *Definitions*. The terms used in paragraph (c) of this section shall have the following meanings.

(1)(i) *Qualified Health Information Network (QHIN)* means a Health Information Network that is a U.S. Entity that has been Designated by the Recognized Coordinating Entity (RCE) and is a party to the Common Agreement countersigned by the RCE.

(ii) *Participant* means a U.S. Entity regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive information via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes.

(iii) *Subparticipant* mans a U.S. Entity regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either:

(A) a Participant-Subparticipant Agreement to use the services of a Participant to send and/or receive information; or

(B) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used of the Common Agreement to send and/or receive information.

(iv) *Connectivity Services* means the technical services provided by a QHIN.

(v) *Framework Agreement(s)* means any one or combination of the Common Agreement, a Participant-

§ 171.301 - Manner Exception – TEFCA Reasonable and Necessary Activities
QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable. (2) QHIN Services means any technical services provided within a QHIN.
Preamble FR Citation: 88 FR 23871 **Specific questions in preamble?** Yes
Regulatory Impact Analysis: Please see 88 FR 23903 for estimates related to this proposal.
Public Comment Field: The Trusted Exchange Framework and Common Agreement (TEFCA) Condition attempts to offer an additional approach to Actors to help facilitate reaching agreeable terms with a requestor for fulfillment of an EHI request. However, at this stage, the health care community is still in the process of establishing TEFCA as a viable means of exchange. The AMA views TEFCA as an opportunity to better enable all interested parties in having access to patients' longitudinal health record, but until the network is fully operational and all exchange parties realize the value of TEFCA, the TEFCA Condition should not be added to the Manner Exception. It is likely that this approach eventually aligns with the Cures Act's goals for interoperability and the establishment of TEFCA by acknowledging the value of TEFCA in promoting access, exchange, or use of EHI in a secure and interoperable way. **Still, we urge ONC to take a wait-and-see approach with adding this condition until TEFCA is fully established.** Information Blocking Actors should be encouraged to focus on other conditions, particularly the Alternative Manners Condition, available under the Manner Exception. Instituting a TEFCA Condition may be warranted once Actors that have chosen to become part of the TEFCA ecosystem begin to prioritize the use of this mechanism for exchange for sharing EHI with requestors who have also chosen to become part of the TEFCA ecosystem.