American College of Physicians
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October 3, 2024

Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
Chief Artificial Intelligence Officer (Acting)
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Re: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)

Dear Assistant Secretary Tripathi:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the ASTP Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Information Blocking

Reproductive Health Care and Information Privacy

Internal medicine physicians provide care, information, and treatment to pregnant patients, including those with unwanted pregnancies. In certain circumstances, they may help patients understand their options after a positive pregnancy test, prescribe a medication abortion, or offer follow-up care after a self-managed abortion. The 2022 U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* eliminated the federal right to access abortion, allowing states to determine its legality without limitation. This has led to new state-level restrictions and prohibitions, resulting in significant health data and privacy implications. Some states are beginning to criminalize patients, physicians, and others who assist with or facilitate abortion. The decision significantly changed the legal and political environment around access to comprehensive reproductive health care, including abortion. This has caused internal medicine physicians and other health care professionals who assist with or facilitate reproductive health care to become particularly concerned about the highly sensitive information regarding this care being weaponized against them or their patients.

ACP advocates for strong privacy protections for patients' personal health information (PHI). The College's 2021 position paper, *Health Information Privacy, Protection, and Use in the Expanding Digital Health Ecosystem*, emphasizes building trust within the patient-physician relationship and the health

care system as a fundamental component of ACP policy.[1] In its policy recommendations, the College highlights the challenge of protecting individuals' PHI while balancing the potential benefits of using PHI to improve care. Our policy stresses the importance of promoting trust, protecting patient privacy, and maintaining transparency in the use of patient data.

Insufficient data privacy and security laws contribute to a lack of trust in the health care system, creating a barrier to care for many patients. ACP strongly believes that patients must feel confident in receiving care and engaging with the health ecosystem without the inappropriate disclosure of their PHI. Such disclosures could lead to a loss of trust in physicians and the health care system, as well as patients withholding relevant health information and avoiding care out of fear of misuse of their information. Producing and maintaining this trust necessitates robust data privacy and security laws and regulations that are comprehensive, transparent, understandable, adaptable, and enforceable. Information related to an individual's reproductive cycle and health, as well as details indicating reproductive health care sought, enabled, or received, is particularly sensitive and personal. Fear of legal consequences may lead individuals to avoid necessary reproductive health care services and withhold relevant information from health care professionals, negatively impacting their health and future care plans.

Given the role of internal medicine physicians in caring for pregnant patients and the shifting legal landscape after *Dobbs*, ACP released a 2023 policy brief, *Reproductive Health Policy in the United States*.[2] In this brief, ACP expressed concerns about the chilling effects that overly restrictive state laws criminalizing the provision of medically accepted care will have on physicians' ability to practice medicine as aligned with their education and expertise. We stated that it is inappropriate for private, third-party persons to interfere in the patient-physician relationship by pursuing civil or criminal charges for the provision of health care services that do not involve them. ACP reaffirms its position that laws and regulations should not mandate the withholding or provision of care or information that, in the physician's clinical judgment based on clinical evidence and standard of care, is necessary or appropriate for a particular patient during a patient encounter.

In the policy brief, ACP supports individuals' right to make their own decisions in partnership with their physician or health care professional regarding their reproductive health. This includes choices of contraceptive methods and whether to continue a pregnancy. ACP opposes government restrictions that would limit equitable access to reproductive health care services, including family planning, sexual health information, the full range of medically accepted forms of contraception, and evidence-based, clinically indicated abortion guided by biomedical ethics. ACP also opposes laws and regulations that penalize the provision, receipt, referral, assistance, or facilitation of clinically appropriate health care services that meet the standard of care.

Most importantly for the context of this proposed new information blocking exception, the brief states that "*ACP opposes the use of personal health information—including prescribing data, internet searches, private communications, mobile application data, and geolocation data, among other information—to*

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[1] Rockwern B, Johnson D, Snyder Sulmasy L; Medical Informatics Committee and Ethics, Professionalism and Human Rights Committee of the American College of Physicians. Health Information Privacy, Protection, and Use in the Expanding Digital Health Ecosystem: A Position Paper of the American College of Physicians. *Ann Intern Med*. 2021;174:994-8. [PMID: 33900797] doi:10.7326/M20-7639.

[2] Serchen J, Erickson S, Hilden D, et al. Reproductive Health Policy in the United States: An American College of Physicians Policy Brief. *Ann Intern Med*.2023;176:364-366. [Epub 28 February 2023]. doi:10.7326/M22-3316.

prosecute or penalize individuals for seeking and/or obtaining clinically appropriate reproductive health care services, including abortion."

The College strongly supports the privacy protections finalized in the HHS *HIPAA Privacy Rule to Support Reproductive Health Care Privacy* final rule. In comments on the proposed rule, the College shared concerns about the chilling effects of new reproductive health care laws on patients' access to care, willingness to seek necessary care, and openness to share relevant health information. The College commended the Administration for taking initial measures to strengthen protections for patient reproductive health data and called for the Administration to undertake additional efforts to enhance privacy protections more broadly for health information not currently covered by existing frameworks or the scope of the proposed rule.

The College also shared concerns about the impact of the proposed prohibition of PHI disclosure and information blocking regulations and shared its worries that health care professionals, medical practices, and their staff will be expected to take on the additional burden of complying with two very nuanced sets of federal health information regulations that jointly constitute a complex regulatory scheme that seems to impose conflicting and contradictory expectations and requirements on regulated entities. The College emphasized that not complying with either set of regulations could cause significant distress and burden. We recommended creating an exception for reproductive health care data under the information blocking regulations as a way for HHS to mitigate distress.

Our comments below are founded on these fundamental aspects of ACP policies on reproductive health care and health information privacy.

Definitions

ASTP proposes to codify in the information blocking regulations that certain specified practices will constitute an "interference" under the information blocking definition. Some of the specified practices that would constitute an "interference" include actions taken by an actor to impose delays on other persons' access, exchange, or use of electronic health information (EHI); non-standard implementation of health IT and other acts to limit the interoperability of EHI or how EHI is accessed, exchanged, or used by other persons; improper inducements or discriminatory contract provisions; and failures to act when action is necessary to enable or facilitate appropriate information sharing, such as where access, exchange, or use of an individual's EHI is required by law or where it is permitted by law and not subject to restrictions requested by the individual to which an actor has agreed.

We appreciate the clarity and examples of acts or omissions that would constitute an interference and implicate the information blocking definition. While this clarification is helpful, actors would benefit from expanding and explaining the acts, omissions, and circumstances that qualify as interference under the examples detailed in the proposal.

Privacy Exception

ASTP proposes to revise the Privacy Exception's Respecting an Individual's Request Not to Share Information sub-exception by removing the existing limitation to restrictions permitted by other applicable laws. Under this proposal, any practice that meets the requirements specified in the sub-exception would not be considered information blocking, regardless of whether other valid law compels the actor to disclose EHI against the individual's expressed wishes.

The College shares ASTP's concerns that after *Dobbs*, actors might deny or terminate an individual's requested restrictions on sharing their EHI due to uncertainty about whether the actor is aware of and can account for laws that might override the individual's requested restrictions. As the agency acknowledges, clinicians may be uncertain whether information blocking penalties or disincentives might be imposed in addition to costs they may incur to confirm whether they are, by other authorities, required to provide access, exchange, or use of EHI despite the individual's wishes. This revision would reduce the information blocking compliance burden by simplifying clinicians' analyses of whether the sub-exception is applicable where the clinician is inclined to agree to the individual's requested restrictions and would address actors' uncertainty about state laws' applicability. The College thanks ASTP for this revision, which ACP strongly supports.

Infeasibility Exception

Segmentation Condition

ASTP proposes to make changes to the *segmentation* condition to enhance clarity and certainty and to provide for its application to additional situations. Currently, the *segmentation* condition references (in subparagraph (i) of § 171.204(a)(2)) EHI that cannot be made available due to an individual's preference or by law, and (in subparagraph (ii) of § 171.204(a)(2)) EHI that the actor may choose to withhold per the Preventing Harm Exception. ASTP/ONC proposes to revise the condition (§ 171.204(a)(2)) to focus subparagraph (i) on EHI that is not permitted by applicable law to be made available and to explicitly cross-reference in subparagraph (ii) the proposed Protecting Care Access Exception and the existing Privacy Exception in addition to the existing Preventing Harm Exception.

We agree with ASTP that these changes provide clarity in several situations. The explicit reference to the Privacy Exception is helpful where an actor subject to multiple laws with inconsistent preconditions for sharing health information adopts the more restrictive of the laws' preconditions and cannot unambiguously segment EHI for which a more restrictive precondition has not been met from other EHI that could be shared in jurisdictions with less restrictive preconditions. We agree that the explicit reference to the proposed Protecting Care Access Exception and the Privacy Exception would be helpful where an actor does not have the technical capability to unambiguously segment the EHI and the actor has chosen to withhold from other EHI that they could lawfully make available.

We also appreciate ASTP's acknowledgment that there is significant variability in health IT products' capabilities to segment data (e.g., to enable differing levels of access to data based on the user and purpose). Some actors who wish to withhold specific EHI the proposed Protecting Care Access Exception may not yet have the technical capability needed to unambiguously segment the EHI for which the exception would apply from other EHI that could be exchanged lawfully. Therefore, we appreciate and support the proposed explicit cross-references to the Privacy Exception and the proposed Protecting Care Access Exception. We believe the explicit cross-references will provide clarity and certainty to actors and ease some of the burden associated with compliance.

Third Party Seeking Modification Use Condition

ASTP proposes to revise the *third party seeking modification use* condition so that it would not apply when third party modification use is sought (1) by any HIPAA-covered entity or business associate from an actor that is their business associate, and (2) by any health care professional who is not a HIPAA-covered entity from an actor whose activities would make the actor a business associate of that same health care professional if that health care professional were a HIPAA-covered entity. This proposal is intended to recognize the need of covered entities and their business associates to regularly modify EHI

held by other business associates of the same covered entity and that health care professionals who are not HIPAA-covered entities often have similar relationships with actors who provide services that would make the actor a business associate if the health care professional were a HIPAA-covered entity, and that these clinicians may need or want a third party to modify EHI held by such actors on their behalf.

The College believes this proposal is vague and would appreciate clarity on its intended function and scope.

Responding to Requests Condition

ASTP proposes to revise the *responding to requests* condition to offer actors a more flexible response timeframe where the reason(s) for infeasibility is consistent with the exception's *manner exception exhausted* or *infeasible under the circumstances* conditions. Under the proposal, the actor could satisfy the *responding to requests* condition by:

(1) Initiating within 10 business days of the actor receiving request good-faith collaborative engagement with the requestor to discuss the potential infeasibility of the request as received and potentially feasible alternative ways to achieve information sharing.
(2) Where discussions and negotiations reach a result other than successful fulfillment of access, exchange, or use of EHI for the requestor, providing the requestor a written response indicating the reason for infeasibility within 10 business days of the actor's determination of infeasibility or the discontinuation of discussions.

ASTP includes an alternative proposal for an additional requirement to establish a maximum timeframe(s) for an actor's determination of the infeasibility of a particular requested access, exchange, or use of EHI related to the manner exception. Under this alternative proposal, the College believes that 10 business days after the date the actor receives an initial request would be a reasonable maximum timeframe for determining infeasibility.

For infeasibility consistent with the *uncontrollable events*, *segmentation*, and *third party seeking modification use* conditions, ASTP proposes to retain the *responding to requests* condition's existing requirement to respond within 10 business days of the actor receiving the request. However, ASTP proposes to revise the wording of the condition from "receipt of" to "the actor receiving," so it is more immediately apparent when the 10-business-day timeframe starts when fulfilling a request is infeasible because of uncontrollable events.

We agree that the proposed revised wording is likely to help actors differentiate between requests that can be received and processed using only automated means and requests that require human intervention for the actor to receive the request. The College appreciates this clarification.

Protecting Care Access Exception

ASTP proposes the Protecting Care Access Exception to address actors' concerns about potentially implicating the information blocking definition if they choose not to share EHI where an actor believes in good faith that sharing such EHI could risk exposing a patient, health care professional, or facilitator of lawful reproductive health care to potential legal action based on what care was sought, obtained, provided, facilitated, or (specific to the *patient protection* condition) is often sought, received, or medically indicated for the patient's health condition(s) or history.

Under certain specified conditions, the proposed exception would apply to practices likely to interfere with EHI access, exchange, or use that an actor believes in good faith could result in a risk of potential exposure to legal action, including investigation, that the actor believes could potentially be brought against patients, health care professionals, or those who help make providing or receiving care possible for the mere fact that a person sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which it was provided, or where a patient has health conditions or history for which reproductive health care is often sought, obtained, or medically indicated.

More specifically, the proposed *patient protection* condition would apply to practices implemented to reduce the patient's risk of potential exposure to legal action. In contrast, the proposed *care access* condition would apply to practices an actor implements to minimize potential exposure to legal action based on the mere fact that reproductive health care occurred for persons other than the person seeking or receiving care, who provide care or are otherwise involved in facilitating the provision or receipt of reproductive health care that is lawful under the circumstances in which it is provided. The proposed exception is intended and designed to apply where either or both the *patient protection* and *care access* conditions are met in complement to the proposed *threshold* condition.

We share the concerns for patient trust and care access and clinicians' fear of exposure to legal action where reproductive health care was provided. The rationale for this proposal identifies the concerns about patients and health care professionals' potential exposure to legal action and patient trust and care access that the College shared in its comment letter and policy brief. We are extremely pleased that ASTP has sought to allay these concerns.

The proposed exception also meets policy goals and recommendations from ACP's position paper on health information privacy, referenced above. The College recommends that "When personal health information requests are made by entities that are not the individual or an entity authorized by the individual, physicians should not be penalized for not complying with requests that, in their judgment, are inappropriate under disclosure rules after notifying the requester and the individual that the request is being denied." We appreciate that ASTP's proposals will empower clinicians to use their judgment in determining the appropriateness of health information disclosure and ensure clinicians will not be penalized when withholding reproductive health care information due to fear of exposure to legal action.

ACP also appreciates the clarification that ASTP uses EHI "potentially related to reproductive health care" to mean EHI that shows or would carry a substantial risk of supporting an inference that the patient has health condition(s) or history for which reproductive health care is often sought, obtained, or medically indicated. We appreciate the clarification that the exception would cover instances where a reasonable inference could be made that a patient inquired about or expressed an interest in receiving reproductive health care.

Requestor Preferences Exception

The proposed Requestor Preferences Exception would apply where an actor honors a requestor's preference(s) expressed or confirmed in writing for: (1) limitations on the amount of EHI made available to the requestor; (2) the conditions under which EHI is made available to the requestor; and/or (3) the timing of when EHI is made available to the requestor for access, exchange, or use. The proposed exception is meant to apply in situations where the requestor may prefer to receive less EHI available to the requestor than an actor has and would be permitted to make available under the HIPAA Privacy Rule or where the requestor may not want particular EHI to be available to the requestor immediately,

perhaps preferring the EHI not be available until a certain period has elapsed or until certain conditions are met.

Research has shown that patients may feel overwhelmed or anxious when receiving automatically released medical testing results, even if the results are benign.[3,4,5,6] One study determined that "Patients wanted policymakers to understand that patients are unique, and they want to individualize their preferences for receiving health information with their clinicians. […] Both [clinicians and patients] expressed an urgent need for tailoring implementation of the [information blocking regulations] to avoid unintended harm and distress for patients," noting that patients want to discuss what type of information they want and how they want it delivered.[7] A July 2024 *Washington Post* piece also highlights varying patient preferences for timing and conditions of receiving test results.[8]

The College supports this proposed exception, as it enables patient autonomy and control over sharing their PHI. The exception allows health care professionals to honor the EHI sharing preferences of patients without fear of penalty. We appreciate that the Requestor Preferences Exception would allow for the type of tailoring patients and other requestors of health information desire. However, the exception (particularly the *transparency* condition requirements) is complicated and will be overly burdensome to meet, requiring too much effort by clinicians to document and comply with the exception and conditions' requirements. We encourage ASTP to devise a less complicated scheme for the appropriate use of this exception.

While we support the intent of these information blocking proposals, the College emphasizes its belief that the information blocking regulations and exceptions are particularly complicated and remain confusing to the physician community. The operation of the proposed changes to existing and new exceptions is difficult to understand. Legal consultation fees will significantly increase the financial costs of overburdened small and independent medical practices and the complexity of the proposals will contribute significantly to compliance burden. We urge ASTP to consider less burdensome requirements for the appropriate use of these proposed modified and new exceptions.

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[3] Salmi L, Hubbard J, McFarland DC. When Bad News Comes Through the Portal: Strengthening Trust and Guiding Patients When They Receive Bad Results Before Their Clinicians. *Am Soc Clin Oncol Educ Book* 44, e433944(2024). DOI:10.1200/EDBK_433944.

[4] Bruno B, Steele S, Carbone J, Schneider K, Posk L, Rose SL. Informed or anxious: patient preferences for release of test results of increasing sensitivity on electronic patient portals. *Health Technol (Berl)*. 2022;12(1):59-67. doi:10.1007/s12553-021-00628-5.

[5] Pillemer F, Price RA, Paone S, et al. Direct Release of Test Results to Patients Increases Patient Engagement and Utilization of Care. *PLoS One*. 2016;11(6):e0154743. Published 2016 Jun 23. doi:10.1371/journal.pone.0154743.

[6] Arvisais-Anhalt S, Ratanawongsa N, Sadasivaiah S. Laboratory Results Release to Patients under the 21st Century Cures Act: The Eight Stakeholders Who Should Care. *Appl Clin Inform*. 2023;14(1):45-53. doi:10.1055/a-1990-5157.

[7] Brooks JV, Zegers C, Sinclair CT, et al. Understanding the Cures Act Information Blocking Rule in cancer care: a mixed methods exploration of patient and clinician perspectives and recommendations for policy makers. *BMC Health Serv Res* 23, 216 (2023). https://doi.org/10.1186/s12913-023-09230-z.

[8] Fenit Nirappil, Online portals deliver scary health news before doctors can weigh in, *The Washington Post*, July 26, 2024, https://www.washingtonpost.com/health/2024/07/14/medical-test-results-online-patient-portal/.

Health IT Certification Program Updates: New and Revised Standards and Certification Criteria

New Imaging Requirements for Health IT Modules

ASTP proposes to revise certification criteria to include certification requirements to support capturing and documenting hyperlinks to diagnostic imaging. As ASTP acknowledges, access and exchange of diagnostic imaging results is a known challenge, and better capture and documentation of diagnostic imaging results within EHRs can improve access to this information at the point of care and interoperability of these results between health care professionals, which can reduce redundant testing and support diagnostics.

The College supports the proposal's intent to improve the accessibility and interoperability of diagnostic imaging. However, we caution that this information should be stored on the imaging host's EHR platform (rather than the clinician's platform), with access provided through a link to assuage potential data storage concerns that smaller or independent practices might have.

Revised Clinical Information Reconciliation and Incorporation Criterion

ASTP proposes to revise the "clinical information reconciliation and incorporation" (CIRI) certification criterion to expand the number and types of data elements that Health IT Modules certified to this criterion would be required to reconcile and incorporate. ASTP also proposes a new functional requirement allowing end users to configure how their product handles information received from external sources (i.e., enabling user-driven automatic CIRI).

The College supports the proposal's intent to encourage developers to include features allowing clinicians to configure how their product handles information received from external sources. ACP supports the primary proposal of requiring CIRI of all USCDI data elements rather than requiring CIRI for only a limited set of additional USCDI data elements. We agree that this revision will benefit clinicians by reducing the burden of incorporation and reconciliation in clinical workflows, which may otherwise have occurred manually, and that requirements supporting automatic reconciliation would help provide clinicians with important clinical information that can improve overall patient care and safety.

Revised Electronic Prescribing Certification Criterion and New Real-Time Prescription Benefit (RTPB) Criterion

ASTP proposes revising the Electronic Prescribing certification criterion to require developers to update their health IT modules (certified to the criterion) to use the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 and provide that update to customers by January 1, 2028, to maintain module certification. The College supports the interoperability and potential medication prior authorization improvements that are intended and likely to result from this proposal.

ASTP proposes establishing an RTPB certification criterion based on NCPDP RTPB standard version 13 and including this certification criterion in the Base EHR definition. The proposed certification criterion includes a functional requirement that enables users to send and receive patient-specific benefits, estimated cost information, and therapeutic alternatives for medications and vaccine products within workflow at the point of care. As ASTP acknowledges, RTPB tools empower prescribers and their patients to compare the patient-specific cost of a drug to the price of a suitable alternative, compare prescription costs at different pharmacies, view out-of-pocket costs, and learn whether prior authorization for a specific drug is required.

Some clinicians believe RTPB tools are useful and have reduced burden through decreased patient phone calls regarding medication costs. However, other clinicians' experience with RTPB is glitchy and interruptive, and, at times, the prices listed in RTPB tools differ from the actual price under 340B programs. Inaccurate information through RTPB tools reduces the utility of this technology and is associated with increased burden for clinicians.

While the College supports this proposal and believes the improvements in access to RTPB information are likely to benefit clinicians and their patients, we strongly emphasize several points: (1) the accuracy of the information presented through RTPB tools is critical and dispositive of their success; (2) EHR vendors should create a structure to ensure the accuracy of the information present and should be responsible for the installation of this option; (3) the helpfulness of these tools could be improved if patients and more members of the care team (rather than only the prescribing physician) has access to them; (4) alert burden and clinical efficiency, in addition to accuracy, should be among the foremost considerations in the development and implementation of these tools; and (5) additional add-on or third-party services, modules, or charges should not be required for these tools.

Revised End-User Device Encryption, Encrypt Authentication Credentials, and Multi-Factor Authentication (MFA) Criteria

ASTP proposes revising the End-User Device Encryption Certification Criterion to include a new requirement that Health IT Modules certified to this certification criterion encrypt EHI stored server-side. The agency also proposes adopting the latest NIST Federal Information Processing Standard (FIPS) Annex A standard.

The College supports these proposed changes to improve health information security and prevent unauthorized access to EHI. ACP believes that health IT and other digital technologies should incorporate privacy and security principles within their design and consistent data standards that support privacy and security policies and promote safety. The College supports adding this new requirement, which will improve the security of EHI in alignment with the latest NIST-approved encryption algorithms. As ASTP acknowledges, server-side data encryption prevents unauthorized data access in many scenarios, including those involving a server breach, theft, or improper disposal, and mitigating these risks using encryption is a best practice for all server developers.

To improve the protection of EHI and mitigate cybersecurity risks, ASTP proposes to revise the "encrypt authentication credentials" certification criterion by replacing the current "yes" or "no" attestation requirement and instead requiring health IT modules that store authentication credentials to protect the confidentiality and integrity of the stored authentication credentials according to October 12, 2021, version of Annex A of the FIPS 140-2 industry standard or via hashing in accordance with the standard specified in § 170.210(c)(2). As ASTP acknowledges, this proposal will help to ensure that stolen or leaked authentication credentials will be useless in the event of a cyberattack. The College supports these proposed changes to improve health information security and prevent unauthorized access to EHI.

ASTP proposes revising the MFA certification criterion by replacing the current "yes" or "no" attestation requirement with a specific requirement to support MFA and configuration for three certification criteria: "view, download, transmit to 3rd party"; "standardized API for patient and population services" (for "patient-facing" access); and "electronic prescribing." ASTP believes these updates match industry best practices for information security, particularly for important authentication use cases in health IT.

The College agrees that these proposed updates will improve information security and support the proposal overall. However, we believe that small or independent practices should be allowed to use freely available authenticators rather than those that require a subscription fee. Additionally, we believe some of the language in this proposal is open to interpretation (e.g., requiring "the ability to authenticate users using multiple means to confirm that users are who they claim to be"). We seek clarity regarding whether the proposal is intended to require authentication of users through multiple means to confirm identity or simply the ability to authenticate users through multiple means.

Proposed Revised and New Certification Criteria for Health IT Modules Supporting Public Health Data Exchange and New Standardized Application Programming Interface (API) for Public Health Data Exchange

ASTP seeks to establish minimum functional capabilities and exchange standards for health IT and health IT for public health to send and receive public health data by proposing: (1) to update existing certification criteria for reporting public health data to include new and updated standards; (2) to establish new criteria for reported public health data, including the ability to receive, validate, parse, and filter data according to standards; and (3) a new, standardized Fast Healthcare Interoperability Resources (FHIR)-based API for public health data exchange.

More specifically, ASTP proposes to revise or add an array of certification criteria (e.g., functional exchange and transmission requirements, use of newer HL7 standards and IGs, etc.) that relate to:

(1) *Immunization information*, expected to facilitate complete, longitudinal patient immunization histories, supporting the bi-directional exchange and interoperability of structured immunization data between EHRs, IISs, and intermediaries;
(2) *Syndromic surveillance*, expected to provide additional information, such as patients' acuity and comorbidities, informing public health agencies' assessments of emerging public health threats and identification of potential infectious disease outbreaks;
(3) *Reportable laboratory orders and results*, expected to increase data exchange and interoperability between clinicians, laboratories, and public health agencies, providing more complete patient-level information for contact tracing, patient outreach, direct care, and other clinical and public health activities;
(4) *Computerized provider order entry—laboratory*, expected to ensure that systems creating laboratory orders can transmit orders and receive associated results and values electronically, according to national standards, creating more complete patient information available to clinicians throughout the laboratory workflow;
(5) *Cancer registry and pathology reporting*, expected to promote interoperable exchange of more complete and accurate cancer data between clinicians and public health, allowing better clinical and public health decision-making and evaluation of program interventions aimed at cancer prevention and early detection, as well as increased efficiency and reduced burden of reporting (e.g., automation enabled by standardization);
(6) *Electronic case reporting*, expected to improve consistency, efficiency, and interoperability of reporting and exchange between health care and public health, reducing burden by enabling automatic, complete, accurate data to be reported in real-time to public health agencies;
(7) *Antimicrobial use and resistance reporting*, expected to enable sharing of more specific and complete antimicrobial resistance information with public health agencies;
(8) *Health care surveys*, expected to make collection and reporting of data for health care surveys easier;

(9) *Prescription drug monitoring program (PDMP) databases*, expected to improve data interoperability between health IT systems and PDMPs, which will reduce clicks/burden on providers to access the PDMP and improve their access to information needed for clinical decision-making by integrating query information into clinical workflows within health IT systems, increasing patient-centered and guideline-concordant care and improving prescribing practices and monitoring of drug misuse and diversion; and
(10) *Birth reporting*, expected to improve the interoperability of systems involved in birth reporting and improving the timeliness, accuracy, and completeness of birth reporting data.

ASTP also proposes to adopt a new criterion for a standardized FHIR-based API for public health data exchange, including FHIR capabilities such as subscriptions, bulk data export, and verifiable health records and requirements for authorization and authentication, among others. These proposals are expected to reduce reporting burden and expand public health authorities' access to data for various public health uses through improved standardization and interoperability of public health data.

According to ASTP, the proposals will benefit clinicians, public health practitioners, and their patients by reducing barriers to public health data interoperability and improving public health response and decision-making. The increased interoperability and information exchange from EHRs to public health authorities using HL7 FHIR-based standards might allow public health to reduce burden, streamline data sharing, and protect patient privacy.

As the College stated in its 2023 position paper, *Modernizing the United States' Public Health Infrastructure*: "*ACP supports the development of a modern national public health data infrastructure capable of real-time bidirectional data sharing among public health departments, physicians, hospitals, laboratories, and others. The federal government should develop common data collection and reporting standards to achieve interoperability and advance health equity. Efforts to allow information sharing among health care and public health entities should include strong patient privacy and confidentiality protections and establish clear, understandable, adaptable, and enforceable rules on how data will be used."*[9] The College strongly supports these proposals to advance public health interoperability and information exchange, particularly while preserving patient privacy, as long as increased interoperability also leads to decreased requirements for what will become duplicative reporting, such as in the reporting of certain communicable diseases.

In its 2017 position paper, *Putting Patients First by Reducing Administrative Tasks in Health Care*, the College recommended that, "[t]o facilitate the elimination, reduction, alignment, and streamlining of administrative tasks, all key stakeholders should collaborate in better utilizing existing health information technologies, as well as developing more innovative approaches"; that "[t]he use of EHR data collection capabilities for secondary or alternative purposes, such as for billing documentation, measure and public health reporting, regulatory compliance, and others, must be redesigned in a manner that does not distract or detract from patient care and that effectively and efficiently provides patients with access to their own information"; and that "[a]ll stakeholders must work to ensure that reporting requirements are modified and standardized to take full advantage of the capabilities inherent in EHR technology" emphasizing that "[r]eporting burdens would be reduced dramatically if all stakeholders agreed to use

[9] Crowley R, Mathew S, Hilden D, et al; Health and Public Policy Committee of the American College of Physicians. Modernizing the United States' Public Health Infrastructure: A Position Paper From the American College of Physicians. *Ann Intern Med*.2023;176:1089-1091. [Epub 18 July 2023]. doi:10.7326/M23-0670.

the same data and structure definitions."[10] The College appreciates these proposals, which largely meet the goals and approaches recommended by ACP.

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

ASTP proposes to include 14 new certification criteria as modular API capabilities. Five of these are new or more advanced criteria that are not similar to existing capabilities, which would be required to support: (1) program requirements for API-based workflow triggers for decision support interventions (DSIs) (2 criteria); (2) issuance of verifiable health records according to the Substitutable Medical Applications and Reusable Technologies (SMART)Subscriptions Framework standard (2 criteria). The nine remaining proposed criteria (related to functional registration, dynamic registration, asymmetric certificate-based authentication, SMART App Launch user authorization, SMART Backend Services system authentication and authorization, asymmetric certificate-based system authentication and authorization, SMART Patient Access for Standalone Apps, SMART Clinician Access for EHR Launch, and asymmetric certificate-based authentication for B2B user access) are similar to existing capabilities.

The proposals related to *workflow triggers for DSIs* are expected to improve standardization and interoperability of CDS Hooks technology, including workflow improvements, facilitating more patient-specific results from CDS tools. The proposals are also expected to save time, decrease the cognitive burden for clinicians, and reduce the risk of adverse health events and duplication of lab tests. The proposals related to *verifiable health records* are expected to improve interoperability of patient health information (e.g., immunization and infectious disease-related laboratory test information) through a verifiable form of patient-held records, benefitting both patients and clinicians. The proposals related to *subscriptions* are expected to improve the interoperability of patient health information, enabling more timely access to records for patients and clinicians and more up-to-date decision support modules for clinicians.

The College supports the intent of these proposals and the expected benefits to interoperability and patient care.

Patient, "Provider," Payer-to-Payer, and Prior Authorization APIs

ASTP proposes a set of certification criteria that reference HL7 FHIR R4 implementation specifications (developed by the HL7 Da Vinci Project) that align with CMS-established API requirements. The agency proposes to adopt and require current versions of the IGs CMS recommended in the CMS Interoperability and Prior Authorization Final Rule. The certification criteria would also incorporate certification criteria for modular API capabilities proposed elsewhere in HTI-2, including registration, authentication, authorization, workflow triggers for DSIs, and subscription capabilities. According to ASTP, adopting these certification criteria would improve standards-based interoperability and patient and clinician access to health care data held by payers. These proposals allow Certified Health IT to support a more effective exchange of clinical, coverage, and prior authorization information to reduce administrative burden.

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[10] Erickson SM, Rockwern B, Koltov M, et al; for the Medical Practice and Quality Committee of the American College of Physicians. Putting Patients First by Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physicians. *Ann Intern Med*.2017;166:659-661. [Epub 28 March 2017]. doi:10.7326/M16-2697.

ASTP proposes to adopt the "Patient Access API" certification criterion to specify requirements for health IT that payers can use to enable patients to access health and administrative information using a health application of their choice, including payer drug formulary information and patient clinical, coverage and claims information. Patients' access to this data enables more informed health care decision-making. This proposal also aligns with CMS' *Interoperability and Patient Access* final rule requirements for payers to establish Patient Access APIs.

As stated in comments to CMS on the *Reducing Provider and Patient Burden by Improving Prior Authorization Processes* proposed rule, the College supports efforts to place pertinent health information in the hands of patients and make it more easily accessible. This offers the opportunity to enhance patient-physician collaboration, empower patients to participate in health care decision-making and the self-management of their well-being, and result in more safe, efficient and effective care.

ASTP proposes to adopt two "Provider Access API" criteria to specify requirements for clinician and payer systems to support clinician access to payer information, including patient clinical, coverage, and claims information. Access to this data can inform better care coordination, increase care quality, and facilitate participation in value-based care. This proposal aligns with CMS' *Interoperability and Prior Authorization* final rule requirements for payers to establish "Provider" Access APIs.

As ACP shared in its comments on CMS' *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule, the College believes that clinicians should have access to their patient's clinical data, irrespective of payer contracts, to the extent permitted by law, when a verifiable patient-physician relationship exists. Internal medicine physicians must have a complete picture of their patients' health and treatment history and all relevant clinical data to diagnose and treat them effectively. However, this access must be patient-centric, and the College encourages using existing HIPAA-compliant systems to determine whether a patient-physician relationship exists.

ASTP proposes to adopt a payer-to-payer API to specify requirements for health IT that payers can use to facilitate electronic exchange between payer systems. These proposals are expected to allow health information to follow patients when they switch insurance plans and, according to ASTP, can enable coordination of care, increased patient empowerment, and reduced administrative burden. These proposals align with CMS requirements for payers to establish Payer-to-Payer Access APIs originally finalized in CMS' Interoperability and Patient Access final rule and updated in the Interoperability and Prior Authorization final rule.

The College supports the intent of CMS' proposal to facilitate the continuity of patient health information even when they switch payers. However, as stated in our comments to CMS on the *Reducing Provider and Patient Burden by Improving Prior Authorization Processes* proposed rule, the College remains deeply concerned about payers' increased access to clinical information impacting coverage decision-making. While physicians have controlled the patients' clinical data in determining what to submit to obtain reimbursement for care provided, payers now have access to information outside the scope of the specific service being billed. It is possible that payers could impose barriers or restrictions on coverage for medically necessary care that a patient may have received previously. Clinicians often do not have access to the results of a prior test. Still, if the payer's record indicates that the test has been performed, the payer often denies coverage for the test even though it is medically necessary. As a more specific example, if a patient had an echocardiogram 10 years ago for chest pain but now needs one for a new murmur, this could trigger a denial. ACP strongly contends that payer access to patient clinical data

should not disadvantage beneficiaries and should never be a determining factor for coverage. CMS or ASTP should require payers to attest that USCDI information exchanged between payers cannot be used to limit access to care in any manner. ACP believes that alternatively, payers should not be allowed to deny coverage based on knowledge that a test was previously performed unless the payer shares the results of the prior tests with the ordering clinician.

ASTP proposes to adopt two "Prior Authorization API" criteria to specify requirements for health IT that can be used by "providers" and payers to conduct electronic prior authorization (e.g., requirements for clinicians to request coverage requirements and assemble documentation for prior authorization and payers' ability to provide information about coverage and documentation requirements and receive prior authorization requests from clinicians). Systems certified to these criteria can greatly reduce the administrative burden arising from prior authorization. This proposal aligns with CMS requirements for payers to establish Prior Authorization APIs and for participants in Promoting Interoperability programs to report on new Prior Authorization measures, finalized in CMS' *Interoperability and Prior Authorization* final rule.

In its comments on CMS' *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule, ACP emphasized its enduring support of CMS' goal of expanding interoperability in the healthcare system through improvements to the electronic exchange of healthcare data and the streamlining of processes related to prior authorization. These concepts are consistent with ACP's *Patients Before Paperwork* initiative, which seeks to reinvigorate the patient-physician relationship and improve patient care by challenging unnecessary practice burdens. The current processes for prior authorization approval are burdensome and costly for physician practices and can take time away from patient care. These issues are exacerbated by individual payers, each with their approaches, rules, and requirements for prior authorization.

The College also advocated that the adoption and consistent implementation of standards would help reduce variability across EHRs and health IT systems and commended CMS for helping to move the policy needle in this direction. The College reiterates that health care entities must be united on reducing the prior authorization burden, including vendors being willing to incorporate new functionalities into their systems and organizations having the necessary resources to implement those functionalities in a timely way.

In comments to ONC on its *Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria* request for information, the College emphasized that there is a need for real-time decisions concerning prior authorization requests, as receiving a response to a prior authorization request after the patient has left the office causes additional, unnecessary administrative work outside of the patient visit and can delay appropriate treatment for the patient. A timely response at the point of care is integral to streamlining this process. Additionally, the College suggested that ONC should require that if the payer's response is an adverse coverage decision, the response should include precisely what documentation is needed from the clinician for the payer to reverse the decision. The College reaffirms its opinion that for electronic prior authorization to be meaningfully useful to the clinician, decrease burden, and improve patient care, the response from the payer must contain actionable information so the clinician can either easily provide any missing information or provide a clinically appropriate alternative to their initial prescription.

The College also recommended that ONC adopt a single set of certification criteria for prior authorization that accounts for the full, HIPAA-compliant workflow for prior authorization transactions. In its comments, ACP highlighted that while the functional capabilities described in the proposed rule would be helpful, the benefits of electronic prior authorization functionality will not be realized until vendors make it available and organizations adopt it. Again, we emphasize that under-resourced health systems and practices currently suffer the most in terms of prior authorization burden, and they are also the least likely to be able to afford electronic prior authorization implementation expenses. Therefore, having certified electronic prior authorization functionality is not enough; the products and functionality must be affordable to reduce the prior authorization burden meaningfully. Ideally, these functionalities would be incorporated into regularly scheduled EHR updates and system upgrades that are part of existing contracts without additional cost or subscription.

Additionally, the College encouraged ONC to incentivize vendors to incorporate electronic prior authorization capabilities into certified health IT by fostering the development of systems that could be affordably implemented into existing workflows and would provide timely responses critical to patient care to physicians. We highlighted that barriers to electronic prior authorization include EHR vendors' willingness to incorporate electronic prior authorization capabilities into their EHR systems. We recommend that ONC incorporate these standards and capabilities into its certification criteria and further incentivize their incorporation into EHR systems. We, therefore, applaud ONC for proposing this prior authorization certification criterion and look forward to its expected benefits for physicians and their care teams.

In comments to CMS on the *Reducing Provider and Patient Burden by Improving Prior Authorization Processes* proposed rule, the College emphasized that the PA API should be tested and piloted to help determine if it truly decreases burden. We reaffirm the need for testing of the API and suggest that pilots could include non-technical policy proposals incentivizing the adoption of APIs.

Conclusion

The College appreciates the opportunity to provide feedback on these important health care interoperability proposals. We look forward to continuing to work with ASTP to improve physicians' experience of health IT and the quality and safety of patient care. Please contact Nadia Daneshvar, JD, MPH, Health IT Policy Associate, at ndaneshvar@acponline.org with comments or questions about the content of this letter.

Sincerely,

Ross W. Hilliard, MD, FACP
Chair, Medical Informatics Committee
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