AMERICAN ACADEMY OF FAMILY PHYSICIANS

October 3, 2024

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

Re: RIN 0955–AA06; Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability

Dear National Coordinator Tripathi:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 130,000 family physicians and medical students across the country, I write to provide comments on the recent proposed rule from the Assistant Secretary for Technology Policy and Office of the National Coordinator (ASTP/ONC) for Health Information Technology (IT) on Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2).

The AAFP has long supported ASTP/ONC's efforts to advance interoperability of health IT. Interoperability is essential for ensuring family physicians have access to meaningful, actionable data at the point of care, which in turn enables them to provide high-quality, patient-centered care across the lifespan. Truly interoperable health records will also reduce administrative tasks for physicians and facilitate patients' access to their health data. We appreciate ASTP/ONC proposing several changes that seek to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. Among several other recommendations detailed in our comments, **the AAFP recommends ASTP/ONC**:

- **Not place requirements on physicians to use certified technology without also requiring physicians' exchange partners – frequently payers – do the same, and on the same timeline. Having all exchange partners use standardized, certified technology will better support the agency's goal of nationwide interoperability.**
- **Establish a standard process for the inclusion of new criteria into the Base Electronic Health Record (EHR) Definition. That standard process must include a system that creates a new criteria first as a modular criterion without inclusion in the Base EHR Definition.**
- **Finalize proposed modifications to the Privacy, Infeasibility, Protecting Care Access, and Requestor Preferences exceptions within information blocking regulations. We urge the agency to continue prioritizing simplification of the conditions under which each exception can be used, which would provide needed clarity for physicians and reduce their administrative burden.**

ONC Health IT Certification Program Updates

The United States Core Data for Interoperability Version 4 (USCDI v4)

The United States Core Data for Interoperability (USCDI) is a standard for data that must be accessible through certified health IT (EHRs and other health IT products) for numerous

certification criteria. ASTP/ONC proposes to update the USCDI standard to Version 4 (USCDI v4) to expand the amount of data available to be used and exchanged for patient care. Under this proposal, both USCDI Version 3 (USCDI v3) and USCDI v4 would be referenced as applicable in the USCDI standard for the time period up to and including December 31, 2027. USCDI v3 would expire in the USCDI standard on January 1, 2028.

The AAFP supports the proposal to advance to USCDI v4 and believes the updated version will likely improve data exchange across health care settings by including new and relevant data elements, thereby enhancing patient care. We believe ASTP/ONC should continue to advance USCDI to expand the breadth and depth of highly structured clinical data to support deep integration across EHR systems, and we believe the phased implementation proposed here allows sufficient time for health IT developers to update their systems and for health care practices to adapt to the new standards. Long-term, this will allow for more effective care coordination, which will ultimately improve patient outcomes. We urge ASTP/ONC to move forward with the proposal to advance to USCDI v4. This is an important step in improving the quality, safety, and efficiency of health care in the United States.

Minimum Standards Code Sets Updates

ASTP/ONC proposes to update the minimum standard code sets for race and ethnicity in § 170.207(f) to include recent changes in the Office of Management and Budget (OMB) standards and the Centers for Disease Control (CDC) standards.

The AAFP supports these proposed updates to the minimum standard code sets for race and ethnicity. These changes align with recent revisions to federal standards, as we have long called for, increasing harmonization across federal programs. The OMB and CDC standards align with the AAFP's policy to support the ability to disaggregate race and ethnicity data and to ensure health equity across all races and ethnicities. The phased implementation and clear expiration dates proposed for older standards provide a structured transition period for health IT developers and health care clinicians, promoting smoother adoption and minimizing disruption.

New Imaging Requirements for Health IT Modules

ASTP/ONC proposes to revise three certification criteria for Health IT Modules by adding new provisions to include support of an "imaging link" that would enhance access to diagnostic images. The agency proposes to define "imaging link" as "technical details which enable the electronic viewing or retrieval of one or more images over a network." Additionally, ASTP/ONC proposes to review the "view, download, and transmit to 3rd party" certification criterion to increase functional support for downloading of diagnostic quality and lower quality images. They also propose to add an imaging link to diagnostic images in Continuity of Care Documents (CCDs).

Though certification criterion from the 2014 Edition Proposed Rule allowed EHRs to link to images, it was removed in the 2015 Edition due to changes in the Centers for Medicare and Medicaid Services (CMS) EHR Incentive Program. Now, ASTP/ONC believes promoting access to and the exchange of images through links may encourage more widespread adoption and integration of these data pathways, as well as reducing burdens associated with physical media exchange. The agency proposes that Health IT Modules would be required to support this functionality on and after January 1, 2028.

The AAFP supports the proposed new imaging requirements for Health IT Modules. Enabling electronic access to diagnostic images through links in EHRs will significantly improve interoperability and reduce the burden of using physical media. This change will facilitate better care coordination and empower patients – supporting the AAFP's policy on patient-physician confidentiality – by providing easier access to their medical images. Primary care physicians and patients must function in a health care environment influenced by a complex web of legislation, regulation, and independent decisions of public and private payers. Navigating this complicated system of public regulations and private business decisions places primary care physicians in a situation that is increasingly burdensome, overwhelming, and a significant source of burnout. Even seemingly small changes, like ASTP/ONC has proposed here, can help reduce physician burden and improve their experience as an EHR user.

Revised Clinical Information Reconciliation and Incorporation Criterion

ASTP/ONC proposes to revise the "clinical information reconciliation and incorporation" certification criterion at (§ 170.315(b)(2)). These changes include:

- A primary proposal requiring Health IT Modules to reconcile and incorporate all USCDI data elements as per at least one version of the USCDI standard in § 170.213;
- An alternative proposal requiring Health IT Modules to reconcile and incorporate data elements from an additional six USCDI data classes beyond the three currently required;
- New functional requirements that would introduce user-driven automatic reconciliation and incorporation; and
- An implementation deadline of January 1, 2028, for health IT developers to have updated their modules to comply with these criteria and provide the updated version to customers.

The AAFP supports these proposed revisions to the clinical information reconciliation and incorporation criterion, with a strong recommendation that the primary proposal be finalized instead of the alternative. The primary proposal's requirement to include all USCDI data elements ensures comprehensive data integration, which is crucial for effective care coordination and patient safety. We believe information reconciliation and incorporation is a critical function of Health IT Modules, and we do not support watering down the criterion as outlined in the alternative proposal. Expanding the number and types of data elements to be reconciled and incorporated will reduce burden on physicians and staff, and it has the potential to enhance the completeness and accuracy of patient records. The proposed deadline of January 1, 2028, would allow ample time for developers and health care practices to implement these changes, promoting smoother transitions and minimizing disruptions. The AAFP hopes that this timeline would allow these new functional requirements for user-driven automatic reconciliation and incorporation to be streamlined in clinical workflows, which is critical to making the functionality usable.

Revised Electronic Prescribing Certification Criterion: Electronic Prescribing Standard

ASTP/ONC proposes to update the electronic prescribing certification criterion at § 170.315(b)(3) to permit health IT developers to maintain health IT certification compliance with the current version of the criterion, National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071, for the time period up to and including December 31, 2027. Beginning January 1, 2028, the agency proposes that developers be required to have updated to NCPDP SCRIPT standard version 2023011 and have provided that update to their

customers. ASTP/ONC also proposes to remove some of the transactions within the SCRIPT standard that are currently identified as optional.

The AAFP does not object to the proposed changes and outlined timeline for health IT developers to upgrade to NCPDP SCRIPT standard version 2023011 and has supported other policy proposals to advance the adoption and widespread use of NCPDP standards. We appreciate ASTP/ONC proposing consistent, phased implementations here and throughout this proposed rule so that developers and physicians can adequately plan and prepare for these updates.

Revised Electronic Prescribing Certification Criterion: Proposed Transactions

ASTP/ONC proposes to remove the requirement for Health IT Modules to support the "request and receive medication history" transactions (RxHistoryRequest, RxHistoryResponse) from the electronic prescribing certification criterion (§ 170.315(b)(3)(ii)(A)(6)), due to several challenges and low adoption rates. Despite this proposed removal, the agency encourages continued support for these transactions through industry efforts, and they note compliance with these transactions will still be necessary for CMS requirements related to Part D medications.

While we acknowledge the existing challenges with adoption and implementation of the “request and receive medication history” transactions, the AAFP believes this functionality is vital for ensuring comprehensive medication management and patient safety. **If patient medication histories are integrated into the EHR such that family physicians have seamless access to that data, we do not object to this proposed removal. However, if family physicians do not have ready access, the AAFP strongly recommends that these transactions not be removed from the electronic prescribing certification criterion**. We also recommend ASTP/ONC provide enhanced support and guidance for health IT developers to overcome known implementation challenges, ensuring that critical medication history data remains accessible and consistent across health IT systems.

ASTP/ONC proposes to require specific transactions for electronic prior authorization within the electronic prescribing certification criterion (§ 170.315(b)(3)(ii)(A)(10)), using NCPDP SCRIPT standard version 2023011. These transactions include PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and the newly proposed PANotification transaction. Currently optional, ASTP/ONC proposes that these transactions would become mandatory to enhance interoperability and reduce administrative burdens.

The AAFP strongly supports the automation of prior authorizations – especially for medications – and overall, we urge ASTP/ONC to drive adoption of electronic prior authorization across the health care ecosystem. However, it is unclear if these transactions proposed to be made mandatory have been tested in the real world to verify that they will achieve the intended goal of automating prior authorizations without also causing serious consequences, such as increasing prescriber burden or driving further consolidation in the EHR market toward a few large developers. Real-world testing is critical to ensuring that health IT is effective and interoperable for the physicians, clinical staff, and other end-users that rely on EHRs every day.

The AAFP strongly believes it is important to conduct real-world testing before requiring the adoption of new health IT standards, including these transactions. If these transactions

have been real-world tested, and if a majority of the currently certified EHR technology (CEHRT) vendors can properly implement the standards in the outlined timeframe, then we would support adding these transactions to the electronic prescribing certification criterion. **If real-world testing has not been completed, this proposal should not be finalized and these transactions should remain optional**.

Revised Electronic Prescribing Certification Criterion: Additional Proposals

ASTP/ONC proposes to update the "electronic prescribing" certification criterion (§ 170.315(b)(3)(ii)(D)) to require Health IT Modules to allow users to enter, receive, and transmit structured and codified prescribing instructions (Signatura or Sig) in compliance with the NCPDP SCRIPT standard version 2023011. The agency believes that standardizing prescription directions will improve accuracy, reduce errors, and enhance communication between prescribers and pharmacists. Currently optional, ASTP/ONC proposes to make this structured and codified Sig format mandatory.

The AAFP supports the proposal to mandate the use of structured and codified prescribing instructions for the electronic prescribing certification criterion. Standardizing the Sig format will enhance the clarity and consistency of prescription instructions, which will reduce the potential for errors and improve patient safety and outcomes. The structured format will facilitate better communication between prescribers and pharmacists, streamlining the prescribing and dispensing processes. Given that the first structured and codified Sig standard was published in 2005 as part of the ASTM Continuity of Care Record Standard, ongoing advancements in the NCPDP SCRIPT standard, and the industry's growing familiarity with this functionality, we agree with ASTP/ONC that it's appropriate to now require this functionality of certified Health IT Modules.

ASTP/ONC proposes to update the electronic prescribing certification criterion to include the ability to capture and exchange race and ethnicity information for certain prescription-related electronic transactions using the NCPDP SCRIPT standard version 2023011. This proposal aligns with the Pharmacy Interoperability and Emerging Therapeutics Task Force's recommendation to support interoperability and improve the consistency of demographic data documentation across clinician types. The transactions impacted include fill status notifications (RxFill), change prescriptions (RxChangeRequest, RxChangeResponse), cancel prescriptions (CancelRx), and renew prescriptions (RxRenewalRequest, RxRenewalResponse).

The AAFP is dedicated to improving the health of patients, families, and communities, and we are deeply committed to improving population health and advancing health equity. Family physicians help mitigate health inequity, including systemic racism, by collaborating with community stakeholders to affect positive change in the populations they serve. **However, the collection of race and ethnicity data in and of itself does not improve equity; it is the meaningful use of those data to create positive change that improves equity**. While the proposed rule provides some general discussion of how these data might be used, the specific uses and discussion of how those uses would improve equity is unclear. The AAFP does not object to ASTP/ONC finalizing these proposals, but we encourage the agency to have a detailed public discussion in which specific uses for these data that would help reduce health inequities be clearly identified.

ASTP/ONC proposes to include the "electronic prescribing" certification criterion (§ 170.315(b)(3)) in the Base EHR definition (§ 170.102). This change would align with the

proposal put forth in the following section of this letter to add the "real-time prescription benefit" certification criterion (§ 170.315(b)(4)) to the Base EHR definition, which ASTP/ONC believes would ensure that essential functionalities for electronic prescribing and real-time prescription benefits are part of the foundational requirements for EHR systems. The AAFP's recommendations in response to the proposed Base EHR definition changes can be found below.

New Real-Time Prescription Benefit Criterion

In the immediately preceding section of this letter, the AAFP referenced ASTP/ONC's proposal to include the "electronic prescribing" certification criterion (§ 170.315(b)(3)) in the Base EHR definition (§ 170.102). That change would align with the proposal put forth in this section to add the "real-time prescription benefit" certification criterion (§ 170.315(b)(4)) to the Base EHR definition, which ASTP/ONC believes would ensure that essential functionalities for electronic prescribing and real-time prescription benefits are part of the foundational requirements for EHR systems.

The AAFP strongly agrees with ASTP/ONC that, when implemented effectively, real-time prescription benefit tools can empower physicians and their patients to choose among clinically acceptable alternative medication treatments while weighing coverage and point-in-time costs. This is consistent with AAFP policy, which notes that physicians must have real-time information made available to them about drug formularies at the point of care. Such information facilitates shared decision making between physicians and their patients about the best treatments available to them, the cost of those treatments, and associated insurer utilization management requirements or other restrictions that may require patients to try an alternative. Enabling these conversations at the point of care can help reduce care delays and patient frustration. However, the AAFP is concerned that ASTP/ONC's proposals to add new criteria to the Base EHR Definition throughout this proposed rule (including real-time prescription benefits, provider access API – client, provider access API – provider, and the new public health criteria) may increase burden on physicians due to rushed development to meet timelines. It also has the potential to drive further consolidation in the EHR market—not due to customer demand, but due instead to policy decisions.

For these reasons, the AAFP urges ASTP/ONC to not include the real-time prescription benefit criterion in the electronic prescribing criterion. Doing so would allow electronic prescribing to be included into the Base EHR Definition without the new criterion. Instead, the real-time prescription benefit should be a stand-alone module criterion for now. Additionally, we support ASTP/ONC's proposal to focus the real-time prescription benefit on medications and immunizations at this time.

We strongly urge ASTP/ONC to establish a standard process for the inclusion of new criteria into the Base EHR Definition. That standard process must include a system that creates a new criteria as a modular criterion without inclusion in the Base EHR Definition. Then, based on developers' ability to voluntarily meet the criteria and market demand for this functionality, the criteria could be added to the Base EHR Definition in a subsequent year.

Health IT Modules Supporting Public Health Data Exchange

ASTP/ONC proposes to modify current certification criteria and adopt new criteria for Health IT Modules supporting public health data exchange in § 170.315(f), including referencing newer

versions of exchange and vocabulary standards and proposing two additional certification criteria for birth reporting and bi-directional exchange with a prescription drug monitoring program.

The AAFP is very supportive of public health data exchange and believes public health agencies should be required to use the same standards as those required of CEHRT. **We are broadly supportive of these proposals, which we believe could benefit family physicians, public health practitioners, and the patients they serve by meaningfully improving public health data interoperability**. The AAFP agrees with ASTP/ONC that public health data exchange holds considerable promise for the health care system. However, we believe meaningful advancement will only take place when all parties actively participate in meeting the data exchange requirements and are incentivized to use the same standards nationwide. We encourage ASTP/ONC to consider other ways to expand the alignment of public health IT infrastructure through collaborations across the Department of Health and Human Services (HHS), including increased coordination with the CDC's Data Modernization Initiative.

Revised Standardized API for Patient and Population Services Criterion to Align with Modular API Capabilities

ASTP/ONC proposes to revise the certification criterion in § 170.315(g)(10) to align with other proposals in this rule and increase clarity on patient and user access to information through certified APIs using patient-facing applications, including support for multi-factor authentication for patients, support for imaging links in data response requirements, and support for issuing verifiable health records as proposed in § 170.315(j)(22).

The AAFP has long supported policies that guarantee the appropriate security of protected health information while working to improve patients' access to their data, as well as the ability to share patients' health information across the care team. We are strongly supportive of making data reliably interoperable while maintaining patient confidentiality, and we agree that patients' ability to access their health information through secure third-party applications of their choosing through a smartphone or similar device is a step in the right direction. The AAFP has supported efforts to improve this type of accessibility but remains particularly concerned about the privacy, security, use, and transfer of patient and consumer health data in the ecosystem outside of Health Insurance Portability and Accountability Act (HIPAA), where it is largely unprotected by federal laws or regulations. **We support these proposals and encourage ASTP/ONC to consider all avenues for ensuring application vendors' transparency with patients regarding how their health information could be used**.

Patient, Provider, and Payer APIs

ASTP/ONC proposes new certification criteria for "prior authorization API – provider" (§ 170.315(g)(34)) and "prior authorization API – payer" (§ 170.315(g)(35)). These criteria would establish requirements for Health IT Modules to facilitate clinicians' requests for coverage information and prior authorization decisions, and for payers to accept these requests and send necessary documentation and decisions. The goal is to streamline the prior authorization process, reduce delays in care, and lessen the administrative burden on both physicians and payers. The proposed certification criteria are based on the HL7 FHIR Da Vinci Burden Reduction Implementation Guides and would support real-time access to payer approval requirements, documentation, and rules at the point of service.

Prior authorizations are a significant source of administrative burden for physicians, and we support all public and private payers adopting standardized digital prior authorization processes using evidence-based criteria to promote conformity, improve timeliness, and reduce administrative burdens for physicians and patients. **While we appreciate ASTP/ONC's efforts to promote bi-directional prior authorization interoperability between EHRs and payers, the AAFP does not support the proposed certification criteria being required at this time**. Instead, we support the proposed certification criteria being voluntary, because real-world testing is needed before their use is mandated to ensure these criteria are widely adoptable and support the goal of decreasing the burden of prior authorizations.

ASTP/ONC proposes revisions to the real-world testing requirements for certified health IT developers. These changes include adding new certification criteria (§ 170.315(g)(20), (g)(30) through (36), and 170.315(j)) to the real-world testing requirements in § 170.405. Developers must participate in Condition and Maintenance of Certification requirements and submit annual real-world testing plans and results. This aims to ensure continued interoperability and data exchange. Developers with modules certified to both § 170.315(g) and corresponding § 170.315(j) criteria will not need to submit duplicative real-world testing plans or results.

The AAFP is extremely supportive of real-world testing, and we believe it is critical to ensure products and standards facilitate the intended uses without negative, unintended uses. Health care is a complex, adaptative system that cannot always be predicted, which means testing must be done. We are disappointed that ASTP/ONC's discussion of real-world testing does not include requirements for standards to ensure standards will: (1) help achieve the intended goal; (2) be adoptable by a large portion of the market; and (3) support end-user workflows. While it is positive to see the large advancement in the number of standards and criteria in the certification process, the impact of these standards on the front lines of health care are not fully known. **We strongly encourage ASTP/ONC to advance real-world testing to cover standards and criteria before they are mandated in regulation**. Additionally, a more rigorous definition of "5: Mature" in the HL7 Maturity Model should be used to exclude Connect-a-Thons as a form of real-world implementation.

ASTP/ONC proposes to add certification criteria to the Base EHR Definition, including a provider access API, prior authorization API, and NCPDP electronic prescribing standards.

The AAFP does not support adding these certification criteria to the Base EHR Definition at this time. We reiterate our earlier recommendation for ASTP/ONC to establish a standard process for the inclusion of new criteria into the Base EHR Definition. That standard process should include a system that creates a new criteria as a modular criterion without inclusion in the Base EHR Definition. Then, based on developers' ability to voluntarily meet the criteria and market demand for this functionality, the criteria could be added to the Base EHR Definition in a subsequent year. **We also recommend ASTP/ONC work with CMS to require all payers that participate in federal programs, including Medicare Advantage organizations, adopt and use certified payer APIs as a condition of their participation in those programs**. That would help assure physicians that their EHRs will communicate with payers in a standardized and effective way and reduce their administrative burden long-term.

The AAFP encourages ASTP/ONC to be mindful of the potential cost of these API proposals to physician practices—particularly small, independent, and rural practices. With each federally required transition to a new functionality, such as the CEHRT requirements for Merit-Based Incentive Payment System (MIPS) participation, health IT vendors find ways to incrementally

charge physicians for each update and enhancement. While physicians understand the need for health IT vendors to be profitable, these unexpected fees have become excessive and can be a tremendous financial burden on small and independent practices. Given CMS' intent to mandate the use of certified electronic prior authorization APIs for physicians but its hesitancy to require payers to do the same, we are concerned family physicians will again have to pay for these upgrades without any guarantee that payers will support standardized APIs. Considering most primary care physicians are in-network with several private payers, in addition to Medicaid, Medicaid managed care, Medicare, and Medicare Advantage plans, the AAFP worries that these upgrade fees will compound and quickly become unmanageable. A 2023 internal survey of 20,000 AAFP members showed that 30 percent of respondents reported receiving payments from 14 or more payers within the past 12 months; almost half contracted with more than 10 payers. **With this in mind, we strongly encourage ASTP/ONC to identify and leverage policies that reduce or prevent health IT vendor fees associated with updated EHR functionality**.

Information Blocking Enhancements

Defined Terms

ASTP/ONC proposes enhancements to information blocking regulations by revising defined terms, which the agency believes will provide additional regulatory clarity. The definition of "health care provider" will be updated to explicitly reference 42 U.S.C. 300jj(3) and definitions for "laboratory" and "pharmacist" will be incorporated from 42 U.S.C. 300jj(10) and 42 U.S.C. 300jj(12), respectively.

While the AAFP acknowledges that the term "provider" is broadly used and accepted to mean a professional who directly provides health care services or to mean facilities or institutions that provide health care, we strongly oppose the use of the term "provider" as a substitute for the term "physician" or to imply non-physician clinicians are the equivalent of physicians. The generic term "provider" may create confusion for patients or be used as a tactic to encourage the use of health care professionals of perceived lower cost in place of physicians. **However, we do support common definitions across the regulatory ecosystem and therefore do not object to this proposed change.** Disparate definitions for the same terms across different health IT and other health care regulations can create confusion and administrative burdens for physician practices working to ensure they are in compliance, and we appreciate ASTP/ONC's efforts to align definitions throughout regulations.

ASTP/ONC proposes to codify the definition of "health information technology" from 42 U.S.C. 300jj(5) for information blocking purposes, which would encompass hardware, software, integrated technologies, and related services designed for electronic health information (EHI) management. To further clarify the scope of information blocking, a new section (45 CFR 171.104) would list practices that constitute interference, defined as actions that "prevent, materially discourage, or otherwise inhibit" access, exchange, or use of EHI. These proposed enhancements aim to ensure stakeholders have a clear and consistent understanding of the terms and practices associated with information blocking, as well as promote better access, exchange, and use of EHI.

The AAFP welcomes this proposed additional clarity on the scope of information blocking. As we have repeatedly shared with ASTP/ONC, physicians continue to report

confusion with provisions of the information blocking regulations, including on the appropriate application and documentation of information blocking exceptions, what is considered an "unreasonable practice" when evaluating for information blocking, and the parameters governing "actual knowledge" as an expected enforcement priority. Family physicians want and need best practices and implementation guides that they can reference as they strive to understand and comply with these regulations. **We continue to urge ASTP/ONC to work with CMS and HHS to develop a suite of educational resources designed specifically for small and independent physician practices, many of which are still unaware or underinformed of information blocking requirements**. For optimal clinician usability, developed resources should be concise and actionable, outlining the insights, steps, and actions practices need to take to ensure they are fulfilling information blocking requirements. We strongly encourage ASTP/ONC and CMS to engage physicians in solo and independent practices in the resource development process to ensure their educational and operational needs are fully met.

ASTP/ONC proposes clarifications regarding practices that would be unlikely to interfere with the access, exchange, and use of EHI under the information blocking definition. Specifically, it would not be considered interference for Qualified Health Information Networks (QHINs), Participants, or Sub-participants to comply with the requirements of the Trusted Exchange Framework and Common Agreement (TEFCA) and its associated terms of participation and standard operating procedures. However, practices not specifically required by TEFCA documents or affecting non-participants may still constitute interference and must comply with applicable exceptions in part 171. Non-compliance with EHI access, exchange, or use requests via adopted standards could be considered interference and would not be covered by the TEFCA Manner Exception.

The AAFP supports ASTP/ONC's clarification regarding the application of "interference" to TEFCA requirements. It is important for TEFCA entities to share information that is not explicitly in the Common Agreement, if withholding that information would be considered information blocking should the entity not be part of TEFCA. We agree that no entity should be given the exception to information block, regardless of TEFCA participation.

Privacy Exception

ASTP/ONC proposes to revise the Privacy sub-exception "Individual's Request Not to Share EHI" to remove the current limit that applies the exception only to individual-requested restrictions on EHI sharing that are permitted by other applicable law. The agency proposes to extend the availability of the § 171.202(e) sub-exception to an entity's practice of implementing restrictions the individual has requested on the access, exchange, or use of an individual's EHI.

The AAFP supports this proposed revision, as we believe it will provide guidance to physicians who otherwise might deny an individual's requested restrictions on sharing their EHI due to uncertainty about laws that could supersede these requests. Due to changes in federal and state laws, family physicians are often uncertain of their responsibilities when laws conflict, in addition to being unclear on the extent of information blocking requirements. We encourage ASTP/ONC to finalize this proposed revision, which aligns with our Patient-Physician Confidentiality and Information Technology Used in Health Care policies.

Infeasibility Exception

ASTP/ONC proposes modifications to the “segmentation” condition in § 171.204(a)(2) to provide clarity and make it applicable to more situations. The current segmentation condition applies when actors cannot separate EHI that cannot be shared due to legal or individual preference from other EHI. The proposal includes focusing subparagraph (i) on EHI not permitted by applicable law and explicitly cross-referencing the proposed Protecting Care Access Exception (§ 171.206) and the existing Privacy Exception (§ 171.202) in subparagraph (ii). The proposed revision ensures that the segmentation condition continues to apply in situations where actors cannot unambiguously segment EHI that cannot be shared due to law or individual preference from EHI that can be shared. This includes situations where preconditions for use or disclosure under the HIPAA Privacy Rule or other applicable laws have not been met. The proposal also includes extending the segmentation condition to cases where actors adopt more restrictive privacy policies due to multiple laws with inconsistent preconditions. An alternative proposal suggests referencing only Privacy Exception sub-exceptions other than denial of access based on unreviewable grounds (§ 171.202(d)).

The AAFP appreciates ASTP/ONC raising the importance of data segmentation to protect patient privacy, as we have raised concerns regarding the lack of meaningful, effective data segmentation capabilities for years. **We strongly support this proposal to ensure that the segmentation condition continues to apply in situations where actors cannot clearly separate EHI that cannot be shared, due to law or individual preference, from EHI that can be shared**. Current technology has severe limitations on supporting the segmentation of EHI, is not easy for end-users to utilize, and does not cover all EHI. We disagree with commenters who suggest that health care professionals would delay adoption of segmentation technology if given this exception. On the contrary, physicians and other health care professionals would welcome segmentation technology that made it easy for practices to share only the information that should be shared. The AAFP strongly urges ASTP/ONC to work with health IT developers and health data management platforms to advance meaningful data segmentation capabilities. Given the lack of industry progress in this area, we also urge the agency to examine how it can spur action to respond to growing threats to patient privacy, the patient-physician relationship, and patient and clinician safety.

ASTP/ONC proposes modifications to the "responding to requests" condition in the Infeasibility Exception (§ 171.204). Currently, actors must provide a written reason for the infeasibility of fulfilling a request for access, exchange, or use of EHI within ten business days. The proposed changes would introduce different timeframes for responses based on specific conditions under § 171.204(a). The requirement for a written response within ten business days would remain for certain conditions (uncontrollable events, segmentation, and third-party seeking modification use). Additionally, the proposal retains flexibility in the format and delivery mechanism of the response. The revisions aim to clarify the start of the ten-day period and consider alternative enhancements, such as maximum timeframes for determinations of infeasibility and aligning timeframes with the HIPAA Privacy Rule's provisions for individual access to protected health information (PHI).

The AAFP supports these proposed changes, and we continue to urge HHS agencies to work together to align regulatory timeframes for responding to requests in order to ease the regulatory complexity for practices. Additionally, the AAFP opposes the alternative proposals outlined here that would enhance the revisions to § 171.204(b) by adopting different maximum timeframes for determining infeasibility and aligning with the HIPAA Privacy Rule's provisions. Changing the rules in this manner would increase administrative burden on practices

that are already managing a complex set of regulations, many of which are not harmonized. Introducing additional timeframes for responding to requests further complicates compliance efforts and increases the risk of errors. Practices are already struggling with the existing regulatory landscape, and adding more layers of complexity will detract from their ability to focus on patient care. Therefore, the AAFP recommends maintaining a single, clear timeframe to ensure consistency and reduce administrative burden for physicians and practices.

Protecting Care Access Exception

ASTP/ONC proposes a new Protecting Care Access Exception (§ 171.206) to the information blocking regulations. This exception is designed to address concerns about potential legal actions related to the access, exchange, or use of EHI that indicates or is related to reproductive health care. The exception would apply to any actor, including those not covered by HIPAA, who restricts EHI sharing to protect individuals, health care practitioners, and facilitators from legal risks associated with providing, seeking, or facilitating lawful reproductive health care. The exception requires meeting a threshold condition and at least one of two additional conditions, and it aims to preserve patient trust, promote patient safety, and support the continued use of modern, interoperable health IT systems. This proposal responds to changes in the legal landscape following the *Dobbs v. Jackson Women's Health Organization* decision and seeks to mitigate the chilling effect of state laws restricting reproductive health care.

We strongly support the proposed Protecting Care Access Exception (§ 171.206). This exception is crucial in the current legal environment, where state laws may threaten the confidentiality and availability of reproductive health care. The AAFP is strongly supportive of the "HIPAA Privacy Rule to Support Reproductive Health Care Privacy" final rule and agreed with HHS' conclusion that there was a need for heightened protections for reproductive health information in a post-*Dobbs* legal landscape. Reproductive care is highly personal and private for many patients, and without appropriate protections, patients may refrain from sharing their full health history with their primary care physician out of fear of inappropriate use or disclosure of their PHI. By providing a clear framework for when EHI related to reproductive health care can be withheld, this exception would help protect the privacy and safety of patients and physicians. The proposed exception would also ensure that health IT systems remain fully electronic and interoperable, which is essential for maintaining high standards of care and patient safety. **However, we recommend that the scope of the Protecting Care Access Exception be broadened beyond reproductive health to encompass any situation where health care in one jurisdiction may pose legal risks to patients or physicians in another jurisdiction**. This broader approach would better address the varied and evolving legal threats faced by physicians and patients, helping ensure comprehensive protection and maintain trust.

Requestor Preferences Exception

ASTP/ONC proposes a new Requestor Preferences Exception (§ 171.304), which was developed to offer entities certainty that it would not be considered information blocking to honor a requestor's preferences "expressed or confirmed in writing" for limitations on the scope of EHI made available [to the requestor]; the conditions under which EHI is made available; and the timing of when EHI is made available for access, exchange, or use.

The AAFP supports the Requestor Preferences Exception, which will provide essential clarity and protections for physicians and other actors. However, we note that honoring a patient's request to limit or delay the release of information is only possible if the technical capability

exists. While we support this proposed exception, the AAFP recommends ASTP/ONC establish a certification criterion that would require health IT developers to provide the technical capability to delay the release of certain EHI, permit patients to control notifications for new test or lab results, and detail where EHI is made available. Without the necessary technical capability, patients' preferences cannot be fully honored, and we urge ASTP/ONC to require health IT developers to implement these capabilities.

Conclusion

Thank you for the opportunity to provide comments on this proposed rule. The AAFP appreciates ASTP/ONC's ongoing efforts to advance interoperability; improve transparency; and support the access, exchange, and use of electronic health information. We look forward to continuing to partner with ASTP/ONC to reduce physician administrative burdens and improve patients' access to their health data. Should you have any questions, please contact Mandi Neff, Regulatory and Policy Strategist, at 202-655-4928 or mneff2@aafp.org.

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