AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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The Honorable Seema Verma
Administrator
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (RIN 0938-AT99)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the notice of proposed rulemaking (NPRM) entitled "Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications" (Proposed Rule), published in the Federal Register on December 18, 2020 (85 Fed. Reg. 82586).

We greatly appreciate CMS' efforts to build on its Interoperability and Patient Access final rule (Final Rule) to improve the electronic exchange of health care data, reduce physician burden, and streamline processes related to prior authorization. As detailed later in this letter, we believe CMS should utilize this NPRM as a way to test new standards and thoroughly assess their viability and impact across stakeholder groups prior to CMS undertaking any rulemaking that would change existing Health Insurance Portability and Accountability Act (HIPAA) electronic standard mandates. This approach would help to ensure that any standards are adequately tested and vetted prior to being mandated for federal adoption across all HIPAA covered entities while simultaneously taking concrete steps to advance CMS' policy goals. Moreover, we believe CMS

should consider provision of positive financial incentives to physicians and vendors to participate. Additionally, we recommend that CMS include Medicare Advantage plans in the scope of the rule to increase the volume of impacted patients, which would further motivate physicians and vendors to implement these new standards. We urge CMS to enhance such standards testing by adding a requirement for a formal analysis and public report of the outcomes of the technologies implemented under this rule to ensure the proper feedback loop with standards development organizations and developers. Our comments reflect reading and analyzing the NPRM through this trial-based lens and include recommendations to improve the initial trial framework and best position it for success. **Absent modifications to this initial testing phase, we have concerns that this proposal will fail to achieve its goals due to insufficient participation, will confuse payers about their obligations, will inadvertently increase burden on physician practices, and will fall short of providing patients with access to meaningful information about their health care.** The table enclosed with this letter reflects the AMA's response to and recommendations on CMS' specific proposals.

CMS' proposal recognizes the significant burdens that prior authorization places on both timely, quality patient care and physician practices, as shown in the 2019 AMA Prior Authorization Physician Survey[1] results and the stories featured on our grassroots advocacy website, FixPriorAuth.[2] We note that many provisions of this rule align with, or could easily be adjusted to address, the prior authorization reforms outlined in the Prior Authorization and Utilization Management Reform Principles (Principles)[3] and Consensus Statement on Improving the Prior Authorization Process (Consensus Statement).[4] Notably, all areas of the Consensus Statement—to which the health insurance industry has already agreed—could be operationalized via this rule as written or as adjusted based on our suggestions: selective application of prior authorization; regular review and adjustment of prior authorization lists; improved communication and transparency; protections for continuity of patient care; and automation to improve process efficiency. We applaud CMS for taking this important step to require plans to implement these critical prior authorization reforms, as health plans' progress in voluntarily implementing the Consensus Statement improvements has been minimal over the past three years, as illustrated by AMA survey data.[5]

Additionally, we strongly support CMS' proposal to require payers to collect attestation statements from third-party apps accessing patient data via application programming interfaces (APIs) to provide patients with insight into such apps' privacy practices. The AMA has advocated for such a policy, and we appreciate CMS' leadership in recognizing that such transparency is imperative to maintain patient trust in both the health care system and emerging

[1] AMA, 2019 Prior Authorization Survey Results: Measuring progress in improving prior authorization, *available at* https://www.ama-assn.org/system/files/2020-06/prior-authorization-reform-progress-update-2019.pdf.
[2] https://fixpriorauth.org/
[3] AMA, Prior Authorization and Utilization Management Reform Principles (2017), *available at* https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf.
[4] AMA, Consensus Statement on Improving the Prior Authorization Process (2018), *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.
[5] AMA, 2019 Prior Authorization Survey Results: Measuring progress in improving prior authorization, *available at* https://www.ama-assn.org/system/files/2020-06/prior-authorization-reform-progress-update-2019.pdf.

technologies. As evidenced by this proposal, CMS recognizes that patients deserve—and can have—both access **and** privacy. **We urge the Office of the National Coordinator for Health Information Technology (ONC) to follow CMS' lead and require via future rulemaking a similar attestation requirement for the patient access APIs it certifies.**

Finally, we are pleased that CMS is seeking stakeholder input on a variety of topics, including granular data controls, positive incentives for adoption of electronic prior authorization processes, and strategies to accelerate adoption of standards related to social risk data. Each of these topics will require careful thought from an array of stakeholders. Moreover, they will require deliberate coordination among multiple federal agencies to ensure that proposed policies do not increase physician burden, consider impacts on health equity, and empower the physician-patient relationship.

In closing, thank you for this opportunity to share the views of the AMA regarding the proposals, issues, and questions that CMS has raised in its NPRM. Our comprehensive comments are found in the enclosed chart. If you have any questions, please contact Laura Hoffman, Assistant Director, Federal Affairs, at laura.hoffman@ama-assn.org.

Sincerely,

James L. Madara, MD

Attachment

Proposal	Support as Proposed, Support with Modification, or Oppose	Additional Comments
Overarching Issues		
Proposed new requirements would be effective January 1, 2023.	Support as proposed	The AMA supports CMS' proposed effective date of January 1, 2023. However, we flag for CMS that physicians will also be required to use new 2015 Edition Cures Update electronic health record (EHR) technology by that date. While CMS states that it does not believe substantial technical changes will be required to support its new application programing interface (API) and other technical proposals, we note that the EHR vendor community has already identified several complexities and challenges complying with the Office of the National Coordinator for Health Information Technology (ONC) 2015 Edition Cures' certification requirements by the end of 2022. Moreover, ONC is not making CMS' proposed technical changes part of its own certification program—therefore leaving important CMS provisions like the Provider Access API voluntary for EHR vendors to implement. Since EHR vendors will have a range of new technologies rolling out just before CMS' proposed 2023 compliance deadline, we question how many EHR vendors will spend time and resources on adopting the Provider Access API, let alone making several of the other meaningful CMS provisions highly usable in their EHR products. Said another way, CMS needs to consider what will become a priority for EHR vendors as regulatory requirements bottleneck near the end of 2022. The AMA is concerned physicians may miss out on realizing several of CMS' important proposals. Prior to requiring health care stakeholders adopt technical requirements, CMS should work with the EHR vendor community and identify a practical timeline that balances the realities of EHR development with PA improvements CMS is seeking to promote.
Scope of payers – particularly exclusion of MA plans	Support with modification	• As described earlier, we appreciate many of the proposals in this NPRM, but believe for them to truly make a difference in burden reduction, CMS must expand the scope of the policy to include Medicare Advantage (MA) plans as those plans (1) have more PA requirements than the plans currently in scope, (2) cover a much larger proportion of patients than do the payers impacted by

		this rule, and (3) have been found to have high rates of inappropriate denials, according to a 2018 Office of Inspector General Report.[1] In addition, commercial payers with MA lines of business are active participants in the Da Vinci Project workgroups that created the standards referenced in this rule and would therefore be expected to already have the PA-related APIs in development. • We support CMS' stated intention to align BlueButton 2.0 with the proposals, if finalized, for the Medicare FFS program. • This is a limited patient population that may not be representative of the entire patient population in terms of technology adoption and usage. • We caution CMS against making assumptions regarding physician interest in electronic PA based on the technology adoption observed following the provisions of this rule. For most practices, the electronic PA workflow described would only be available for a small percentage of the patient panel, making it unlikely that physicians would invest in EHR updates and implement a new PA process. • It will be important for Medicaid payers to receive funding quickly to start building the technology for these programs.
Patient Access API		
CMS is proposing to require the use of the CARIN IG for Blue Button, the PDex IG, and the PDex US Drug Formulary IG for the Patient Access API.	Support with modification	• Generally, we support this concept since having various payers use different processes for information exchange can exponentially increase burden and costs. • However, we note that the named Implementation Guides (IGs) are not yet published—CMS should not propose required use of IGs that have not completed the Health Level Seven (HL7) publication process. This supports the need for CMS to approach this proposal as a demonstration—physicians and payers alike will benefit from real-world testing of these standards. • We appreciate CMS' proposal to permit regulated entities to use an updated version of any of the IGs proposed for adoption if the updated IG does not disrupt an end user's ability to access data through any of the specified APIs.

[1] HHS Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials. OEI-09-16-00410 September 2018. Available at: https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf.

		However, **we encourage CMS to clearly define what "disruption" means and who determines when it occurs.** • The AMA also notes that since several of the proposed IGs are at the standard for trial use (STU) ballot level, codifying these IGs in regulations at this time may unintentionally stall the continued development of the IGs. At the time CMS releases its final rule, all impacted payers and health IT developers will begin work on implementing technology to support the newly required IGs and standards. They will need a stable set of implementation guidance as a foundation for their development. Unfortunately, an STU IG means that guides can go through additional refinement and several more changes before they become "normative" with strict rules for use. HL7, the standards development organization that manages each IG and standard proposed by CMS in this rule, states that an STU ballot level "is used to vet content that is deemed 'ready to implement' by sponsoring work group, but where there has not yet been significant implementation experience." The AMA is concerned about the downstream implications of including IGs and standards in regulation that have not had significant implementation experience. • Furthermore, HL7 states that "STU specifications are time-limited and give an opportunity for the community to exercise the specification in real-world implementation before the specification is 'locked down' and forward and backward compatibility rules come into play." By including these IGs in regulation, CMS is effectively "locking down" the IGs in an STU state. In this case, CMS may inadvertently require the use of technical standards before they are ready for "primetime" and, at the same time, freeze the standards in regulation while impacted payers and health IT developers work to meet CMS' compliance date. The HL7 standards community may be reluctant to update or make necessary changes to these IGs to give the impacted entities a solid foundation to develop from. This could result in CMS' proposed IGs being locked in a perpetual state of limbo. • **The AMA urges CMS to consider all ramifications of regulating the use of non-normative standards. For instance, the AMA reiterates its recommendation that CMS consider starting with a demonstration program before requiring compliance with its proposals.**

CMS is proposing that impacted payers be allowed to conform with either the US Core IG or the PDex IG to facilitate making the required USCDI data available via the Patient Access API.	Oppose	• The AMA is concerned with providing impacted payers the optionality to choose which IG to adopt. CMS implies that the Provider Access API is mapped directly to the requirements of the Patient Access API. CMS also states that it intends for the Provider Access API to integrate directly within a physician's EHR workflow. The AMA supports CMS' efforts to reduce physician burden using EHRs. Yet, the development, and the resulting fees charged to physicians by EHR vendors to integrate the Provider Access API in their products, could be considerable. Physicians are already required to use EHRs certified to the US Core IG. Since the Patient Access API and Provider Access API are linked, it is not clear what additional costs physicians could incur if IGs that overlap with the requirements of the Provider Access API are used inconsistently. Ultimately, we question why CMS would propose a payer IG policy that could result in incompatibility with physicians' EHRs—therefore negating the usefulness of the Physician Access API. **The AMA strongly urges CMS to adopt policies where physician costs and burden are minimized. To this end, we recommend that CMS identify what can be accomplished through the use of certified EHR technology that physicians are required to adopt for participation in federal reporting programs. Additionally, CMS should outline what the expected physician return on investment will be if payers use PDex vs. US Core. CMS should justify why payers have been given implementation choices if the impact has not been clearly identified or communicated to the end-user community.**
"If a patient can see the supporting documentation shared with their payer they might better understand what is being evaluated and even potentially help providers get the best and most accurate information to payers to facilitate a successful prior authorization request, thus potentially avoiding unnecessary delays in care and reducing burden on providers and payers."	Support with modification	• The AMA strongly supports patients having the tools in place to engage with the delivery of their health care. Patients should also be made aware of the status of their care, in both an administrative and clinical context, and have the opportunity to contribute additional medical or other information if they wish to do so. We appreciate that CMS shares the AMA's desire to improve patient engagement. Throughout the proposed rule, CMS discusses the benefit of expanding patients' access to PA and other administrative workflows. Increasing transparency can better ensure that payer and clinician workflows are based on the patient's needs. • CMS also makes several references to patients "providing missing information," "producing missing documentation," and helping "get the best

"This proposed requirement could provide patients with an opportunity to better follow the prior authorization process and help their provider and payer by producing missing documentation or information when needed." "The proposed requirement to make available information about pending and active prior authorization decisions and associated documentation through the Patient Access API is expected to allow beneficiaries to more easily obtain the status of prior authorization requests submitted on their behalf, so that they could ultimately use that information to make more informed decisions about their health care, improve the efficiency of accessing and scheduling services, and if needed, provide missing information needed by the state to reach a decision."		and most accurate information to payers." The AMA reiterates that it supports providing patients an option to engage in the PA process. However, we are very concerned that patient engagement could easily become a patient requirement by payers—dragging patients into administrative workflows which are burdensome for everyone involved. For instance, we foresee payers coopting a patient's right to contribute information as yet another condition for PA approval or, worse yet, a new requirement for all PAs. Administrative workflows should never hinge on requirements that patients must engage. We are also concerned that discrepancies in information submitted by a physician and patient could lead to payer confusion, adding further PA delays and denials. Patients who either do not wish to engage or cannot or do not understand the administrative requirements should never be put in the position where their lack of engagement delays their own care. Without additional clarity from CMS, we are concerned CMS' intent will not be clear and inadvertently promote policies that could have the unintended consequence of requiring patients to check in and "keep the ball moving" on administrative workflows. **The AMA urges CMS to clarify that payers should never require, as part of a PA approval, PA review, or any pending or active PA process, that patients contribute or review information.**
CMS is proposing to require impacted payers to make available to patients information about any pending and active prior authorization decisions (and related clinical documentation and forms) for items and services via the Patient Access API conformant with the HL7 FHIR Da Vinci Payer	Support	• The AMA appreciates CMS' desire to provide patients with information about their PA decisions. We are pleased that our previous recommendation to include this information in the Patient Access API is included in this NPRM. • CMS notes that the Patient Access API would not display denied or expired PA decisions, assuming them to be no longer relevant. However, while the API would show a change in status if a pending PA was denied, it is not clear how long the API would need to retain this information. **We recommend that**

Data Exchange (PDex) IG no later than one (1) business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization.		**CMS clarify how long PA denial information should be retained in the API to ensure that patients have sufficient time to access this information.**
CMS seeks comment on whether payers should be required to include info about prior authorization decisions regarding prescription drugs or covered outpatient drugs via the Patient Access, Provider Access, or Payer-to-Payer APIs. CMS asks for any specific considerations re: the role of PBMs.	N/A	• Patients also have a critical need for accurate, current data about prescription drug costs, coverage, and PA status. The prescription drug coverage information available to both physicians and patients must be in perfect alignment, as any discrepancies in data will result in confusion and frustration. The National Council for Prescription Drug Plans (NCPDP) is developing both physician- and consumer-facing real-time pharmacy benefit standards. Because the data populating these NCPDP standards derives from a different source (i.e., pharmacy benefit manager vs. major medical plan), inclusion of prescription drug information in the APIs developed for this rule may be difficult, particularly under the given compliance deadline. We strongly support patient access to prescription drug coverage data, including PA status, but we note that other standards/tools are being developed for this purpose.
CMS is proposing to require that impacted payers establish, implement, and maintain a process to facilitate requesting an attestation from a third-party app developer requesting to retrieve data via the Patient Access API that indicates the app adheres to certain privacy provisions.	Support with modification	• AMA applauds CMS' proposal and urges ONC to adopt a similar policy for its patient access APIs. • CMS specifically requests comment on the payer's obligation to send the data regardless of whether the patient responds to the notification of the app's attestation result, particularly if the answer is no. Because patients have a right to access under HIPAA to their information in a variety of formats, we believe payers should need to provide the requested information to patients even if the app's answer to the privacy attestation is no. • **We urge CMS to require that app developers be required to attest to each item independently (i.e., CMS should require a line-item, rather than an all-or-nothing, approach to attestation).** This would allow patients to select apps that have privacy values most like theirs, make more informed decisions while shopping for apps with which they are comfortable sharing personal health information (i.e., better ability to "comparison shop"), and bolster trust in the use of emerging technologies.

		• We note that in addition to the industry best practices identified by CMS in its proposal (the CARIN Alliance's Code of Conduct and the ONC Model Privacy Notice), the eHealth Initiative and Center for Democracy and Technology have developed a Consumer Privacy Framework for Health Data.[2] Funded by the Robert Wood Johnson Foundation and with engagement and help from a Steering Committee of leaders from healthcare entities (including the AMA), technology companies, academia, and organizations advocating for privacy, consumer, and civil rights, the framework consists of a set of detailed use, access, and disclosure principles and controls for health data that are designed to address the gaps in legal protections for health data outside HIPAA's coverage. The framework also includes a proposed self-regulatory program to hold companies accountable to such standards. **We urge CMS to include this framework as an example of industry-developed best practices in future publications given its broad applicability to a wide range of patient data, its attempt to serve as a benchmark to shape industry conduct and influence companies' approaches data privacy, and the diversity and expertise of organizations who provided feedback on the framework.** • The AMA does not support CMS' proposal that payers would not be required to ask for and capture attestations of apps participating in private industry third party app attestation processes. We do not view apps participating in a voluntary private organization equivalent to meeting the necessary transparency and reporting requirements CMS outlines in its proposed rule. While we see a role for private industry third parties to establish best practices, create guidelines, and develop data privacy and security frameworks, **we do not believe the act of simply consolidating statements made by app developers into one "app gallery" or list provides the necessary data use transparency information that CMS has rightfully stated that patients deserve.** • The AMA strongly supports CMS' acknowledgment that providing patients direct and immediate access to an apps attestation will "help inform patients about an app's practices for handling their data." We also agree that requiring

[2] The draft framework is available here: https://cdt.org/press/cdt-and-ehi-release-draft-consumer-privacy-framework-for-health-data/. The final framework is anticipated to be released in early January 2021.

		CMS' proposed provisions in a payer's attestation request will "help patients understand if and how the app will protect their health information and how they can be an active participant in the protection of their information." Yet, for patients to benefit from app attestation transparency, they must have consistent access to app attestations that are provided by an authoritative source with the backing of federal oversight. If, for instance, a payer chooses to use a private industry third party as an app attestation clearinghouse, and therefore is not required to directly request and capture app attestations, patients will not benefit from having direct and immediate access to critical information such as how an app uses, shares, markets, or sells their health information. Patients will also lose out on direct knowledge of an app's express consent policy and how to discontinue app access to their information. Patients will instead need to find, review, and match their personal preferences with one or more codes of conduct. These codes may be updated, changed, or reversed at any time without the patient's knowledge. Over time, such private industry organizations may effectively function as reliable third-party reviewers. However, trust in these efforts must first be established (e.g., ensuring private industry bias is not influencing an entity's efforts). Again, the AMA recognizes the value of private industry third parties defining data use boundaries; however, we do not support using an online list as a proxy for payers enforcing regulated data privacy requirements. **The AMA recommends that, for now, CMS require payers to directly request and collect an app's attestation to a series of privacy provisions, regardless of that app's participation in alliances, collaboratives, or other private industry efforts.**
CMS is proposing to require impacted payers to report certain metrics about patient data requests via the Patient Access API quarterly to the agency.	Support	• We support payers reporting the names of the unique apps that access the payer's API and recommend that this information be reported on a quarterly basis. • **We also urge CMS to require payers to make public the answer each app provides to the privacy attestation.** • We caution CMS not to make broad assumptions regarding patient interest in using Patient Access APIs based on these metrics; as previously noted, the rule applies to a limited scope of patients whose use and access to technology may not reflect that of the overall US population.

CMS is proposing two technical changes to regulatory text: (1) clarify that the Patient Access API must make available clinical data as defined in the USCDI Version 1; and (2) replace "enrollees" and "beneficiaries" with "parties."	Support	• We support CMS' proposal to be more specific about the types of clinical information that payers must make available via its APIs, as well as the clarification that multiple types of entities (e.g., payers and providers) may access APIs. • Does CMS intend to make this change applicable to all of the payers impacted by its Patient Access rule? For example, will the requirement for MA plans still require the API to make available to patients, "clinical data, including laboratory results?" If so, **we urge CMS to extend these technical changes to all payers impacted by the Patient Access Rule to promote consistency for payers and patients alike.**
CMS is proposing that the Provider Directory API be conformant with the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0.	Support	• We are supportive of CMS's efforts to ensure that Provider Directories are accurate and current. We support CMS' proposal that Provider Directory APIs conform with a single IG. However, we oppose any aspect of this proposal that would impose additional regulatory requirements on physicians, including any shortened timeframes for physicians to update their information with payers.
Payer-to-Payer Exchange		
CMS is proposing to extend the patient-initiated Payer-to-Payer Data Exchange requirements to state Medicaid and CHIP FFS programs.	Support as proposed	N/A
CMS is proposing that impacted payers must implement and maintain a Payer-to-Payer API to facilitate the exchange of patient information between impacted payers, both with the approval and at the direction of the patient and when a patient moves from one payer to another as permitted, and in accordance with applicable law.	Support with modification	• We support this proposal to the extent that it will promote continuity of care and prevent new PA or step therapy requirements. We recognize that this proposal is an extension of the policy finalized in CMS' Patient Access and Interoperability final rule (i.e., it is a mechanism of operationalizing, rather than altering, the underlying policy). However, as noted in our comments in response to the Patient Access and Interoperability proposed rule, we continue to have concerns about whether excessive data access will lead to increased PA and patient profiling, which could limit coverage and access to care. For example, a payer could determine that the patient had already received imaging or another service from another plan and automatically deny coverage of that imaging service or require unnecessary PA requirements that delay needed care. Even when patients already have coverage, there are examples of payers

		making coverage decisions based on patient information that neither the patient nor the patient's physician knew the payer was receiving.[3] • Accordingly, we urge CMS to prohibit payers from using information that a beneficiary's former plan sends to the beneficiary's new plan to discriminate against a beneficiary—both newly covered and those in the application process. **CMS should require that payers (a) attest that USCDI exchange between plans cannot be used as a basis to deny or delay coverage, increase rates, or implement step therapy; (b) display information to that effect on their website and in coverage documents; (c) cannot require an applicant or enrollee to request that a previous payer send the information to the payer as part of the enrollment process; and (d) provide language to that effect on enrollment forms and websites.** • We also note that CMS' characterization of "payers [providing a] more holistic view of a patient's care across providers over time" is not necessarily accurate. First, it is important to note that beneficiaries who do not receive insurance through their employer may go with the least expensive option during each open enrollment, which may change from year to year. Beneficiaries who do receive insurance through their employer may change payers with each new job. Additionally, as many patients can likely attest, payer information can be complex and erroneous. Physicians and the information stored in physician EHRs are the optimal source of truth with respect to clinical data about a patient's health care. **We encourage CMS to avoid characterizing payer records as the most accurate and helpful for patients.**
CMS is proposing that impacted payers implement the Payer-to-Payer API in accordance with the specified HL7 FHIR version 4.0.1 IGs, as well as the HL7 FHIR Bulk Data Access (Flat FHIR) specification, to support exchanging patient data including but	Support with modification	• The AMA supports this proposal, but we urge CMS to require payers to honor the established/ongoing PA approvals from a patient's prior payer. Both the PA Principles and Consensus Statement support this concept as a means to protect the continuity of ongoing care when patients change benefit plans.

[3] Marshall Allen, *You Snooze, You Lose: How Insurers Dodge The Costs Of Popular Sleep Apnea Devices*, National Public Radio and ProPublica (Nov. 21, 2018), available at https://www.npr.org/sections/health-shots/2018/11/21/669751038/you-snooze-you-lose-how-insurers-dodge-the-costs-of-popular-sleep-apnea-devices.

not limited to: adjudicated claims and encounter data (not including cost information), clinical data as defined in the USCDI, and information related to pending and active prior authorization decisions.		
Provider Access API		
CMS is proposing to require that impacted payers implement and maintain a Provider Access API that utilizes HL7 FHIR version 4.0.1 to facilitate the exchange of current patient data from payers to providers, including adjudicated claims and encounter data (not including cost information), clinical data as defined in the USCDI, and information related to pending and active PA decisions.	Support	• The AMA supports physicians being able to access patient data from payers to support care coordination, including insight into treatment that a patient may be receiving from another clinician. We also strongly favor physicians' access to PA status in the Provider Access API. However, as noted in our comments on the Patient Access API, we suggest that CMS clarify how long the API must retain information regarding PA denials; both physicians and patients should be allowed sufficient time to access data on PA denials following the health plan's decision.
Through a cross-reference to the Patient Access API requirements, CMS is proposing that the Provider Access API also require adherence to the same technical standards, API documentation requirements, and discontinuation and denial of access requirements as the Patient Access API.	Support with modification	• As previously stated in this letter, the AMA is concerned with the potential unintended consequences of tying the Patient and Provider Access API requirements together. CMS is proposing that the Provider Access API require adherence to the same technical standards, API documentation requirements, and discontinuation and denial of access requirements as the Patient Access API. CMS also states that it intends for the Provider Access API to integrate directly within a physician's EHR workflow. The AMA supports CMS' efforts to reduce physician burden using EHRs. Yet, the development, and the resulting fees charged to physicians by EHR vendors to integrate the Provider Access API in their products, could be considerable. Physicians are already required to use EHRs certified to the US Core IG. CMS is also proposing that impacted payers be allowed to conform with either the US Core IG or the PDex IG to facilitate making the required USCDI data available via the Patient Access API.

		• Since the Patient Access API and Provider Access API are linked, it is not clear what additional costs physicians could incur if IGs that overlap with the requirements of the Provider Access API are used inconsistently. Said another way, binding the Provider Access API to a second set of API requirements (i.e., Patient Access API) where those requirements may change between payers or even among payer lines of business may negatively impact the usability and physician experience with the Provider Access API. Ultimately, we question why CMS would propose a payer IG policy that could result in incompatibility with physicians' EHRs—therefore negating the usefulness of the Physician Access API. **The AMA strongly urges CMS to adopt policies where physician costs and burden are minimized.**
CMS is proposing that a provider that is not in network would need to demonstrate to the patient's payer that they do have a care relationship with the patient.	Support with modification	• The AMA seeks further clarity from CMS on what it would expect a physician to provide to a payer to demonstrate a care relationship with a patient. Our members continue to highlight instances where payers use time-consuming and burdensome practices (e.g., via PA requirements) as tactics to dissuade physicians from using their own professional judgment. These tactics can come in the form of lengthy documentation requirements, obfuscation of guidelines used by payers, delays in responses to requests, denials without clear explanation, and inefficient workflow demands (e.g., requiring the use of cumbersome payer web portals). The AMA appreciates CMS' effort to address several of these issues through the proposals in this rule. However, we are concerned that by leaving the methods to demonstrate care relationships up to the payers, that determination could result in another set of unnecessary, time-consuming, and burdensome payer practices that will negatively impact patient care. **The AMA suggests CMS clarify that physicians will not be expected to use methods that are beyond what in-network providers would need to take to demonstrate a relationship with a patient or that take physicians outside of their normal workflows to demonstrate a care relationship. For instance, the CMS companion guide on the HIPAA-mandated eligibility transaction supporting Medicare Beneficiary Matching could serve as a model for what should be required to facilitate beneficiary matching. In short, we recommend requiring out-of-network providers to demonstrate their relationship with the patient by supplying to the payer the patient's**

		insurance plan member ID, first and last name, and date of birth. Above all, we stress the need for payers to do what is in the best interest of the patient, regardless of the provider's in- or out-of-network status with any particular payer.
CMS is proposing to have payers implement one API solution that does not leverage the Bulk specification for a single patient request (as discussed in section II.B.3. above in this proposed rule), and a second solution that uses the Bulk specification for requests for more than one patient.	Support	N/A
Prior Authorization		
CMS seeks comment on whether there are steps it can take to increase use of the X12-278 standard and what challenges will remain if it is more widely used.	N/A	• The AMA has long supported use of standard electronic transactions to improve the efficiency of the burdensome PA process. However, as noted in the NPRM, industry adoption of the X12-278 is extremely low, having no doubt been hindered by the lack of an electronic standard for clinical attachments. Without a standard method for exchanging the clinical documentation needed to support most medical service PAs, it is highly unlikely that the X12-278 will achieve widespread use. Additionally, few if any payers use unsolicited X12-278 transactions to communicate final PA decisions after initial "pends," which further discourages use of the standard transaction. • CMS references the continued use of the X12-278 in tandem with the Da Vinci PAS API. The AMA seriously questions the value or role of using the X12-278 in this model, as it appears that the transaction's only function is to maintain HIPAA compliance. The black box "translation" of FHIR to the X12-278 in the middle of the PAS workflow is wasteful and will no doubt increase administrative costs for both physicians and health plans—both of which will need to use clearinghouses or other intermediaries to accomplish this translation. Additionally concerning is the potential for errors resulting from 278-to-FHIR mapping. Indeed, discussions at HL7 workgroups and events

		suggest that one of the main challenges for successful PAS implementation involves the FHIR-to-278 mapping. • **We encourage CMS to allow HIPAA exceptions for any health plans that wish to pilot the PAS standard without including the X12-278 (i.e., FHIR-to-FHIR model).** This will allow the industry to test this new technology and inform any future decisions/changes regarding PA electronic standards under HIPAA. We anticipate imminent arrival of the attachment rule and encourage CMS to coordinate internally to prevent misalignment. We harbor significant concerns that the standards referenced in the forthcoming attachment rule will not align with those referenced in this rule, which would create the disastrous situation of different health plans using different workflows and electronic transactions for PA. Such variation across the industry would be extremely burdensome and costly for physician practices.
CMS is proposing to require that impacted payers implement and maintain a FHIR-based prior authorization Documentation Requirement Lookup Service (DRLS) API conformant with the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG: Version STU 1.0.0 and the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR): Version STU 1.0.0 IG, populated with their list of covered items and services, not including prescription drugs and/or covered outpatient drugs, for which prior authorization is required, and with the organization's documentation requirements for submitting a prior authorization request, including a	Support with modification	• The AMA strongly supports the provision of information regarding PA requirements and payer documentation needs within physicians' EHR workflow, which aligns with CMS' proposal to require payers to implement a DRLS API based on the CRD and DTR guides. This technology operationalizes concepts in both the PA Principles and Consensus Statement related to improving the transparency of payer PA requirements and documentation requests, as well as saves physicians and staff the hassles associated with obtaining this information from myriad payer websites and policy manuals. However, the AMA has identified the concerns outlined below regarding the provisions of the rule. • Having various payers use different processes for PA exponentially increases PA burdens. Multiple PA APIs would be costly and burdensome for physicians to support. **The AMA encourages CMS to specify that a single DRLS API should be used to house coverage and documentation requirements for all participating payers.** • CMS is naming STUs that are not normative, which could cause issues. o We note that the named IGs are not mature—CMS should be transparent about this fact and that this proposal will essentially serve as a demonstration project. This technology is currently untested, and we urge CMS to require implementing payers to report on outcomes of the use of the technology. The

description of the required documentation.		results of implementation should be publicly reported and analyzed to ensure that the standards are appropriately updated to correct errors and to improve usability. ○ We also note that providers are generally under-represented in Da Vinci workgroups and in HL7 Connectathons, raising further questions about the viability of these APIs in real-world practice settings. It will be critical for CMS to ensure sufficient testing of these nascent standards in practices of all sizes and a representative sample of EHR vendors before considering future rulemaking regarding PA standard mandates. • By naming a specific IG, it could potentially freeze progress on IG development. While we recognize the flexibility offered by the Standards Advancement Process outlined by both CMS and ONC in previous regulation, we caution that by naming a specific IG without an accompanying provision that implementers can adopt updated versions as they are approved by HL7 (particularly given that CMS is designating the use of STU IGs and not Normative IGs), CMS may inadvertently stifle innovation and evolution of the IG. • Furthermore, the AMA seeks additional information from CMS on how it has determined a clear and practical process for payers to navigate HL7 IG versioning. For instance, as the CDR and DTR IGs migrate from version to version (e.g., 1.0 to 1.1) and STU to Normative, how is CMS assuring patient care and physician workflows will not be negatively impacted? We remind CMS that an STU IG means the guides themselves may change and backwards compatibility between STU versions is not guaranteed. The misalignment between payers and physicians using IGs of different versions could cause delays in patient care and impact treatment. What controls will be in place to ensure an orderly transition to new HL7 standards and versions across the health IT environment? How will CMS measure and monitor the impact on patients, physicians and their medical practices due to different payer implementations of these guides? • CMS should consult with Division of National Standards to ensure that policies are coordinated and the larger implications of the proposal for all stakeholders are considered. Typically, changes to standards are done through a different

		part of CMS, rather than a rule regulating payers. We are concerned about the potential unintended and disruptive consequences of adopting non-normative standards through this non-traditional rulemaking process. • We also caution that guardrails are necessary to ensure that payers are only accessing necessary protected health information in implementation of DRLS APIs. CRD/DTR technology should only be triggered when a physician initiates a medical service order for a particular patient; **CMS should explicitly prohibit payers from "eavesdropping" and accessing EHR data when a physician merely opens a patient's electronic record.** • CMS inquires if payers should be required to post PA requirements and documentation specifications on websites as an interim step to implementing a DRLS API. The AMA does **not** support this approach, as it merely perpetuates the status quo, which forces physicians and practice staff to exit the EHR workflow and navigate many different payer websites to obtain this information. • CMS requests information regarding ways to incentivize vendor and physician adoption of these APIs. As previously noted, the limited patient population targeted in this rule will serve as a barrier to physician adoption, as practices are unlikely to invest in new technology and workflows usable for only a small subset of their patient panel. Moreover, it is not clear if a physician's EHR will readily identify patients for which the DRLS API is available, which serves as a further barrier to physician adoption. • As stated previously, expanding the reach of the rule to MA plans would increase the likelihood of physician adoption and vendor development of the API technology. We also urge CMS to re-envision this rule as a demonstration project and consider provision of positive financial incentives to physicians and vendors to participate. Ensuring sufficient practice and vendor participation in testing the nascent FHIR standards will be crucial in evaluating their viability and readiness for more widespread implementation across payers.
CMS is proposing to require impacted payers to implement and maintain a	Support with modifications	• The AMA strongly supports an end-to-end automated PA process that integrates with physicians' EHR workflow, and the PA Principles and

FHIR-based Prior Authorization Support (PAS) API that would have the capability to accept and send prior authorization requests and decisions, and could be integrated within a provider's workflow, while maintaining alignment with, and facilitating the use of, HIPAA transaction standards. Provider use of the PAS API would be voluntary and payers may maintain their existing methods for processing prior authorization requests.		Consensus Statement reinforce the importance of standard electronic PA technology. We generally support adoption of a PAS API but offer the following comments and suggested amendments. • Having various payers use different processes for PA exponentially increases PA burdens. Multiple PAS APIs would be costly and burdensome for physicians to support and add unnecessary complexity to EHR vendor integration. For this reason, **we urge CMS to require payers to utilize a single PAS API that would house PAS exchange for all participating payers.** • The AMA also harbors significant reservations regarding the unprecedented access to EHRs enabled by the Da Vinci PAS guide. **We urge CMS to require adequate protections so that payers are only able to access EHR data relevant for a particular PA request and ensure that physicians have the opportunity to review any patient data before it is sent to the payer.** • As noted previously, it is crucial that any rulemaking issued by the Division of National Standards regarding an electronic attachment standard align with the provisions of this rule; otherwise, physicians will face the enormous burden of supporting multiple methods of clinical data exchange across payers. • The AMA is unclear of the value of the FHIR-to-X12-278 translation imposed in the middle of the PAS workflow; it appears that this is required for the sole purpose of maintaining HIPAA compliance, which has little intrinsic value. Rather, we foresee this translation as increasing administrative costs for both practices and health plans while also introducing possible data errors from mapping problems. As such, **CMS should grant HIPAA exceptions to remove the requirement of X12-278 usage and promote direct FHIR-to-FHIR exchange for this pilot implementation of the Da Vinci guides.** CMS can glean important lessons from such testing implementations to inform future rulemaking related to PA electronic standards. • The AMA strongly supports the proposal to require impacted payers to include a specific reason for denials of PA requests. Additionally, to align with the Principles, **we urge CMS to require impacted health plans to provide complete information detailing the reasons for PA denials, including indication of any missing information, the clinical rationale for the adverse**

		determination (e.g., national medical specialty society guidelines, peer-reviewed clinical literature, etc.), the plan's covered alternative treatment, and details on appeal rights and process.
CMS is proposing several policies that would require impacted payers to respond to prior authorization requests within certain timeframes. • 72 hours for urgent PAs; 7 days for non-urgent • Does not apply to QHP issuers on the FFEs	Support in concept (requirement for response timeframes), but not specific proposed timelines	• The AMA supports and highly appreciates the overall concept of the requirement for payers to respond in a particular timeframe, but the proposed timeframes are too long. The AMA's PA physician survey[4] clearly shows the association between PA requirements and treatment delays and abandonment, negative clinical outcomes, and even serious adverse events, such as hospitalizations and patient death. Accordingly, **we strongly object to the proposed timeframes for PA final decisions (72 hours for urgent PAs and 7 days for nonurgent decisions) as they are much too long to prevent patient harm. The AMA urges CMS to instead mandate the PA processing timeframes outlined in our PA Principles (24 hours for urgent PAs and 48 hours for standard PAs).** • Moreover, the AMA believes that any PA submitted using the Da Vinci FHIR PAS API should be processed in "near real-time," as noted in CMS' proposal at 85 Fed. Reg. 82610. Indeed, using a technology with "fast" in the name implies that both physicians and health plans should see significant reduction in PA processing time. In addition, requiring real-time processing for PA requests submitted via PAS APIs will serve as significant incentive for physicians to adopt this technology. • CMS also proposes to maintain allowance for an extension of 14 days if a health plan determines additional information is needed. The AMA strongly objects to this provision, as we believe that permitting health plans to issue multiple requests for clinical documentation will result in further patient care delays and practice burdens. Additionally, health plans' PA documentation requirements should be sufficiently transparent—especially with implementation of the DRLS API—to prevent these repetitive information requests.

[4] https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf

		• **The AMA also urges that the 24- and 48-hour PA processing timeframes detailed in the PA Principles be extended to FFE QHPs, in addition to Medicaid, Medicaid managed care, and CHIP plans.**
CMS is proposing that impacted payers publicly report certain metrics about prior authorization processes for transparency.	Support	• The AMA strongly supports the collection of data and public reporting of health plans' PA program metrics to increase transparency and support improvements in this burdensome process, as detailed in the Principles. **We urge CMS to fully leverage this provision not to just increase visibility into plans' PA requirements but to also require the data to be used for key program improvements.** There is no indication from CMS about how these metrics will be used, and we request that CMS outline specifically how the data can be used to benefit patients and physicians. Our suggestions include: o Payers should be required to remove PA requirements for services that meet certain thresholds of approval rates. o CMS should use the data for enforcement activities against plans that do not comply with the mandated processing timeframes or have high rates of PA denials overturned upon appeal. • These PA program metrics should also be easily accessible to physicians and patients making decisions regarding plan contracting or selection, respectively, as well as included in programs that rank plan performance (e.g., star ratings).
CMS seeks comment on issues regarding denials of provider claims for approved prior authorizations. CMS asks what requirements would be appropriate to include in a policy to ensure that claims that meet certain guidelines for approved authorizations are not denied. Also requested are other requirements that would be appropriate to include in a policy to ensure that the claims that meet certain guidelines for approved authorizations are not denied.	Support	• As stated in the Principles, the AMA advocates that, to allow sufficient time for care delivery, a payer should not revoke, limit, condition or restrict coverage for authorized care provided within 45 business days from the date authorization was received. Health plan denial of claims for services that previously were approved places both physicians and patients at substantial financial risk. **We urge CMS to protect physicians and patients by prohibiting plans from denying payment for approved services when clinical scenarios prevent the initiation of a new or updated PA request.** Examples include: o During the course of a procedure or surgery, a clinician may decide that a different but related service to the one approved is more appropriate for a patient. Payers should offer flexibility in their claims adjudication systems so that approved codes can be "cross-walked" to related procedures to prevent claim denial.

		○ Rapidly evolving clinical circumstances during an invasive procedure may require a physician to perform an additional or different service than that originally approved by the plan. Requiring physicians to pause surgery to obtain PA for the new/additional service is impractical and dangerous. CMS should therefore require plans to establish protocols for such scenarios (e.g., allowing retrospective approvals) to prevent unnecessary claim denials and financial risk for physicians and patients.
CMS seeks comment on "gold-carding" or similar programs under which payers relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance.	Support	• The AMA applauds CMS' interest in gold-carding programs and notes that both the Principles and Consensus Statement support such initiatives. We believe that physicians with strong records of following evidence-based guidelines should be rewarded by being exempt from PA requirements. In addition to reducing physician burdens, such gold-carding programs will also reduce PA volume for payers and therefore decrease plans' administrative waste. We believe that creation and maintenance of programs that selectively apply PA requirements should pose no significant costs to payers, as plans already collect and analyze physician performance data for network placement and provider profiling programs.
CMS seeks comment on the following: • Whether there should be certain restrictions regarding requirements for repeat prior authorizations for items and services for chronic conditions, or whether there can be approvals for long-term authorizations. CMS asks what alternative programs are in place or could be considered to provide long-term authorizations for terminal or chronic conditions. • Whether a prior authorization decision should follow a patient when they change from one QHP on the Exchange to another, or to another	N/A	• The AMA encourages CMS to place restrictions on repetitive PAs for treatment for chronic conditions, as these duplicative requirements are not only administratively burdensome for both physicians and payers, but they can often interfere with continuity of care and place patients at risk for dangerous interruptions in therapy. Notably, both health care professional and health plan organizations agreed in the Consensus Statement to "[s]upport continuity of care for medical services and prescription medications for patients on appropriate, chronic, stable therapy through minimizing repetitive prior authorization requirements." The AMA maintains that PA approvals should extend for the duration of therapy to prevent avoidable interruptions in care and unnecessary practice hassles. • The Consensus Statement also supports "[s]ufficient protections for patients undergoing an active course of treatment when there is a formulary or treatment coverage change or change of health plan that may disrupt their current course of treatment." **The AMA urges CMS to require health plans to create protections for new members on chronic treatment to prevent**

health plan impacted by this proposed rule, and under what circumstances that prior authorization could follow a patient from payer to payer. • Whether prior authorizations should be valid and accepted for a specified amount of time, and who should determine how long an existing approved prior authorization from a previous payer should last and whether prior authorization should be regulated by amount of time and/or by condition. • Solutions to standardizing prior authorization forms, including the possibility of developing an HL7 FHIR-based questionnaire for prior authorization requests. • How to potentially phase out the use of fax technology to request and send information for prior authorization decisions and what barriers must still be overcome to accomplish this goal.		**harmful care disruptions, to include requiring plans to accept a previous payer's PA approval for at least an initial 60-day grace period, as indicated in our Principles.** • Moreover, we presume that the Payer-to-Payer API would allow the new plan to review the supporting clinical documentation used by the previous payer for PA approval. As stated above, **CMS should require plans (1) to honor a previous payer's PA approval for at least 60 days, (2) request and obtain the PA supporting clinical documentation from the previous payer to establish the PA approval in the new payer's system, and (3) only request additional information from the physician if it is not included in the Payer-to-Payer API data exchange.** • We note that building the technology to support highly variable PA documentation requirements across ***many different payers for a large number of medical services*** will likely be time- and resource-prohibitive for health plans, intermediaries, and EHR vendors. **The AMA therefore strongly supports efforts to standardize at least a "super set" of data elements needed to support PA decisions for specific services**, even though specific coverage requirements are bound to differ from payer to payer. We note that the HL7 Uniform Structure and Coding Elements for Prior Authorization[5] is pursuing this exact goal. **We urge CMS to strongly encourage payer participation in this effort, as we believe that harmonization in PA data sets across payers will be necessary for the PAS model to be scalable across a large number of health plans, medical services, and PA criteria**. • CMS solicits input on how to potentially phase out use of fax machines for exchanging PA-related data. The AMA generally supports efforts to minimize use of faxes for PA data submission, as fax technology represents an antiquated, burdensome, and staff-time-intensive PA workflow. However, we note that for small and/or rural practices, fax machines may remain the only realistic method to exchange PA data with payers for the foreseeable future. CMS should therefore require payers to maintain fax capability to ensure that

[5] See https://confluence.hl7.org/display/DVP/Uniform+Structure+and+Coding+of+Elements+for+Prior+Authorization+PSS.

		practices lacking the resources to implement FHIR PAS technology are not left without a means to communicate with health plans.
Implementation Specifications		
ONC is proposing to adopt the implementation specifications described in this regulation at 45 CFR 170.215—Application Programming Interfaces—Standards and Implementation Specifications as standards and implementation specifications for health care operations.	Support with modification	• The AMA encourages CMS to coordinate with ONC on its response to our questions regarding STU/Normative IG versioning issues, potential consequences for payer optionality in adopting PDex or US Core, electronic physician documentation requirements by payers to demonstrate care relationships (e.g., capturing information the EHR), and potential issues with linking Patient Access API and Provider Access API technical standards.
RFIs		
CMS is seeking input for potential future rulemaking on whether patients and providers should have the ability to selectively control the sharing of data in an interoperable landscape. CMS requests comment on whether patients and/or providers should be able to dictate which data elements from a medical record are shared when and with whom.	N/A	• **The AMA strongly supports policies that would provide patients and physicians/provider organizations the ability to selectively control sharing of data, including the ability to select which data elements from a medical record are shared, when, and with whom.** The AMA released a set of Privacy Principles[6] in early 2020, which seek to provide individuals with greater granular controls over how their information is used and shared. Granular controls will serve to increase interoperability, as they will provide patients and clinicians with an option for sharing information in a more sophisticated and nuanced way—i.e., beyond the current ultimatum of "all or nothing" data sharing. Technology developers must start thinking more about how to permit individuals to securely share pieces of information—for example, an individual might want to share only a medication list or diagnosis list as opposed to his or her entire medical record—and building those capabilities into technology from the start (i.e., "privacy by design"). FHIR supports data controls like segmentation; however, we are concerned those controls are an afterthought in FHIR-based API design and will become "bolt-on" functions—drastically increasing their costs and limiting their usefulness. The AMA has been told that FHIR developer efforts are first focused on "just

[6] Available at https://www.ama-assn.org/press-center/press-releases/ama-issues-new-principles-restore-trust-data-privacy.

		making the technology work" and that "patient data protections and privacy controls are outside their scope." The downstream consequences of this approach will negatively impact physicians and patients. Developers need to address privacy concerns and incorporate privacy considerations as a part of the development process of any new technology. Mechanisms to monitor and control data access, patient consent and privacy, and ensure data provenance, governance, and enforce state and federal law must be inherent in FHIR development.
CMS is seeking comment on how CMS might leverage APIs (or other solutions) to facilitate electronic data exchange between and with behavioral health care providers, and also community-based organizations, who have lagged behind other provider types in adoption of EHRs.		• The AMA appreciates CMS' interest in facilitating electronic data exchange between and with behavioral health care providers and community-based organizations (CBOs). We believe these providers and professionals are vital in supporting patients' longitudinal care. We also agree there has been an absence of work in this space to support their unique needs. The AMA recommends that CMS first consider efforts already in place that, if replicated, could address behavioral health and CBOs. For instance, the AMA is participating in a consensus-driven workgroup of cross-industry experts to tackle the challenge of sensitive health data exchange. The Protecting Privacy to Promote Interoperability (PP2PI) workgroup includes over 150 members comprised of patients, providers, health systems, heath IT developers, informaticists, and federal and state regulators. While the initial use case focuses on adolescent health, there are several parallels between adolescent health and behavioral health data exchange—particularly regarding data privacy and patient confidentiality. The AMA suggests CMS consider the steps the PP2PI is taking to promote interoperability while protecting patient privacy. For instance, CMS should consider answering the following questions as a foundation for its effort: 1. How will CMS support the development of use cases and requirements to guide the specification, scoping, and profiling design work? 2. How will CMS support the development of a minimal set of data elements, mapped to the USCDI and linked through use cases, in order to address all elements of the medical record and impacted health IT systems?

		3. How can CMS work with HL7 workgroups and leverage use cases to highlight opportunities for standards development or modification? 4. How can CMS support consensus-driven guidance around the following as it pertains to behavioral health information? a. Developing terminology value sets to define categories of sensitive data. b. Identifying benefits/risk and recommendations for role-based vs. user-based security strategies. c. Recommendations for visualizations of redacted data. d. Recommendations for utilization of redacted data in clinical decision support. e. Recommendations for break-the-glass emergency access to data. 5. How can CMS promote the development of guidance needed to inform IG creation and published by HL7? 6. How can CMS develop educational materials in support of the overall effort?
CMS is seeking comment on how to reduce barriers, and actively encourage and enable greater use of electronic prior authorization, particularly among providers who could benefit most by being able to engage in the prior authorization process directly from their workflows. CMS requests comment specifically on including an Improvement Activity under the Merit-based Incentive Payment System (MIPS) to support the use of the Prior Authorization Support (PAS) API.		• The AMA acknowledges that standard electronic PA offers the potential to significantly reduce practice burdens and accelerate care delivery. We identify the following barriers to widespread adoption of electronic PA among physicians and some potential solutions: ○ In order for the DRLS and PAS APIs to represent a worthwhile investment of valuable technology dollars and practice training resources, the scope of payers using these tools will need to be significantly broadened to at least include MA plans. Most practices will simply not see significant value in adopting these APIs for such a limited number of patients. As noted previously, **CMS should not interpret low adoption of APIs under this rule as an indication of a lack of physician interest in electronic PA and/or the need for a mandate on practices to use these APIs.** Again, the small number of plans and patients impacted by the rule will limit physician adoption. ○ **In addition to broadening the scope of the rule to include MA plans, CMS should consider other means to incentivize physician and vendor implementation of these FHIR APIs. As mentioned above, requiring**

		near real-time responses for PA requests submitted via the PAS API would majorly benefit physicians and encourage them to adopt the technology. Physicians would likely view this as a powerful incentive to adopt the technology and vendors could turn their offering of the services into a competitive advantage. Additionally, CMS should consider modeling this rule more in terms of a demonstration and offer incentives to practices and vendors—perhaps in a few targeted markets—to participate in testing the FHIR APIs. We fear that without a more targeted approach that will entice physician and vendor participation, CMS will not obtain the valuable data needed to assess the maturity of the FHIR standards and engage in informed decision-making regarding future standards rulemaking. ○ In line with our comments about CMS approaching these policies via a demonstration project, CMS may be able to determine whether the policies serve as appropriate incentives for physicians to adopt electronic PA processes. CMS and ONC should avoid requiring the use of certain standards before they are appropriately tested in the real world. ○ CMS could permit program integrity enforcement bodies to consider in their enforcement activities a physician's adoption of electronic PA standards. We caution that this should be a positive enforcement and is not a suggestion to require physician adoption of the electronic PA standards to avoid additional program integrity activity. • We also note that for physicians to broadly adopt this technology, they must see a significant, appreciable benefit. If the PAS model merely automates the current tedious PA process and still requires completion of lengthy questionnaires (vs. auto-extraction of relevant structured data from the EHR), physicians will see little value in the API and refrain from adoption. • We support CMS' concept to create an improvement activity to positively incentivize physicians to adopt electronic PA technology. This type of positive incentive is a better way to promote physician adoption than a regulatory requirement. We oppose inclusion of this concept in any other category of MIPS. We also request that CMS articulate the rationale for placement of this in MIPS, given that the NPRM's provisions do not currently apply to MIPS/Medicare FFS.

CMS requests information on how it can reduce or eliminate the use of fax technology across programs where fax technology is still in use.		• The AMA fully supports advancement of automation to promote interoperability and ease physician and patient burdens, but we caution that sometimes manual and legacy methods (e.g., fax technology) must remain available to physicians who simply cannot adopt emerging technology (for example, the cost of complying with constant regulatory changes and requirements to upgrade EHR technology is sometimes prohibitive for physician practices, especially those that are small and/or in rural areas).
CMS requests information on barriers to adopting standards, and opportunities to accelerate adoption of standards, related to social risk data. CMS recognizes that social risk factors (for example, housing instability and food insecurity) influence patient health and health care utilization. In addition, we understand that providers in value-based arrangements rely on comprehensive, high-quality social risk data. Given the importance of these data, we look to understand how to better standardize and liberate these data.		• We appreciate CMS' recognition that individuals may benefit from social service agencies and community-based support programs. Of course, under current law, covered entities may share a patient's protected health information (PHI) with non-covered entity health care providers for treatment purposes (including care coordination) without a patient's authorization. Conversely, covered entities must generally obtain a patient's authorization before sharing PHI with non-health care providers (which are, by default, non-covered entities) for non-treatment purposes and, under current law, must limit such disclosures to the minimum necessary.[7] The AMA believes that patients should have notice of and understanding around how their health care data is used within the health care system and should have a say in whether their data is shared by covered entities with parties outside of the health care system, particularly for purposes beyond treatment. Notwithstanding the above, the AMA recognizes that social service and community-based support programs often provide significant assistance to individuals who may not otherwise receive it and understands why access to a patient's PHI can be beneficial to an individual, particularly when the individual is unhoused, has limited access to health care services, or receives multiple supports across a spectrum of services and organizations. Physicians often struggle with how to best care for these patients without violating HIPAA. Unfortunately fear of enforcement by the Office for Civil Rights (OCR) can complicate care coordination efforts that involve activities beyond health care. The AMA has recommended to OCR that to help covered entities feel more comfortable with making such judgments—especially considering their fear of OCR enforcement—the

[7] 45 CFR 164.506.

		agency should explore options for data sharing agreements between covered entities and social service programs in their patients' communities that aim to reduce friction while still maintaining patient privacy. Information sharing concepts are explored in an issue brief by the National Center for Medical-Legal Partnership, housed within the Milken Institute School of Public Health at the George Washington University.[8] We are aware that OCR has recently issued an NPRM that touches on care coordination issues and we plan to provide comprehensive comments in response. • In the meantime, we encourage CMS to coordinate with HL7's Gravity Project, which is doing work in this space. The Gravity Project's social determinants of health (SDOH) clinical care FHIR IG has mapped data from popular social screeners, including the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE),[9] into FHIR. Such activity may serve as a model for the industry at large. • While SDOH data has the power to improve patient care and outcomes, the data are often highly sensitive, can lead to stigma, and can create or worsen inequities.[10] Additionally, such SDOH are not permanent; put differently, an individual's social risks and the SDOH that influence them may fluctuate dramatically over time, even in the short-term. The aforementioned Gravity Project has issued Principles for Electronic Health Information Exchange and Data Stewardship that include a recommendation to ensure patients have personal control over their data: "Exchange and use of personal information should account for the diverse needs of all stakeholders, without erecting barriers or diminishing function or quality for those with differing abilities, languages, or cultural contexts…Each individual has the right to consent to, and challenge the collection, content, retention, use or disclosure of information relating to them, including the right to have the particular

[8] *Information Sharing in Medical-Legal Partnerships: Foundational Concepts and Resources*, available at https://medical-legalpartnership.org/wp-content/uploads/2017/07/Information-Sharing-in-MLPs.pdf.
[9] https://www.nachc.org/research-and-data/prapare/
[10] Laura M. Gottlieb, Hugh Alderwick, *Integrating Social and Medical Care: Could it Worsen Health and Increase Inequity?*, The Annals of Family Medicine Jan 2019, 17 (1) 77-81; DOI: 10.1370/afm.2339, available at https://www.annfammed.org/content/17/1/77.full.

		information corrected or omitted."[11] These concepts align with the AMA's Privacy Principles. **We strongly encourage any federal agency promoting the collection and exchange of SDOH data to think critically around privacy protections for patients and the critical need to engage with the patient while discussing social risk factors, including how such data may be shared, for what purpose, and how the patient can amend such data.**

[11] https://confluence.hl7.org/display/GRAV/Gravity+Data+Principles.