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

March 13, 2023

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

Re: File Code CMS–0057–P. Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Dear Administrator Brooks-LaSure:

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 Rule Making (NPRM) outlining proposals to advance interoperability and improve prior authorization (PA) in Medicare Advantage (MA) plans, state Medicaid agencies and Medicaid managed care plans, Children's Health Insurance Program (CHIP) agencies and CHIP managed care entities, and issuers of Qualified Health Plans (QHPs) on the Federally-Facilitated Exchanges (FFEs) published in the *Federal Register* on December 13, 2022 (87 Fed. Reg. 76238).

The AMA developed our Recovery Plan for America's Physicians to address pivotal issues that hinder our physicians from providing optimal care and to seek fundamental changes to create a health system that better supports patients and the physicians who care for them. The plan outlines five pillars to strengthen our physician workforce, recover from the trauma of the pandemic, and improve health care delivery by eliminating some of the most common burdens that threaten to drive physicians from practice. These include:

- Fixing PA to reduce the burden on practices and minimize dangerous care delays for patients.
- Reforming Medicare payment to promote thriving physician practices and innovation.
- Fighting scope creep that threatens patient safety.
- Supporting telehealth to maintain gains in coverage and payment.
- Reducing physician burnout and addressing the stigma around mental health.

The AMA applauds CMS for acknowledging our concerns, as well as those of our patients, in this NPRM. As CMS notes, "[every] reader of this proposed rule is a patient and has received, or will receive, medical care at some point in their life," and we commend CMS for the patient-centric focus of this

proposed rule. Specifically, we appreciate several meaningful proposals addressing significant PA reforms. As commented in greater detail below, the policy changes outlined in the proposed rule align with reforms contained in the AMA PA Principles and Consensus Statement and will significantly improve PA in MA and other impacted programs.[1] **We appreciate that CMS recognizes the burdens associated with PA programs and urge you to adopt these policies as written, or with the strengthening recommendations detailed below, to support judicious, transparent, and clinically appropriate use of PA that protects patients' access to treatment.**

The following outlines our principal recommendations on this proposed rule:

- The AMA strongly supports inclusion of MA plans in the scope of this rule but urges CMS to leverage a regulatory pathway that will apply to all health plans when mandating PA-related implementation guides and transaction standards in any future rulemaking.
- The AMA encourages CMS to further explore the need to designate an electronic transaction standard for drugs covered under a medical benefit.
- We strongly support the requirement for health plans to provide a specific reason for a PA denial but recommend that CMS strengthen this provision to ensure that the information is understandable and outlines clear, actionable next steps.
- The AMA recommends that CMS shorten the required PA processing timeframes to 48 hours for standard PAs and 24 hours for expedited PAs to protect patient safety.
- We strongly support the public reporting of PA program metrics but urge CMS to require plans to report these data at a more granular level and to require posting of the information on a centralized website (e.g., CMS webpage) to enable easy retrieval by physicians and patients.
- The AMA supports encouragement of gold-carding programs and urges CMS to include offering of these programs as a measure in star quality rating programs.
- The AMA recommends that CMS create a formal oversight, audit, and enforcement process to promote accountability and ensure appropriate implementation of the rule's provisions, when finalized.
- The AMA supports CMS' efforts to increase patient access to their medical information through health plan-enabled and maintained application programing interfaces (APIs). The AMA urges CMS to consider how its policies can better strengthen patients' data privacy while limiting physician burden.
- The AMA supports CMS including requirements on health plans to exchange data with physicians using APIs. The AMA strongly suggests that CMS consider how its health plan API requirements align with 21st Century Cures Act requirements around information sharing.
- The AMA supports CMS' policy to require health plans to implement information exchange over APIs to support better-coordinated care as patients transition between plans. The AMA strongly supports requiring health plans to honor the PA approvals from the patient's previous health plan to support continuity of care and protect patients from potentially dangerous disruptions in ongoing treatment.
- The AMA supports CMS' proposals related to API standards, standards maturity, and versioning. However, success in this approach will require that CMS be more involved and track the development and testing of its regulated technical standards.

[1] Consensus Statement on Improving the Prior Authorization Process. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

- We strongly oppose adding burden to physicians and their staff by linking electronic PA (ePA) requirements to CMS' Quality Payment Program (QPP). It is unclear why CMS would tie a physician's success in the QPP to untested ePA technology when CMS' stated goal is to reduce physician burden, PA-related costs, and medical staff time requirements.

In the next section, we provide feedback on the scope of the NPRM and its PA policy proposals. For comments on the technology sections of the NPRM, including the provisions related to ePA, please see **Appendix A.** For the AMA's response to the Requests for Information (RFIs) included in the rule, please see **Appendix B.**

Improving PA Processes: Response to NPRM Scope and PA Policy Proposals

Current PA Landscape

We appreciate CMS' citation of the AMA's annual physician survey throughout the proposed rule and recognition of the patient harms and administrative waste associated with this process. The AMA is releasing data from our most recent physician survey, fielded in December 2022, to coincide with submission of our comments on the NPRM.[2] These data confirm the continuing negative impact of PA on clinical outcomes and practice burdens. Additionally, in a new data point introduced in the 2022 survey, physicians report that PA can increase overall health care resource utilization due to ineffective initial treatments, additional office visits, and immediate care or emergency room visits. The devastating patient and physician stories captured on the grassroots reform website FixPriorAuth.org highlight the human cost of the PA problem and confirm our quantitative survey data.[3]

With mounting concerns regarding the impact of PA on timely, efficient care delivery, many stakeholders have called for PA reform. In 2017, the AMA, along with a coalition of organizations representing physicians, medical groups, hospitals, pharmacists, and patients, released the Prior Authorization and Utilization Management Reform Principles, which outlined critical improvements needed to protect patients' access to necessary treatment.[4] These principles spurred an industry dialog that culminated in the January 2018 publication of the Consensus Statement on Improving the Prior Authorization Process.[5] Notably, the Consensus Statement represented *agreement between health care professional organizations and insurer trade associations* on the need for PA reform. Unfortunately, subsequent AMA physician survey data illustrate that health plans' progress in voluntarily making the agreed-upon changes has been disappointingly slow.[6] **This lack of forward momentum on PA reform underscores the necessity and timeliness of CMS' regulatory action.**

Scope of NPRM

The AMA consistently advocates for a holistic, cross-program approach to PA reform. While we fully support automation of the PA process, as proposed in this NPRM, any successful solution must address

[2] 2022 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[3] See https://fixpriorauth.org/stories.
[4] Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.
[5] Consensus Statement on Improving the Prior Authorization Process, *supra* note 1.
[6] 2021 update: Measuring progress in improving prior authorization. Available at: https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

both the PA process and underlying decision-making. Indeed, without addressing the underlying clinical criteria and PA program policies, even the most streamlined ePA system will fail both patients and physicians and simply deliver a faster inappropriate denial. **We therefore urge CMS to finalize the critical policy reforms that will ensure the clinical validity of PA programs and protections for continuity of care proposed in the CY 2024 Part C and Part D NPRM, as detailed in both the sign-on letter of support signed by the AMA and 119 state medical associations and national medical specialty societies,[7] as well as the AMA's individual comments.[8]**

We strongly support CMS' proposal to extend the provisions of this rule to MA plans in alignment with our comments on the previous iteration of this NPRM published in December 2020. The growing number of seniors enrolled in MA plans—with the most recent number totaling over 31.2 million patients[9]—reinforces the need to include this population in CMS' PA improvement efforts. Beyond the sheer volume of patients in the MA program, several recent analyses flag major concerns with MA PA programs, further strengthening the case for including these plans in rulemaking. An HHS Office of Inspector General 2022 report found that 13 percent of PA requests denied by MA plans met Medicare coverage rules, and 18 percent of payment request denials met Medicare and MA billing rules.[10] More recently, a Kaiser Family Foundation analysis found that MA plans denied two million PA requests in whole or in part in 2021, representing about six percent of the 35 million requests submitted that year.[11] While only about 11 percent of PA denials were appealed, the vast majority (82 percent) of appealed denials were fully or partially overturned, raising serious concerns about the appropriateness of many of the initial denials. Finally, beneficiary disenrollment in MA plans averaged 17 percent in 2021, increasing from an average of 10 percent in 2017;[12] this high voluntary disenrollment rate suggests that MA plans may not be meeting patient's needs due to PA requirements or other coverage limitations. Since fighting PA takes time and resources, the AMA repeatedly hears from our members that PA disproportionately affects marginalized and minoritized communities and the physicians who treat them. **Taken in sum, these data support the need to include MA plans in the scope of this NPRM, as well as to finalize the provisions related to clinical criteria and care continuity proposed in the CY 2024 Part C/Part D NPRM.**

While we appreciate that CMS has extended the scope of this NPRM to include MA organizations, we note that a large number of Americans are covered by health plans outside the purview of the rule. We are specifically concerned with provisions that would create requirements for electronic data exchange for PA for just the impacted plans. While CMS only recommends (vs. requires) adoption of certain Health Level

---

[7] February 13, 2023, sign-on letter to CMS Administrator. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FPA-sign-on-letter-Part-C-and-D-rule.zip%2FPA-sign-on-letter-Part-C-and-D-rule.pdf.

[8] February 13, 2023, AMA comment letter to CMS Administrator. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfr.zip%2F2023-2-13-Letter-to-Brooks-LaSure-re-CY-2024-Medicare-Advantage-v3.pdf.

[9] CMS Contract Summary February 2023. Available at: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2023-02.

[10] Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[11] Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021. https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021.

[12] Commonwealth Fund. Medicare Advantage Disenrollment Rates Can Help Beneficiaries Make Informed Decisions. Available at: https://www.commonwealthfund.org/blog/2023/medicare-advantage-disenrollment-rates-can-help-beneficiaries-make-informed-decisions.

7 (HL7) Fast Healthcare Interoperability Resources (FHIR) implementation guides to meet these requirements, we are concerned that this lays the foundation for insurers to utilize different electronic transaction standards to support PA, based on plan type. As noted by a recent Kaiser Family Foundation analysis, "the promise of a more connected health system will likely require similar standards across plans, but the proposal does not reach the more than 150 million Americans in employer-sponsored coverage."[13] While CMS encourages plans not within the scope of the NPRM to voluntarily adopt the same ePA technology, the AMA is concerned that mandating electronic standards via regulation other than the traditional Health Insurance Portability and Accountability Act (HIPAA) administrative simplification pathway will lead to an untenable, fragmented approach to PA automation across payers, which will increase, rather than reduce, physician practice burdens. The recent release of another NPRM addressing electronic attachment transaction standards for both claims and PA under HIPAA administrative simplification provisions elevates these issues,[14] as health plans may elect to adopt the standards proposed in the attachments NPRM instead of the FHIR-based technology proposed under the current rule. **For these reasons, the AMA urges CMS to leverage a regulatory pathway that will apply to all health plans when mandating PA-related implementation guides and transaction standards in any future rulemaking.** As further detailed in Appendix A, any PA standards must be sufficiently mature, thoroughly tested in real-world settings, and of sufficient value to physician practices of all sizes prior to any CMS mandates.

Appendix B details the AMA's feedback on the RFIs associated with this rule, including the RFI soliciting comments on ways to improve data exchange in the Medicare fee-for-service (FFS) program. We are concerned that this RFI is characterized as seeking information to enhance clinical documentation exchange between providers to support PA programs for Medicare FFS. To the extent that this RFI references the existing limited use of PA in Medicare FFS, we support this initiative. **However, we would be alarmed if this RFI signals an intent to increase utilization of PA in Medicare FFS.** The AMA strongly believes in the "right-sizing" of PA and the critical need for a reduction in the overall volume of items and services requiring authorization. Indeed, increasing PA in Medicare FFS would be out of alignment with industry-wide agreement on the need to selectively apply PA to only outlier physicians and/or services showing a consistent variation in ordering patterns or low approval rates, as detailed in the 2018 Consensus Statement on Improving the Prior Authorization Process.[15] **To protect timely access to care for Medicare FFS beneficiaries, we urge CMS to not proceed with any expansion of PA in traditional Medicare.**

Of note, CMS excludes drugs of any type from the PA-related provisions of this NPRM because "processes and standards for [PA] applicable to drugs differ from the other 'items and services'" addressed. We agree that the workflow for ordering medical services differs from the prescribing process for outpatient drugs. Moreover, the National Council for Prescription Drug Programs (NCPDP) SCRIPT ePA transaction standard supports electronic exchange of data to support prescription drug PA, and CMS

[13]Kaiser Family Foundation. CMS Prior Authorization Proposal Aims to Streamline the Process and Improve Transparency. Available at: https://www.kff.org/health-reform/issue-brief/cms-prior-authorization-proposal-aims-to-streamline-the-process-and-improve-transparency/.

[14]Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard. Available at: https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and.

[15]Consensus Statement on Improving the Prior Authorization Process. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

requires Part D plans to support the SCRIPT ePA standard. However, our understanding is that the NCPCP SCRIPT ePA standard is not being used to exchange data for drugs covered under a medical benefit. As such, excluding all drugs from the provisions of this NPRM leaves a sizable gap, as many medications administered by physicians and/or covered under a medical benefit are subject to PA requirements. Indeed, 99 percent of MA beneficiaries were enrolled in a plan that required PA for Part B drugs in 2022.[16] The steady introduction of life-saving—but costly—specialty medications for conditions such as cancer and autoimmune diseases underscores the need for an automated, efficient ePA process for drugs covered under a medical benefit. Similarities in the process for ordering these office-administered drugs and other items and services suggest that the FHIR-based technology referenced in this NPRM may be an appropriate ePA solution for these medications. **We urge CMS to further research this issue by engaging with electronic health record (EHR) vendors and the relevant standards development organizations (i.e., NCPDP and HL7) to determine the appropriate PA automation solution for drugs covered under a medical benefit.**

Feedback on CMS' PA Policy Proposals

The AMA applauds CMS for listening to our physician members, their patients, the Office of Inspector General (OIG), and many other stakeholders and recognizing the need for important guardrails in PA programs to protect beneficiaries from unreasonable barriers to medically necessary care. The policy changes outlined in the proposed rule address several of the reforms contained in the PA Principles and Consensus Statement mentioned above and have the potential to significantly improve PA in the impacted plans. **We urge CMS to adopt these policies with the strengthening recommendations detailed below to improve the transparency of PA programs and ensure that PA does not create a barrier to medically necessary care for patients.**

a) Reason for denial of PA

CMS proposes to improve communication between payers and physicians regarding the PA process by requiring impacted plans to send information detailing the *specific reason for a PA denial* regardless of the method used to send the PA request—whether by the EHR-based technology discussed in the NPRM, online portal, or fax. In addition, PA decisions sent through EHR-based PA technology would also need to indicate whether the payer approves (and for how long) or denies the PA request, or requests more information from the physician. **We thank CMS for requiring impacted health plans to provide specific denial reasons and agree that clearer information regarding PA disapprovals could help mitigate the patient harms associated with the process, including care delays and treatment abandonment.**

To enhance the value of this proposal, we urge CMS to align this requirement with Principle #11 from the Prior Authorization and Utilization Management Principles,[17] which states that health plans should 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 (if applicable), and details on appeal rights and process. As noted in the NPRM, health

[16] Kaiser Family Foundation. Medicare Advantage in 2022: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings. Available at: https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/.

[17] Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

plans may use codes—either from the designated code list for the X12 278 or proprietary codes/text—to provide denial reasons. Our physician members report that health plans sometimes provide cryptic codes and vague language to describe reasons underlying PA denials, making it difficult for both physicians and patients to follow up. **To prevent care delays and subsequent patient harms, we urge CMS to strengthen this provision and specify that impacted health plans must provide all the information detailed above in PA Principle #11 to ensure that the information included in PA denials is understandable and outlines clear, actionable next steps.**

b) Requirements for PA Decision Timeframes and Communications

We appreciate CMS' acknowledgment that failure to provide timely PA decisions can literally mean life or death for patients, as shown by AMA's annual PA physician survey. Moreover, the 2022 AMA survey shows that beyond these human costs, physicians report that PA can actually increase overall utilization of health care resources,[18] which is the *exact opposite intent* of health plans' PA programs. We believe CMS' proposal to require PA decisions within seven calendar days for standard requests and no later than 72 hours for expedited PAs to be directionally appropriate. However, we strongly recommend that CMS shorten these timeframes to protect patient health and safety. **Specifically, we urge CMS to require standard PAs be processed within 48 hours and expedited PAs within 24 hours to align with AMA policy and the Prior Authorization and Utilization Management Reform Principles (which are formally supported by over one hundred health care organizations and patient groups).** We call special attention to the urgent PA processing timeframe: when care is urgent, 72 hours is simply not a safe amount of time to wait to receive approval for coverage.

We note the synergy between the rule's ePA requirements and our recommended shortened timeframes. If the proposed technology lives up to its promise by integrating PA requirements and documentation needs within clinicians' EHR workflow, digitizing health plans' PA criteria, and automating the exchange of medical data, our recommended 24- (urgent) or 48-hour (standard) processing times are realistic and appropriate. Indeed, we would argue that health plans could leverage this new technology to auto-approve or issue real-time decisions for many PA requests, especially for services that are routinely approved. **We also note that by requiring shortened timeframes for PA decisions, CMS will incentivize physicians to adopt ePA technology.**

Along with recommending tighter processing deadlines, we also urge CMS to specifically state that health plans must provide final PA determinations within these timeframes. Too often, health plans interpret a requirement for a "response" or "decision" within a certain timeline to allow return of a "pended" PA status or a request for additional information. We firmly believe that health plans should be able to respond to initial PA requests immediately with a solicitation of any required supporting documentation; it is completely inappropriate for an insurer to wait 48 hours or longer simply to pend a PA request and only then solicit clinical data. **We therefore urge CMS to further strengthen this provision by requiring plans to provide a final PA determination within the mandated timelines.**

Finally, we strongly encourage CMS to align the processing timeframe for QHP issuers on the FFEs with the requirements for the other impacted plans. We do not agree that shortening the standard PA processing time for QHPs on the FFEs from the current 15 days would pose undue burden on these

[18] 2022 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

plans; indeed, we would argue that allowing over two weeks for a PA response could seriously jeopardize a patient's health and lead to permanent negative clinical outcomes. **We therefore request that CMS set the PA processing timeframe for QHPs on the FFEs to 48 hours for standard PAs and 24 hours for expedited cases to align with our policy and PA Principles.**

c) Public Reporting of PA Metrics

CMS proposes to require impacted payers to publicly report aggregated metrics about their PA programs, including a list of all items and services that require PA, percentage of standard and expedited PAs approved and denied, the percentage of PAs that were approved after appeal, and average and median PA processing time for standard and expedited PA requests. These data would be publicly reported on plans' websites or via a publicly accessible hyperlink. **We commend CMS for proposing improved transparency in health plans' PA programs through public reporting of metrics and agree that this will both encourage improvement in PA processes, as well as support informed decision-making for patients selecting a plan.**

The AMA believes that the utility and value of this public reporting could be strengthened with the following enhancements:

- Along with publishing a list of the items and services that require PA, impacted plans should also be required to **disclose their PA clinical criteria.** This aligns with our PA Principle #1, which states that clinical information referenced in PA criteria "should be readily available to the prescribing/ordering provider and the public."[19]
- While we agree that aggregated PA data can be useful, we urge CMS to also require reporting of this information at a **more granular level**, such as by item or service, or at least by category of service (e.g., imaging, physical therapy, etc.). This would allow physicians to evaluate a plan's PA performance for services relevant in their specialty and prospective patients to assess the plan based on PA metrics related to their clinical condition prior to enrollment.
- We are concerned that both physicians and patients will struggle to locate PA program metrics on payers' websites. The AMA therefore recommends that these data be **published on a centralized, public website**—such as a CMS webpage—to ensure easy access to the information as well as facilitate comparison between plans. We also note that requiring submission of these PA program metrics to CMS for collation and publication would also support the enforcement of this NPRM's provisions, as we recommend later in this correspondence.
- **Finally, we strongly urge CMS to make payer public reporting requirements effective immediately upon finalization of this rule.** Waiting until 2026, as proposed, would unnecessarily delay CMS' efforts to promote transparency. Immediate availability of these metrics will be invaluable in establishing a baseline to evaluate improvements in PA after the other requirements outlined in this rule become effective. In particular, this benchmarking will allow the industry to assess the value and impact of ePA technology.

[19] Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

d. Gold-carding Programs for PA

The AMA appreciates CMS' acknowledgment of the enormous resource drain PA presents for physicians and their practices. AMA survey data quantifies the time and resources that physicians and their staff spend on an ever-growing PA workload, and this burden translates into less clinical time with patients and contributes to an exhausted, burned-out, and overwhelmed workforce. For these reasons, we believe that reducing the overall volume of PA requirements must be a priority in any holistic PA reform effort. In alignment with Principle #20 of our PA Principles,[20] the AMA advocates that health plans should offer physicians at least one physician-driven, clinically-based alternative to PA, such as but not limited to gold-carding or "preferred provider" programs or attestation of use of clinical decision support systems or clinical pathways. Of note, health plan representatives agreed to selective application of PA requirements, such as is accomplished by gold-carding programs, in the 2018 Consensus Statement.

The AMA applauds CMS' encouragement of gold-carding programs, as this would exempt physicians with track records of high approval rates from a health plan's PA requirements. The AMA stands ready to work with CMS to develop meaningful guidelines for gold-carding programs that would reduce the volume of PAs to the benefit of all stakeholders. We also support CMS' suggestion to add a gold-carding measure in quality star programs for MA plans and QHPs to drive payer implementation of these programs that will reduce physicians' administrative workload and minimize patient care delays. In addition, we support CMS' proposal to study the impact of gold-carding programs on diverse patient populations, such as those living with disabilities and chronic illnesses, and physician practices serving rural and traditionally minoritized and marginalized communities. **We welcome the opportunity to work with CMS on ensuring that gold-carding programs benefit the diverse patient populations served by the impacted health plans.**

Additional Program Enhancements

The AMA sincerely appreciates CMS' efforts to address the significant challenges that PA poses for both patients and physician practices. We hope that CMS continues to evaluate additional opportunities for PA reform when finalizing this rule and in future rulemaking. Specifically, we request that CMS adopt the following changes to further improve PA programs in impacted health plans:

- PA-related care delays can be especially devastating for patients with substance use disorders. **For this reason, we urge CMS to require health plans to provide all forms of medications for opioid use disorders without PA or other Utilization Management requirements that create care barriers and delays**.
- In the 2020 iteration of this NPRM, CMS requested feedback on standardizing PA data requests, including the possibility of developing uniform HL7 FHIR-based questionnaires for PAs for certain services. We were disappointed that this issue was not addressed in the current NPRM, as we strongly believe that building standards-based ePA technology to support highly variable PA documentation requirements across many different payers for a large number of medical services will be time- and resource-prohibitive for health plans, intermediaries, and EHR vendors. The AMA advocates for standardization of at

[20] Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

least a "super set" of data elements needed to support PA decisions for specific services, even though specific coverage criteria are bound to differ from payer to payer. **We reiterate that CMS should strongly encourage harmonization in PA data sets across payers to make the technology proposed in this rule scalable across a large number of health plans, medical services, and PA criteria.**

- **To ensure full realization of the value of these proposed improvements to PA programs, we urge CMS to create a formal oversight, audit, and enforcement process to promote accountability and ensure that these provisions, when finalized, are appropriately implemented.** As noted previously, we recommend that health plans be required to submit PA program metrics directly to CMS to support such enforcement; this would allow CMS to confirm that plans are meeting the required processing timeframes. CMS could establish additional documentation and reporting parameters related to the other provisions of the rule; leverage these data to review/audit plans; and appropriately enforce PA program requirements, from issuing corrective action plans through contract termination. We also urge CMS to annually issue an oversight report on plan conformance to PA-related regulations; this will provide the industry with insight into the impact of these new provisions and help identify potential gaps to address in future rulemaking.

Thank you for the opportunity to provide input on this proposed rule and addressing the challenges that PA poses for both patients and our physician members. The AMA welcomes the opportunity to discuss additional changes CMS could consider to further improve PA programs to ensure patients' access to timely care. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD

Attachments

Appendix A

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
Patient Access API		
CMS is proposing a January 1, 2026, compliance date for regulated payers to include information about patients' PA decisions in the already-established Patient Access API	Support as Proposed	The AMA supports the referenced compliance date, as well as CMS policies to make more information available to patients via the Patient Access application programing interface (API), and PA information is particularly valuable. CMS policies should improve the usefulness of the information available to patients, and help patients be more informed decision makers and true partners in the delivery of health care services.
CMS is proposing that impacted payers use the Patient Access API to make related administrative and clinical documentation information available along with PA requests and decisions for items and services (excluding drugs) available to patients no later than 1 business day after the payer receives the PA request or there is another type of status change for the PA	Support with Modification	The AMA strongly supports patients having access to PA requests and decisions along with administrative and clinical documentation information within 1 business day. Patients should have the tools in place to engage with the delivery of their own health care and 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. **It is essential that patients be provided with the same PA information as their physicians to avoid confusion and ensure that health plans are not steering patients away from care ordered by their physicians.** 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. The AMA also wants to raise critical questions around patients having access to this information "within 1 business day." **In an instance when a payer is functioning as a**

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		regulated Actor Health Information Network (HIN) or Health Information Exchange (HIE) under the 21st Century Cures Act Information Blocking Regulation, information is intended to be made available to patients "without delay." Does "within 1 business day" constitute "without delay?" If payers are not functioning as a regulated Actor HIN/HIE in the instance when a patient makes a request through the Patient Access API, do payers need to provide an attestation to this fact when using the "within 1 business day" standard rather than "without delay?" The AMA wants patients to have access to their personal health information as quickly as possible and encourages CMS to ensure that its requirements for making this information available align with the 21st Century Cures Act requirements around information sharing. Alignment across federal regulations will help reduce market confusion around expectations as well as any residual friction associated with data exchange.
CMS seeks comment on whether it should consider policies to require impacted payers to include information about PAs for drugs	Support with Modification	As noted in the scope section of our comments, the AMA believes the exclusion of drugs covered under a medical benefit from the ePA technology proposed in this NPRM to be a serious gap, given the high volume of these drugs that require PA. **We urge CMS to explore the appropriateness of expanding the ePA API requirements outlined in this NPRM to drugs covered under a medical benefit, in consultation with the appropriate standards development organizations and EHR vendors.** Should the proposed PA API be the recommended technology solution for these medications, PA information for drugs covered under a medical benefit should be included in the Patient Access API.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		Patients would also benefit from being able to access prescription drug PA data via the Patient Access API, and we recommend that CMS evaluate adding these data requirements in future rulemaking. Due to the different underlying electronic standard for prescription drug PAs (i.e., NCPDP SCRIPT ePA) and the different payers involved (Part D plans), this concept warrants further research and discussion with the appropriate stakeholder groups prior to being mandated in rulemaking.
Proposed new requirements would apply to MA organizations, state Medicaid FFS and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs	Support as Proposed	AMA supports CMS placing new requirements on these impacted payers, including MA plans, to improve the electronic exchange of health care data and streamline processes related to PA, while continuing CMS' drive toward interoperability in the health care market. As noted earlier, **we urge CMS to leverage a regulatory pathway that will apply to all health plans when mandating PA-related implementation guides and transaction standards in any future rulemaking.**
CMS requests comment how it could or should apply these requirements to Medicare FFS	N/A	The AMA agrees that improved medical documentation exchange between and among physicians, suppliers, and patients in the Medicare FFS program presents some unique challenges. For example, the ordering physician can be different than the rendering physician of items or services, which can be an obstacle to accurate and timely payment. We want to work with CMS to formulate a system for improved information exchange in Medicare FFS as we believe it could enable better care for beneficiaries if covered services are not delayed by inefficiencies. Such steps would ease the burden on physicians and circumvent time-consuming and burdensome paper-based practices that negatively impact patient care. We agree that health IT and the electronic exchange of information would

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		streamline information-sharing processes between ordering and rendering providers, suppliers, as well as patients and minimize any existing obstacles. **However, as stated earlier, the AMA strongly opposes expansion of PA in the Medicare FFS program.** We are concerned that CMS' question is characterized as seeking information to enhance clinical documentation exchange between providers to support PA programs for Medicare FFS. The AMA does support utilizing ePA for the limited use of PA in Medicare FFS. **However, we are strongly opposed to CMS increasing the utilization of PA in Medicare FFS.** Increasing PA in Medicare FFS would be out of alignment with industry-wide agreement on the need to selectively apply PA to only outlier physicians and/or services showing a consistent variation in ordering patterns or low approval rates, as detailed in the 2018 Consensus Statement on Improving the Prior Authorization Process.[21] **To protect timely access to care for Medicare FFS beneficiaries, we urge CMS to not proceed with any expansion of PA in traditional Medicare.** CMS should continue to explore applying the proposed requirements for the Patient Access API and Provider Access API to the Medicare FFS Program. The AMA expects that a Medicare FFS implementation would conform to the same proposed requirements that apply to the impacted payers under this proposed rule, so Medicare FFS providers and patients enrolled in Medicare FFS could also benefit from this type of data sharing. Further

[21] Consensus Statement on Improving the Prior Authorization Process. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		enhancement of and alignment with Blue Button 2.0 would be extremely helpful in making this information available and accessible to providers and patients.
CMS requests comments on how it can help patients understand the privacy and security implications of using a health app within its regulatory authority's scope	N/A	AMA supports the ability of patients to access their health care data and wants to position patients to be more informed decision makers and true partners in the delivery of health care services. In addition, because patients have a right to access their health information under HIPAA in a variety of formats, payers should provide the requested information to patients in the format that they request, including health apps. These apps are a viable option for many patients to utilize, and we strongly encourage CMS to work across all of HHS, and the entire federal government, to educate patients on the privacy and security considerations for moving their personal health data from a HIPAA-regulated environment to a third-party app that likely functions outside of HIPAA. One educational component would be for **CMS to create and use an app attestation program that serves as an authoritative, federally-run source for impacted payers to administer on app developers that request to retrieve data from their systems via the Patient Access API.** Such an attestation program would indicate that the app adheres to certain privacy and security provisions and encourages patients to review this information before they consent to allow that app to retrieve their personal health data with the Patient Access API. We envision that an app developer attestation program would consist of several privacy and security questions, and an app developer's response to each of those questions would be recorded and available to patients interested in

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		using its app. This would allow patients to select apps that have privacy values most like theirs, make more informed decisions while shopping for apps, i.e., better ability to "comparison shop," and bolster trust in the use of emerging technologies. A federally run program would also ensure that patients benefit from having direct and immediate access to critical information such as how an app uses, shares, markets, or sells their health information. There is precedent from CMS for a federally run app registration program. As part of the Blue Button 2.0 API Developer Portal, CMS requires apps to register before accessing patient information. Once registered they are considered Medicare-authorized web apps. In addition, those apps are required to provide a public weblink to their privacy policy and terms and conditions. CMS notes that these links should be easy to access and understand. Medicare-authorized web apps are encouraged to use the Office of the National Coordinator's (ONC) Model Privacy Notice. This process promotes trust, transparency, and improved patient engagement. **The AMA recommends that CMS look to the Blue Button program when developing a means to provide patients with better access to their personal health information while ensuring that patients have access to and understand the privacy considerations when using the Patient Access API.** CMS has previously proposed regulatory language that includes information on how providing patients direct and immediate access to an app's attestation will "help inform patients about an app's practices for handling their data." The agency also discussed how an attestation program will "help patients

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		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." There are many positive characteristics of the private industry third-party app benchmarking frameworks that are currently available—they establish best practices, create guidelines, and develop data and security frameworks. However, third-party frameworks would not necessarily provide the same levels of consistency and transparency that a federally run attestation program would engender. **Third-party frameworks are not a substitute for a CMS registration process.** Creating a Blue Button-like program for Patient Access API apps could further reduce physician burden. Physicians are often asked which apps they would recommend to patients. However, physicians do not have access to trusted and authoritative sources for this type of information. **The AMA strongly encourages CMS to extend its Blue Button 2.0 registration process to Patient Access API impacted payers and provide those patients the same benefits realized by Medicare FFS beneficiaries.**
CMS requests comments about ways to leverage ONC's Model Privacy Notice in terms of educating patients on the tools they need to understand the privacy and security implications of using a health app	N/A	AMA encourages CMS to partner with ONC and across HHS to leverage all available tools in educating patients on the privacy and security implications of using a health app. CMS should think creatively on the best ways to urge impacted payers to use the Model Privacy Notice. CMS should work with the entire community (including patient advocates) to determine the best ways to help communicate the often-challenging privacy policies and practices deployed by health apps.
CMS requests comment on whether it can leverage and build on other	N/A	AMA appreciates CMS' desire to promote the access, exchange, and use of data to improve

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
HHS health information exchange initiatives, such as the Trusted Exchange Framework and Common Agreement (TEFCA), to address privacy and security issues		care delivery and better inform patients. Physicians need secure access to the right information about the right patient at the right time, and TEFCA can help enable this enhanced information exchange. This "triple need" is fundamental to ensure physicians have access to patients' longitudinal health record. The AMA views TEFCA as an opportunity to better enable all interested parties in having access to patients' longitudinal health record in a secure environment. However, while TEFCA may expand the availability of medical information, more can be done to improve the usefulness of and trust in exchanged information. Many of our members report that they can connect to local HIE networks, yet they often cannot access their patients' complete health history. This results in a lack of trust and a belief that important medical information is missing. Physicians will forgo using an HIE if they do not feel they can find and receive a complete patient record. Furthermore, physicians often experience a unidirectional flow of information. While patient information is often requested from physicians' EHR systems, physicians regularly do not receive information when they make similar requests. Additionally, CMS' efforts to increase HIE among health care stakeholders must ensure patient data are protected, safe, and secure. Patients are most comfortable with physicians and hospitals having their data and are least comfortable with their data leaking outside the provider space.[22] Trust is a fundamental aspect of the patient-physician relationship. Even well-informed and knowledgeable patients rely on their physicians to provide them with

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

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		appropriate information, keep personal information confidential, and act in their best interests.[23] **The AMA encourages CMS to work across HHS and the entire federal government to promote trust, strengthen data privacy, and create a more equitable information exchange paradigm between physicians and payers.** Additional information about how CMS should consider potential uses for TEFCA to address privacy and security issues is included in our response to the RFI in that section of our comments.
CMS proposes that impacted payers annually report metrics to the agency in the form of aggregated, deidentified data	Support with Modifications	AMA supports annual reports from impacted payers with aggregated and deidentified data that focuses on the number of times data are transferred via the Patient Access API to a health app designated by the patient. We encourage CMS to consider using this aggregated information in its campaigns that educate patients on the privacy and security considerations for moving their personal health data from a HIPAA-regulated environment to a third-party app that likely functions outside of HIPAA. These data points will be valuable in helping patients and the general public understand their ability to access their personal health information and can accompany resources that help to emphasize the benefits of greater control of one's own personal data. Moreover, as uptake of the Patient Access API grows and more data are shared with health apps, **CMS should consider implementing quarterly reporting to help develop more interest in this program and publicize more positive news.** Overall, we see CMS reporting

[23] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500897/pdf/jgi_204.pdf.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		on program metrics as an avenue for communication about the benefits of patient control over one's own data and use of the Patient Access API.
CMS proposes to replace the "clinical data, including laboratory results" information to be made available via the Patient Access API with "all data classes and data elements included in a content standard at 45 CFR 170.213," which currently references United States Core Data for Interoperability (USCDI) version 1	Support with Modifications	AMA supports replacing the access to "clinical data" requirement with a reference to 45 CFR 170.213, and USCDI v1. This change will ensure that payers have continued flexibility as ONC initiates transitions between versions of USCDI, but also guarantees that access through the Patient Access API remains current with the most up-to-date standardized set of data classes and elements. We do request that CMS add a provision to the Final Regulation that makes clear that impacted payers only need to make the USCDI v1-related patient information that they currently possess accessible via the API—impacted payers are not required to seek out additional information from physicians to supplement patient information. We caution that without this clarification, some impacted payers may overburden physicians with requests for particular data elements on specific patients to complete their USCDI v1 data set. **CMS should emphasize to impacted payers that by making the available USCDI data class and element information accessible to the API, they are <u>not required</u> to seek out additional information from physicians.**
CMS is interested in the best ways to ensure that apps are available and accessible for individuals with disabilities, individuals with limited English proficiency, individuals with low literacy or low health literacy, and individuals with geographic, economic, or other social risk factors that may create barriers to accessing or using technology and apps	N/A	The AMA encourages CMS to adhere to the Principles for Equitable Health Innovation developed by the AMA and collaborators as part of In Full Health, particularly involving end users most impacted in the design process. Specifically for developing apps, CMS may want to look to Universal Design principles and for web-based apps at a minimum require

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		adherence to W3C Web Accessibility Initiative principles. Ideally, as digital solutions are developed, **CMS should promote technologies based on how well developers demonstrate reliable, equitable access and outcomes, especially for minoritized and marginalized populations.** Apps should be readily available in any language spoken by the patient with adaptations for users with vision impairment such as high-contrast text, text-to-speech features, and meaningful alternative text for images. Content should be at a basic reading level with multiple modes of presentation in a well-tested usable layout to support different learning and media consumption styles. Apps should be available across multiple common platforms (e.g., iOS/Android, Mac/Windows) responsive to display on multiple types of devices (e.g., smartphone, tablet, laptop, desktop).
Provider Access API		
CMS is proposing that on or after January 1, 2026, impacted payers would be required to implement and maintain a FHIR API to exchange data with providers	Support as Proposed	AMA supports a January 1, 2026, deadline for impacted payers to implement and maintain a FHIR API that makes patient data available to physicians who have a contractual relationship with the payer and a treatment relationship with the patient. We see the Provider Access API as a vehicle to allow impacted payers to build upon their existing systems and processes to enhance access to patient data, while continuing to protect patient privacy and data security.
CMS is proposing that individual patient data maintained by the impacted payer with a date of service on or after January 1, 2016, must be made available via the API no later than 1 business day after the payer	Support with Modification	AMA supports ensuring that payers are working with physicians to build a robust longitudinal care record for patients. We agree with CMS on the multiple benefits for payers to maintain a longitudinal record of their

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
receives a request for data from an in-network provider		Current patients' health information, and how payers should be at the center of the exchange of this data, as they can make information available to patients and their physicians and can help ensure that a patient's information follows them as they move from physician to physician and payer to payer. In addition, we reiterate the critical questions we previously raised about access to this information "within 1 business day." **In an instance when a payer is functioning as a regulated Actor HIN or HIE under the 21st Century Cures Act Information Blocking Regulation, information is intended to be made available "without delay." Does "within 1 business day" constitute "without delay?"** If payers are not functioning as a regulated actor HIN/HIE in the instance when it receives a request through the Provider Access API, do payers need to provide an attestation to this fact when using the "within 1 business day" standard rather than "without delay?" How will physicians know when a payer is an Actor and therefore realize the benefit of HHS' regulations?
CMS to consider future rulemaking that would include a requirement for sharing patient data with out-of-network providers. The agency requests comment on how payers currently do so, the effectiveness of current processes to validate the treatment relationships between patients and providers when a contractual relationship does not exist with the payer, and what additional program integrity safeguards might be appropriate	N/A	The AMA supports the idea of payers sharing patient data with out-of-network physicians to ensure that physicians have the information that they need to treat patients or provide specialty care or additional primary care services. This sharing of information would contribute to supporting the continuity of care that patients expect when seeking health care services. The AMA requests CMS provide clear guidelines 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

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		dissuade physicians from making 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 is concerned that leaving the methods to demonstrate care relationships up to the payers 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 out-of-network physicians will not be expected to use methods that are beyond what are required of in-network providers or that would take physicians or practice staff outside of their normal workflows to demonstrate a care relationship with a patient.** 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. These data and the associated eligibility and benefit request essentially serve as proof of a scheduled appointment, which was referenced in the NPRM as a means for in-network physicians to establish a care relationship with a patient. **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.**

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
CMS proposes that impacted payers would maintain a process to associate patients with their in-network or enrolled providers to enable payer to provider data exchange via the Provider Access API member attribution	Support with Modification	As previously discussed around a process for out-of-network physicians, the AMA requests CMS provide clear guidelines on what it would expect an in-network 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 making 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 is concerned that leaving the methods to demonstrate care relationships up to the payers 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 and their staff will not be expected to operate outside of their normal workflows to demonstrate a care relationship with a patient.** 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. These data and the associated eligibility and benefit request essentially serve as proof of a scheduled appointment, which was referenced in the NPRM as a means to confirm a care relationship. **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.**

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
CMS is proposing that impacted payers would be required to maintain a process for patients or their personal representatives to opt out of and subsequently opt into having the patient's health information available and shared via the Provider Access API. CMS is also proposing that these payers must make this information available to currently enrolled patients before the Provider Access API is operational and shares any of their data	Support with Modification	AMA supports the idea of broader patient access to their personal health information and data and the requirement for patients to "opt out" of having their health information available and shareable via the Provider Access API. We appreciate CMS' focus on patient-directed exchange with the opt-out provision. Impacted payers should have a clearly defined process for patients to opt out and to subsequently opt back in to sharing this data—and this process should be available before the first date on which the payer makes patient information available via the Provider Access API, and at any time while the patient is enrolled with the payer. In addition, we urge CMS to clarify what guidance they would provide to physicians whose patients have opted out of the Provider Access API. We support the idea that impacted payers must provide information in non-technical, simple, and easy-to-understand language to their patients about the benefits of API data exchange with their physicians, their opt-out rights, and instructions both for opting out of data exchange and for opting in after previously opting out. This information should be made available to patients before the Provider Access API is operational and shares any of their data. The AMA also appreciates the CMS requirements that payers provide this information at enrollment and at least annually, as well as that this information is available in an easily accessible location on the impacted payers' public websites. In addition, as many patients likely consult with their physicians on many of these questions, information from payers should also be made available to physicians so that they have understandable resources that they can use to educate their patients on the benefits of sharing data with

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		providers and payers, the Provider Access API, and the opt out process. It is important to note that the Proposed Regulation discusses how the HIPAA Rules permit health plans to disclose protected health information (PHI), without an individual's authorization, to providers for certain permitted purposes under the HIPAA Rules, such as, for example, treatment, payment, or health care operations (TPO). CMS should clarify for patients that, when a patient opts out of the Provider Access API, their information may still be shared with a physician (outside of the API) for TPO purposes. **CMS should clarify in the Final Regulation that the intent of the Provider Access API is not to interfere with TPO access to patients' PHI.** In addition, the AMA supports the idea that patients should be able to access more granular controls over which data they permit a payer to share, including permitting the sharing of certain data from only specific timeframes. There may be limitations on the ability of certain health technologies to sort a patient's data, but we champion patient-directed data exchange, and want patients to be empowered with more control over their personal health information and how their information should be shared to help direct their own care journey.
CMS is asking if it should develop guidance or address in future rulemaking the specific content of these educational materials	N/A	The AMA encourages CMS to explore the idea of creating specific content for plain language educational materials that advise patients, physicians, and the entire community on the intent of these regulations, relevant health data privacy issues, and the meaning of moving data to a third-party app. This is an opportunity for CMS to partner with ONC, across HHS, and the entire federal government to develop resources that apply to this regulation, but also speak to broader health data privacy issues.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		These resources would be an incredibly valuable tool to empower patients with more information about control over one's personal health information, data exchange, and how they can share information to help direct their own care journey. In addition, resources could help educate on the role that individuals can play in ensuring that physicians have secure access to the right information about the right patient at the right time on that care journey. Development of specific educational content and resources by the federal government would also serve as a valuable tool to reduce burden on physicians. Patients often consult physicians and other health professionals with questions about how to access their health information as well as the benefits and drawbacks of such actions. To help relieve the burden on physicians to create their own patient educational resources to advise on these types of questions, physicians would appreciate the ability to refer patients to trustworthy, plain language information created by the federal government. Such a program from CMS or other government agencies would alleviate much of the burden that currently falls on physicians to educate patients on and help contribute to CMS' overall burden reduction efforts. We encourage CMS and other federal agencies to consult with AMA and the entire stakeholder community (including patient advocates) to develop resources that describe the best ways to communicate the benefits of data exchange across the health care continuum and how one could navigate the often-challenging privacy policies and practices deployed by health apps.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
Payer-to-Payer API		
CMS is proposing that impacted payers implement and maintain a Payer-to-Payer API that is compliant with the same technical standards, documentation requirements, and denial or discontinuation policies as its Patient Access API requirements. CMS is also proposing that impacted payers would implement and maintain a FHIR Payer-to-Payer API to make available all data classes and data elements included in USCDI v1, claims and encounter data, and PA requests and decisions, and related administrative and clinical documentation that the payer maintains with a date of service on or after January 1, 2016	Support with Modification	The AMA is supportive of these requirements. Consistency between the Payer-to-Payer API, Provider Access API, and the Patient Access API is a positive step that should make implementation straightforward, given that CMS is requiring inclusion of the same data classes and elements, adjudicated claims, and encounter data. We agree with CMS that impacted payers have already formatted these data elements and prepared their systems to share these standardized data via the other FHIR APIs, so this infrastructure can be adapted for expanded interoperability use cases. It is also important to note our support for CMS consistency with ONC regulations, so that when newer versions of USCDI are put forward in regulation, impacted payers will have to be consistent with that recognized version. We also encourage CMS to work with ONC on consideration of a Standards Version Advancement Process (SVAP)-like program for impacted payers that could allow for their use of newer versions of adopted standards, along the lines of what ONC has granted certified health IT developers in SVAP. **We do request that CMS add a provision to the Final Regulation that makes clear that impacted payers only need to make the USCDI v1-related patient information that they currently possess accessible via the API. It needs to be clear that impacted payers are not required to seek out additional information from physicians to supplement patient information.** We caution that without this clarification, some impacted payers may overburden physicians with requests for particular data elements on

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		specific patients to complete their USCDI v1 data set.
CMS is proposing the previous and/or concurrent impacted payer is required to respond to a current payer's request through the Payer-to-Payer API within 1 business day of receipt	Support with Modification	The AMA strongly supports patients having the tools in place to engage with the delivery of their own health care and ensuring that when a patient requests that their information be shared from a previous and/or concurrent payer to a new payer, that process is initiated expeditiously. The AMA wants to raise critical questions around CMS proposing that impacted payers respond to a request for this information "within 1 business day." As we have previously discussed, **in an instance when a payer is functioning as a regulated Actor HIN or HIE under the 21st Century Cures Act Information Blocking Regulation, information is intended to be made available to patients "without delay." Does "within 1 business day" constitute "without delay?"** If payers are not functioning as a regulated actor HIN/HIE in the instance when a patient makes a request through the Patient Access API, do payers need to provide an attestation to this fact when using the "within 1 business day" standard rather than "without delay?" The AMA wants to ensure that a patient's personal health information is available as quickly as possible to facilitate care coordination and create a longitudinal record that could be helpful to the patient, physician, or payer. We encourage CMS to ensure that its requirements for making this information available align with the 21st Century Cures Act requirements around information sharing. Alignment across federal regulations will help reduce market confusion around expectations as well as any residual friction associated with data exchange.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
CMS is proposing to require impacted payers to maintain a process for patients to opt in to the Payer-to-Payer API data exchange and to identify their previous and/or concurrent payer(s) prior to the start of their coverage. CMS is also proposing that impacted payers must include an attestation with the request for data affirming that the patient has enrolled with that requesting payer and has opted in to the data exchange	Support as Proposed	The AMA is supportive of CMS requirement that patients must opt into the Payer-to-Payer API Data Exchange. We also support the idea of making this process available to patients during the enrollment process to allow the proposed data exchange to take place as quickly as possible once the patient is enrolled with the new payer. Such a step champions the patient having control over their personal health data and allows them to direct any exchange associated with their data. In addition, initiating this process during enrollment will help support an individual's continuity of care. The AMA also supports the requirement that an impacted payer requesting a patient's data include an attestation with the request that affirms that the patient has enrolled with the requesting payer and has opted into the data exchange. This point contributes to emphasizing that CMS is facilitating patient-directed data exchange.
CMS is proposing that impacted payers provide patients with educational materials regarding the payer-to-payer data exchange at or before requesting opt in and at least annually	Support with Modification	The AMA reiterates support for providing additional resources to patients in non-technical, simple, and easy-to-understand language that supports the care that physicians are able to deliver to them and promotes the benefits of exchange of one's personal health information. Impacted payers can be a helpful source for this information, but we encourage direct involvement from CMS in creating these materials. As we previously included in our comment letter, AMA encourages CMS to explore the idea of creating specific content for plain language educational materials that advise patients, physicians, and the entire community on the intent of these regulations and the benefits of sharing personal health information,

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		as well as relevant health data privacy issues. These resources would be an incredibly valuable tool to empower patients with more information about control over one's personal health information, data exchange, and how they can share information to help direct their own care journey. In addition, resources could help educate on the role that individuals can play in ensuring that physicians have secure access to the right information about the right patient at the right time on that care journey.
CMS is requesting comments on whether PAs from a previous payer should be honored by the new payer, and if these PAs should be limited to a specific timeframe or focused on certain medical conditions	Support	The AMA strongly supports impacted plans being required to honor the PA approvals from a previous payer to support continuity of care and protect patients from potentially dangerous disruptions in ongoing therapy. Under the CY2024 Part C/Part D NPRM, MA plans would be prohibited from subjecting an active course of treatment to PA requirements for a minimum of 90 days when patients transition between payers. To align with the Part C/Part D NPRM, **we urge CMS to require all impacted plans to honor the PA approvals of previous payers for at least 90 days.** We note that much of the value of the Payer-to-Payer Data Exchange would be lost if health plans are merely required to send and receive data regarding existing PA approvals but not use the data to improve patient care and prevent interruptions in ongoing treatment during transitions between plans.
Additional API-related Proposals		
Merit-based Incentive Payment System (MIPS) Eligible Clinicians Under the MIPS Promoting Interoperability (PI) Performance Category—Electronic Prior Authorization (ePA):	Oppose	The AMA does not support CMS' proposal to link PA to the PI component of MIPS. CMS' PI proposal would add unnecessary burden, requiring the manual tracking, documentation, and reporting of every PA request made by a payer so long as the payer has a PARDD API.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the PA is requested electronically from a Prior Authorization Requirements, Documentation, and Decision (PARDD) API (PARDD) application programing interface (API) using data from certified EHR technology (CEHRT). • Should CMS consider alternatives to the proposed numerator and denominator of the measure? Are there changes to these specifications that would reduce the implementation burden for both providers and health IT developers? • What challenges will providers face in identifying those payers that have the PARDD API technology in order to accurately include eligible PA requests in the denominator? • What challenges will providers face in performing the actions included in the measure specifications and successfully reporting the measure if certification criteria are not available in the ONC Health IT Certification Program at the time providers are required		This includes non-electronic PA requests made using fax and mail. PA-related work is costly, time-consuming, and wastes human resources. In its proposed rule, CMS cites a recent Altarum Institute study detailing significant PA-related cost burdens and medical staff time requirements.[24] This corroborates the AMA's findings that physicians and their staff spend almost two business days each week completing PAs, and that many physicians have staff who work exclusively on PA. Yet, **CMS' PI proposal would *contribute* to PA-related burden by adding additional workflow requirements and new documentation processes to calculate CMS' proposed numerator/denominator measure.** AMA physician PA survey data captures the overwhelming volume of PAs practices complete on a weekly basis.[25] Our research shows that it will be excessively challenging for physicians and their staff to track eligible PA requests across mail, fax, and portals and compile the necessary information in a report to CMS. In addition, **identifying which PA requests are eligible for the PI measure will waste time.** CMS is proposing that physicians include eligible PA requests in the PI measure denominator. This would require medical practices to identify which payers offer FHIR ePA technology. Yet, CMS is not proposing payers make this information easily accessible to physicians. Thus, medical practices will need to scour the Internet and call dozens of payers' customer support lines—likely on hold for hours—simply to track down which health plans and insurers meet CMS' ePA

[24] https://www.nihcr.org/wp-content/uploads/Altarum-Prior-Authorization-Review-November-2019.pdf.
[25] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
to report the measure under the Medicare Promoting Interoperability Program or MIPS Promoting Interoperability performance category? • With the understanding that ONC may consider policies in the ONC Health IT Certification Program that could further support this measure, are there alternate implementation timeframes that should be considered?		denominator requirements. Further, the information collection time and cost estimates at the end of CMS' proposed rule woefully underestimate the medical practice effort involved in calculating the new measure's denominator. **The AMA strongly disagrees with CMS' assumptions.** The AMA has also heard from several EHR vendors that their products will likely not have the capability to assist medical practices in tracking the various PA requests needed for PI reporting. In fact, ONC has yet to propose PARDD API requirements as part of health IT certification, which puts physicians in an untenable situation of complying with a CMS requirement without even knowing if their EHRs will support ePA. **It is unclear why CMS would create a numerator/denominator measure that is not automatically calculated by EHRs. Linking PA to the PI component of MIPS is contrary to CMS' goal of reducing administrative burden.** We are also very concerned that adding an ePA measure in PI would set a bad precedent for future PI measures. PI is meant to advance and promote information sharing to better patient care, support the care team, and reduce physician burden. Yet, as discussed throughout our comment letter, PA is the number one issue negatively impacting physicians and interferes with patient care. CMS' own efforts to reform PA exemplifies the need to diminish PA's impact on patients. It is then bewildering why CMS would link PA to a MIPS component intended to strengthen patient engagement. **CMS should refrain from contaminating the PI program with PA—an overused administrative process with documented clinical concerns.**

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		As such, the AMA strongly encourages CMS to abandon its proposal to link PA to PI. However, if CMS insists on this approach, we strongly urge CMS to consider alternatives to the proposed numerator and denominator measure requirement. CMS should consider the following phased approach. • First, as CMS has done in the past with newly added PI measures, **CMS should use a "yes/no" attestation and remove the numerator/denominator requirement.** As discussed, it is unclear if EHRs will be able to support CMS' proposal, and manually calculating thousands of PA requests is wasteful. • Second, if CMS needs to capture the total number of PA requests to monitor ePA uptake, **CMS should request that information from payers, as the payer is most likely to have the capability to track its own PA requirements and provider utilization of its PARDD API.** Moreover, PA is already an administrative burden on physicians, and it falls heavily on physicians of color and physicians serving minoritized communities.[26] CMS should make every effort to not further burden physicians of color and physicians serving minoritized communities. • Lastly, physicians are desperate to reduce PA burden. An ePA process that is efficient, fast, reduces burden and improves patient care will overwhelmingly be supported and adopted by physicians voluntarily. For

[26] https://abcardio.org/wp-content/uploads/2018/08/AB-20180808-physician-payer-white-paper_final-v2.pdf.

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		instance, CMS is proposing shorter timelines for standard and expedited PA requests. FHIR-enabled ePAs will likely expedite physician-payer communications. Indeed, using a technology with "fast" in the name implies that both physicians and health plans should see significant reduction in PA processing time—and thus—drive physician adoption. **CMS should refrain from jumping directly into physician disincentives, i.e., jeopardizing the PI component of MIPS, and instead encourage normal market forces and consumer demand to drive ePA and physician uptake.** CMS can monitor physician ePA use in less burdensome ways and consider future incentives if necessary.
CMS proposes to require payers implement and maintain a FHIR Prior Authorization Requirements, Documentation, and Decision (PARDD) API to facilitate the PA process for all PA rules and requirements for items and services (excluding drugs) for impacted payers. Payers would be required to use those specifications included at 45 CFR 170.215.	Support with Modification	The AMA strongly supports the use of APIs that embed PA requirements and payer documentation needs within physicians' EHR workflow. PARDD API operationalizes concepts found in both the AMA's PA Principles and Consensus Statement. The AMA supports CMS' proposed January 1, 2026, payer compliance date. We agree with CMS' assessment that a phased implementation approach (i.e., allowing health plans to gradually implement their PARDD APIs by adding a certain percentage of services subject to PA each year to the API) would be highly confusing and extremely burdensome for physicians, as practices would need to track highly variable PARDD API availability across plans *and* services. As noted in the AMA's comments on the 2020 PA NPRM, we harbor concerns regarding the requirement to use the X12 278 in tandem with FHIR API technology, as it appears that the

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		transaction's only function is to maintain HIPAA compliance. The black box "translation" of FHIR to the X12 278 will increase administrative costs for physicians and health plans, as clearinghouses or other intermediaries will be needed to accomplish this translation. Additionally concerning is the potential for errors resulting from 278-to-FHIR mapping; indeed, discussions at HL7 workgroups and testing events have raised serious concerns about the accuracy of this mapping**. As such, we urge CMS to closely monitor the results from entities that have been granted a HIPAA exception and are testing direct FHIR-to FHIR exchange, as this could inform future rulemaking related to PA electronic standards.** The AMA supports requiring PARDD APIs based on specifications found in ONC's health IT certification program. The AMA also supports CMS' position to strongly recommend, but not require, that PARDD APIs have the functional requirements outlined in several HL7 FHIR Da Vinci IGs. This should help ensure payers' PARDD APIs are aligned with certified EHRs. **However, we urge CMS to closely follow the development of Da Vinci IGs, i.e., CRD, DTR, PAS.** CMS states it is contemplating future rulemaking to require that PARDD APIs comply with Da Vinci IGs. Prior to a requirement, **CMS should ensure Da Vinci IGs can be certified and tested to a level of conformance that meets CMS' PA reform goals.** The CRD, DTR, and PAS IGs have several data elements and processes that are optionally available for use. **This optionality is by design and at the direction of the payer community.** For example, the CRD IG allows payers to

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		return Internet hyperlinks to physicians. This means that a valid payer response to a physician-initiated coverage requirement discovery can be a weblink to a third-party PA vendor where the physician would have to initiate a PA request through to a payer portal and drop to a manual process outside of their EHR. Additionally, the PAS IG allows payers to return a "pended" PA status in response to a decision request. This means impacted payers could meet CMS decision requirements with vague responses. The AMA is working within the HL7 community to close these gaps but continues to encounter payer resistance. **Without increased CMS intervention and oversight in IG development, it is unlikely IG deficiencies will be resolved on their own—jeopardizing CMS' PA reform goal.** Furthermore, many health IT systems will need to work together for ePA to function properly. Successful ePA interoperability will require an orchestration of health IT modules and products not under ONC certification, e.g., practice management systems, and systems operated at entities not directly under CMS authority, e.g., clearinghouses and intermediaries. **As CMS considers future policies to mandate the use of Da Vinci IGs in PARDD APIs, the AMA suggests CMS and ONC evaluate the following considerations:** • How will gaps in the use of Da Vinci IGs be addressed between certified health IT, e.g., EHRs, and noncertified health IT, e.g., practice management systems? • How will gaps in Da Vinci IG adoption and conformance be monitored and addressed across payers and health plans?

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		• How will FHIR-based API uniformity be assured across all payers and all payer PA programs? • What role can federal regulators play in encouraging or requiring that all health plan trading partners (e.g., intermediaries and clearinghouses) use Da Vinci IGs in a consistent and conformant way? If federal regulations are insufficient, what federal legislation would be necessary to require intermediaries and clearinghouses to adopt and use certified health IT for ePA? • What process is underway to translate HL7 Da Vinci IGs into ONC pre-certification testing and post-certification reporting requirements? How will HL7 workgroup analysis, Connectathon testing reports, individual health IT vendor experiences, and real-world pilot testing inform that translation?
CMS is proposing to extend its policy to allow the use of an updated version of a standard to the Provider Access API, Payer-to-Payer API, and PARDD API. CMS is recommending, but not requiring, certain implementation guides (IG) that were previously proposed and seeks to ensure that implementers use subsequent versions of these IGs without restriction to the version available. CMS seek comment on whether it should propose to require the use of these IGs in future rulemaking and other ways to support innovation and	Support with Modification	The AMA supports CMS updating standards' versions for Provider Access, Payer-to-Payer, and PARDD APIs. The AMA also supports CMS' approach to recommend, but not require, certain FHIR IGs and that subsequent FHIR IG versions may be used. The AMA is a strong advocate for the use of technical standards that are proven, mature, and that have been tested and shown sufficient return on investment in medical practices across geographic locations, e.g., rural vs. urban, practice size, e.g., solo and small, and medical specialty. The AMA has joined the Health IT End-Users (HITEU) Alliance to promote real-world testing of technical standards. These principles

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
interoperability. In addition, CMS seek comment on the process it should use to adopt or allow new versions of standards and implementation specifications over time.		were developed by health information professionals, physicians, hospitals, and other stakeholders that use health IT in the provision of care. As CMS considers its policies on standards, the AMA urges CMS to pay close attention to the HITEU Alliance principles, particularly those on assessing physician impact, measuring success in achieving stated goals, and monitoring standards development and use. These principles can help guide CMS and developers in better responding to physician needs. While the AMA supports CMS' proposals for API use and standards' versioning—as previously stated—success will require that CMS be involved and track the development and maturity of regulated technical standards. **For example, we suggest that CMS designate federal staff to routinely join and monitor HL7 workgroups charged with maturing and balloting CMS-recognized IGs.** More must be done to monitor the impact of health IT standards on front-line clinicians. The AMA is active in several HL7 workgroups and has encountered participants who routinely express their own interpretations of CMS policy as fact or cite their own conversations with CMS staff as a basis for making broad IG development decisions. Misunderstanding and miscommunication obstructs standards development and causes friction between workgroup members. **We urge CMS to ensure standards are being developed that meet physician and patient needs and accurately embody CMS' goals to improve care and reduce physician burden.** Lastly, CMS should consider the following questions as it evaluates its policies to allow

Proposal	Support as Proposed, Support with Modification, or Oppose	Comments
		voluntary stakeholder adoption of health IT standards: • 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?

Appendix B: Requests for Information

A. Improving the Electronic Exchange of Information in Medicare Fee-for-Service (FFS)

The AMA appreciates the opportunity to weigh in on the electronic exchange of information in Medicare FFS. It is important to emphasize that, to the extent that this RFI references the existing limited use of PA in Medicare FFS, we support this initiative. **However, we are alarmed if this RFI signals an intent to increase utilization of PA in Medicare FFS.** The AMA strongly believes in the "right-sizing" of PA and the critical need for a reduction in the overall volume of items and services requiring authorization. Indeed, increasing PA in Medicare FFS would be out of alignment with industry-wide agreement on the need to selectively apply PA to only outlier physicians and/or services showing a consistent variation in ordering patterns or low approval rates, as detailed in the 2018 Consensus Statement on Improving the Prior Authorization Process.[27] **To protect timely access to care for Medicare FFS beneficiaries, we urge CMS to not proceed with any expansion of PA in traditional Medicare.**

The AMA agrees that improved medical documentation exchange between and among physicians, suppliers, and patients in the Medicare FFS program presents some unique challenges. As discussed in the RFI, the ordering physician can be different than the rendering physician of items or services, which can be an obstacle to accurate and timely payment. We want to work with CMS to formulate a system for improved information exchange in Medicare FFS as we believe it could enable better care for beneficiaries if covered services are not delayed by inefficiencies. The exchange of information with providers beyond physicians and hospitals, such as home health agencies, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, and ambulance providers adds an additional hurdle as these providers were not included in the American Reinvestment and Recovery Act (ARRA) Health Information Technology for Economic and Clinical Health (HITECH) Act program.

The AMA supports CMS' efforts to focus providers on electronically exchanging patient information and medical documentation. Such steps would ease burden on physicians and circumvent time-consuming and burdensome paper-based practices that negatively impact patient care. We agree that health IT and the electronic exchange of information would streamline information-sharing processes between ordering and rendering providers, suppliers, as well as patients and minimize any existing obstacles.

CMS should consider encouraging all parts of the provider and supplier communities to voluntarily adopt technologies that could support the electronic exchange of information in Medicare FFS. In addition, the broader use of data standards by providers and suppliers is a tool that CMS should promote to facilitate the electronic sharing of patient data. Ensuring that all parts of the community are educated on existing standards and how to use them is one way that CMS could engage all providers and suppliers on this topic. As we have previously discussed, we support CMS advancing data standards that are sufficiently mature, thoroughly tested in real-world settings, and of sufficient value to practices of all sizes. In addition, **we urge CMS to work across HHS, especially with ONC, on a broader education program about the USCDI and how all health system participants are leveraging USCDI data classes and elements to better exchange patient health information.**

---

[27] Consensus Statement on Improving the Prior Authorization Process. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

We have previously submitted comments to ONC about adding DME Orders as a USCDI Data Element. The AMA supports physicians, suppliers, payers, and patients having the ability to order and track DME electronically to eliminate paper and fax and to ensure accurate ordering, minimize denials, and to reduce time required to supply patients with needed DME and related supplies. As patients move from sites of service, between payers, or when accessing their own medical information, DME information should be structured and included within a common data set associated to the patient. Yet, there is currently no well adopted standard for electronically ordering DME equipment and supplies. Including DME within the USCDI will heighten the importance of DME capture and exchange, promote adoption using FHIR-based standards, and support use cases such as PA.

Moreover, thinking expansively about how to improve the electronic exchange of information in Medicare FFS, **CMS should explore applying the proposed requirements for the Patient Access API and Provider Access API to the Medicare FFS Program.** These steps would be hugely impactful for coordination of patient care and exchange of medical information for all Medicare Beneficiaries. In this regulation, CMS discusses how these proposals do not directly pertain to Medicare FFS, but there are ideas to implement these provisions for Medicare FFS so that people with Medicare FFS and their physicians could also benefit from their data availability. The AMA expects that a Medicare FFS implementation would conform to the same proposed requirements that apply to the impacted payers under this proposed rule, so Medicare FFS physicians and their patients could also benefit from this type of data sharing. Further enhancement of and alignment with Blue Button 2.0 would be extremely helpful in making this information available and accessible to physicians and patients.

B. Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)

CMS is seeking information on opportunities to encourage information exchange under TEFCA. CMS is interested in how TEFCA could support requirements for payers related to provider data access PA processes. CMS is also seeking comments on financial, technical, or other barriers entities could face participating in the TEFCA.

The AMA appreciates CMS' desire to promote the access, exchange, and use of data to inform population health management and care coordination. Physicians need access to the right information about the right patient at the right time. This "triple need" is fundamental to ensure physicians have access to patients' longitudinal health record. The AMA views TEFCA as an opportunity to better enable all interested parties in having access to patients' longitudinal health record. However, while TEFCA may expand the availability of medical information, more can be done to improve the usefulness of and trust in exchanged information.

Many of our members report that they can connect to local HIE networks, yet they often cannot access their patients' complete health history. This results in a lack of trust and a belief that important medical information is missing. Physicians will forgo using an HIE if they do not feel they can find and receive a complete patient record. Furthermore, physicians often experience a unidirectional flow of information. While patient information is often requested from physicians' electronic health record (EHR) systems, physicians regularly do not receive information when they make similar requests. **This asymmetry often occurs when exchanging with payers. CMS must consider how its policies can rebalance this disparity.** While TEFCA includes mechanisms to require data exchange parity under its Data Use and Reciprocal Support Agreement, full end-to-end TEFCA exchange will likely not occur until late 2023. Over the next several months, **CMS should closely monitor (e.g., through physician surveys and**

listening sessions) how TEFCA participation resolves data asymmetry as well as monitor physicians' satisfaction in finding and using complete patient records.

Additionally, CMS' efforts to increase HIE among health care stakeholders must ensure patient data are protected, safe, and secure. Patients are most comfortable with physicians and hospitals having their data and are least comfortable with their data leaking outside the provider space.[28] Trust is a fundamental aspect of the patient-physician relationship. Even well-informed and knowledgeable patients rely on their physicians to provide them with appropriate information, keep personal information confidential, and act in their best interests.[29] In a recent survey of 1000 patients, nearly 75 percent said they are concerned about protecting the privacy of their health data. Six in 10 patients are worried about health data being used by companies to discriminate against them or their loved ones or to exclude them from opportunities to find housing, gain employment and receive benefits. The survey also identified that over 50 percent of patients are "very" or "extremely" concerned that unnecessary access to their data could result in negative repercussions related to insurance coverage, employment, or opportunities for health care.[30] The evidence is clear: patients recognize the value of information exchanged among their providers but worry about the consequences of their information being misused by businesses or other entities, including payers. **Data privacy and data liquidity are not mutually exclusive; CMS has a responsibility to encourage both with equal emphasis.**

To promote trust, strengthen data privacy, and create a more equitable information exchange paradigm between physicians and payers, CMS should consider building its HIE policies on top of the following principles:

- Develop and implement data exchange policies, processes, and programs to better address inequities and disparities among exchange parties. Advancing information exchange equity requires filling gaps in data completeness and quality and developing an information sharing infrastructure capable of consolidating and curating individuals' demographic and health information. **CMS should work with its federal partners to monitor TEFCA information exchange parity and correct imbalances.**
- Create policies that positively incentivize the collection, exchange, and use of actionable and timely information while ensuring information symmetry between physicians and payers. CMS should assess where its MA and HIE efforts intersect such that its policies can help physicians better understand and manage health needs and conditions at the level of the individual, within communities, and across MA populations. CMS should consider the impact of its programs, operations, and MA plan arrangements to promote a strategy that improves quality, experience, and care outcomes. MA models should advance and support population health improvement and the delivery of value-based care—centered on the patient and care team.
- Policies should elevate the collection, exchange, and use of electronic health information in a secure manner while promoting trust, ensuring data integrity, protecting individuals' safety, and adhering to federal and state privacy laws. For example, HIPAA minimum necessary standard requires covered entities to evaluate their practices and safeguards to limit unnecessary or inappropriate access and disclosure of protected health information. **Our members are concerned that by participating in HIEs with payers, MA plans could overreach into their**

[28] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.
[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500897/pdf/jgi_204.pdf.
[30] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.

EHRs and access unnecessary medical information—circumventing HIPAA Rules. The Office for Civil Rights emphasizes that "appropriate limits should be placed on the type and amount of information collected, used, and disclosed, and that authorized persons and entities should only collect, use, and disclose information necessary to accomplish a specified purpose."[31] CMS should reinforce this safeguard through its MA policies and HIE efforts. **CMS should require that MA plans meet the needs of their beneficiaries and perform their roles within trading partner agreements, and CMS should explicitly limit MA plans' HIE data requests to the minimum necessary information needed to meet their business practices.**

- Use of consistent and uniform data exchange standards is critical for interoperability. Physicians are required to utilize certified health information technology (health IT) which goes through federal testing and accreditation. This creates a common information exchange framework between health IT products since they are tested and shown to conform to the same standards. CMS should explore how MA policies can be developed to require that MA plans demonstrate a similar level of conformity. This is particularly important as CMS explores new technologies to address the burden and patient harm caused by MA PA practices. As an example, CMS could require that MA plans adopt, implement, and use health IT that conforms to equivalent industry standards, policies, best practices, and technical guides used in the Office of the National Coordinator for Health IT's Certification Program. **As an initial step, MA plans should be required to document and provide evidence demonstrating how their health IT systems comply with and conform to the same technical guides EHR vendors must meet in ONC's programs.** This should be a prerequisite before CMS requires MA plans join the TEFCA.

As CMS explores polices to promote HIE use, we urge CMS to also consider the technical and resource limitations many physicians face. Most physicians believe it is important to share electronic health information to provide quality care, yet the lack of a convincing value proposition has been a major barrier to HIE use.[32] Although there is likely a net societal benefit of participating in HIEs, the return on investment for individual medical practices may not materialize. Apart from capital expenses and fees, medical practices must also adapt their workflow to benefit from HIEs. HIE adoption can be risky for small medical practices. Implementation costs, including the loss of productivity, can undermine practices' financial stability. Many medical practices lack staff with the skills and experience necessary for HIE implementation. **The AMA urges CMS to review its HIE policies through the lens of burden, costs, and other resource limitations affecting small, rural, and solo practices.** To ensure all medical practices can benefit from CMS' HIE efforts, policies should be crafted to avoid large-scale disruption and huge up-front capital investments by physicians. **CMS should ensure that any HIE incentives are conditioned to support medical practices of all sizes and geographic locations, and that any requirements leverage existing certified hardware and software, e.g., EHRs, already used by physicians.**

C. Accelerating the Adoption of Standards Related to Social Risk Data

CMS seeks input on the barriers to using industry standards for social risk data collection and on opportunities to increase the adoption of such standards.

---

[31] https://www.hhs.gov/hipaa/for-professionals/faq/collection,-use,-and-disclosure-limitation/index.html.
[32] https://www.ama-assn.org/system/files/2018-10/cybersecurity-health-care-infographic.pdf.

CMS Question:

What are best practices regarding frequency of collection of social risk and social needs data? What are factors to be considered around expiration, if any, of certain social needs data?

AMA response:

Additional guidance is needed on how this information should be implemented and reported over time, particularly on whether screening of all social risk and social needs data must be completed annually and whether the referrals or activities from previous measurement periods may satisfy any intervention requirement. In general, where it aligns with federal approaches, we advocate for at least yearly screening. Examples include food insecurity screening via The United States Department of Agriculture (USDA) U.S. Household Food Security Survey Module and housing screening via the Department of Housing and Urban Development (HUD) American Housing Survey (AHS). Screening should be done with awareness of physician and patient burden. To demonstrate clear, consistent justification for services that address social needs and risks, best practice should start with good initial screening and the use of interoperable, standardized formats to collect, code, and exchange screening data across relevant parties with appropriate consent. Additionally, solutions should be able to be designed to allow screening to be context driven.

The AMA urges CMS to consider the 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. In addition to best practices regarding frequency of collection of social risk and social needs data, there is a need to study and clarify best practices related to interventions.

Finally, decisions related to the expiration of social needs data may need to consider the definition of the social need in question. For example, if the definition for food insecurity includes specific criteria (e.g., worrying about running out of food) "at any time in the last 12 months", then "food insecurity" cannot expire sooner that 12 months from the date at which the criteria were first met.

CMS Question:

What are best practices regarding workforce training on collecting social risk and social needs data? How could CMS best support such training?

AMA Response:

Literature from the Gravity Project indicates that, in the absence of barriers (e.g., literacy, language, disabilities etc.), an individual filling in a paper form on their own or using automated or online screening is more effective than when screening is done by an interviewer. To help decide where to place training support, CMS could conduct research on variation in positive yields between online versus interviewer-administered screening for similar populations. Use of automated screening, where possible, is a significant step toward reducing burden. Ideally, to reduce physician burden, there should also be processes in place for administration of screening and initial assessment of screening results by appropriately trained supporting staff.

With respect to guidance on training for collection of this type of data, it begins with the administrator of the screening acknowledging that this is sensitive, personal data. As an example, the "Food Research and Action Center (FRAC) and American Academy of Pediatrics (AAP) toolkit for Pediatricians to Address Food Insecurity" provides guidance on empathetic, sensitive, and culturally effective conversations when addressing food insecurity. Individuals should also have the option to decline to answer questions that they might not be comfortable with. Training of staff should include trauma-informed approaches, cultural humility, and structural competency, so the person collecting the data understands how these factors are driven by larger societal issues and impact health, coming to the patient in the spirit of help without judgment.

Finally, we support the recommendation below from the February 2023 NORC at the University of Chicago (NORC) and the American Health Information Management Association (AHIMA) report on Social Determinants of Health Data:

Policy Recommendation #3: Federal financial and technical support is needed to train providers and operations staff on how best to collect, code and use social needs information. This should include a focus on cultural competency coupled with the recognition that different care settings may require different approaches. It should also include continued and expanded research on how best to collect and code SDOH data, and the workforce skills needed to do so. Government agencies, professional societies, and other organizations—such as AHIMA, CMS' Office of Minority Health, CMS' Center for Medicare & Medicaid Innovation, HL7's Gravity Project—should also leverage their learning collaboratives to share best practices and guidance on the collection, coding, and use of clinically relevant SDOH data for care team members and operations staff, so that they can efficiently use existing knowledge. This may include training appropriate staff on how to use standardized formats to collect and code the data from patients in ways that are effective and adhere to high standards of cultural competency, privacy, and confidentiality.

CMS Question:

What are the challenges in representing and exchanging social risk and social needs data from different commonly used screening tools? How do these challenges vary across screening tools or social needs (for example, housing or food access)?

AMA Response:

Based on feedback we received from Gravity Project subject matter experts, data to represent SDOH domains should only be screened with tools that have been psychometrically tested, including sensitivity and specificity, against gold standard tools. Therefore, the drivers and domains included in a measure should align with data standards such as the HL7 Gravity Project and USCDI. Incorporation of these elements into USCDI, so that they are required as part of the application programming interface (API) certification criterion, is a key step in driving representation and exchange of social needs-related data. At this time, only food insecurity has been finalized and uses a gold standard tool (the USDA Food Security Module). HUD has a gold standard tool for housing instability in development and transportation insecurity screeners are also in development. There are tools currently in the food insecurity domain that may meet content and face validity (the Gravity Project base standard), but they have not been fully tested for sensitivity and specificity against the USDA module and thus may create false positives, and more importantly false negatives.

We are also aware that there are inconsistent definitions of "utilities." We suggest working with the Gravity Project to develop a consistent definition of "Utility Insecurity." Ideally, a single question would be able to clearly identify whether an individual has needs related to utilities (e.g., a question covering all the utility subdomains). Once a utility need has been ruled in, further questions can be used to specify the exact utility needs.

Finally, we support the two recommendations below from the February 2023 NORC and AHIMA report on Social Determinants of Health Data:

Policy Recommendation #1: CMS and other relevant agencies within HHS should establish, in collaboration with standards-setting organizations, health information professionals, physicians, hospitals, and other front-line health care providers and organizations, a set of standardized, clinically valid, and actionable SDOH data elements for collection. This might include a limited set of evidence-based domains, such as food and housing, as priorities while other domains are considered optional. This would allow for a subset of standardized data elements to be collected in a consistent and comparable manner, while recognizing that diverse care settings may not have the same amount of time or resources to collect and act upon these data. Domains prioritized for collection should also align across federal and state healthcare programmatic and reporting requirements.

Policy Recommendation #2: To enhance use of a prioritized set of clinically relevant data to improve outcomes and health, CMS should consider providing financial incentives to providers, Medicare Advantage plans, Medicaid plans, and commercial payers to collect and share SDOH data. Aligning incentives and protocols across CMS programs, commercial payers, and providers would ensure that stakeholders are working together to meet their community's needs.

CMS Question:

What are the barriers to the exchange of social risk and social needs data across healthcare providers? What are key challenges related to exchange of social risk and social needs data between healthcare providers and community-based organizations? If Federal or other regulations are perceived or actual barriers, please identify the specific regulation, policy or guidance and clarifying language that would be necessary to resolve the cited barrier. If no specific language or policy is known, please provide a citation where more information is available related to this barrier.

AMA Response:

A systematic approach is needed to address the barriers and funding challenges related to the screening and exchange of social risk and social needs data between physicians and community-based organizations (CBOs). Principal challenges include lack of data on individual's social needs; lack of data on the capabilities of potential community partners; lack of mature partnerships between physicians and CBOs; and difficulty determining how to assess return on investment of this work. Even within a health care system, multiple screening tools may be in use across the organization so a process is required to build consensus around a single screening tool and a uniform method for collecting the data. Organizations also need established policies and governance structures (for issues like consent, privacy, and non-covered entities) that are guided by staff, physicians, and patient representatives. There must also be options for individuals to decline to answer questions that they are not comfortable with. Ideally, screening data should be integrated into the EHRs so that it is easily accessible by appropriate physicians and team members. However, EHR vendors are only beginning to offer tools to facilitate this work.

A "closed-loop" referral is most likely a preferred way to connect patients with CBOs. However, this requires vetting on the part of the physician. Many physician practices, especially small physician practices, may not have the bandwidth or expertise to handle this. For example, the Mount Sinai Health System has formally aligned with selected CBOs by bringing them into its clinically integrated network. This creates opportunities for these CBOs to participate in Mount Sinai's payer contracts and potentially be reimbursed directly for services.

We are also aware of some health systems contracting with community resource referral platforms, but there is a cost to setting up licensing agreements, training staff, modifying clinical workflows, customizing the platforms and integrating them with their EHR. The benefit of the platform is also contingent on the extent to which CBOs use them. There are also instances where insurers and physicians select different vendors which forces CBOs to work with multiple platforms and adds to the administrative burden. CBOs range from sophisticated organizations with strong administrative capacity to small charities with dedicated staff but limited resources. To meet the demand, CBOs need sustainable funding.

In general, interoperable standards are a requirement for the effective collection, representation, aggregation, and exchange of this data. As mentioned in the prior responses, definitions for social risks and needs vary across tools. Even for tested and vetted tools, representation and coding of data acquired from those tools may vary. Interoperable, meaningful data requires:

- consistency in screening tools;
- consistency in definitions and coding for screening findings and conditions (at a minimum, consistent ICD-10-CM codes); and

- consistency in structures for data exchange.

Implementation of interoperability standards related to social risk data varies widely. The Gravity Project's terminology development work and Fast Healthcare Interoperability Resources (FHIR) SDOH Clinical Care Implementation Guide are excellent steps towards standardizing and improving the exchange of this data across physicians and organizations.

Finally, we support the recommendation below from the February 2023 NORC and AHIMA report on Social Determinants of Health Data:

Policy Recommendation #4: Federal government should provide funding, technical resources, and infrastructure to support coordination and connectivity at the state and local level between health care organizations and CBOs. Many of the solutions to addressing SDOH needs rely on collaboration between the health and social services sectors. This type of cooperation is happening in pockets at the local level. Many providers are reticent to ask their patients about their SDOH needs without first having the community-based support system to which they can refer the patient so that these needs can be met. Federal incentives are needed for states to create better alignment—across coordinating agencies to improve coordination, collection, and, ultimately, impact.

CMS Question:

What mechanisms (EHRs, HIEs, software, cloud-based data platforms, etc.) and/or standards are currently used to capture, exchange, and use social risk and social needs data? What challenges, if any, occur in translating, collecting, or transferring social risk factor data in these platforms to Z codes on claims?

AMA Response:

EHRs, health information exchanges (HIE), software, and cloud-based data platforms have varying levels of support for screening. Social needs-related data elements are often collected via custom platforms with non-interoperable fields and non-standard exchange mechanisms. Currently, terminology standards available to represent screening results include ICD-10-CM, LOINC and SNOMED CT. Labor of screening and subsequent interventions to address social risks and needs could be captured with Current Procedural Terminology.[33] USCDI specifies appropriate terminology standards for these classes. As illustrated in the February 2023 NORC and AHIMA report on Social Determinants of Health Data, the degree to which these standards are implemented today is variable. In addition to the variability in terminology standards, there is similar variability in the use of exchange standards including FHIR. An on-going challenge is incentivizing "users," regardless of whether they are regulated by CMS, to document and share the data using interoperable coding standards (e.g., ICD-10-CM) and exchange structures (e.g., FHIR R4).

The Gravity Project continues to establish Z codes to represent social risks and needs. However, definitions of specific social risks and needs often vary across tools. Therefore, two tools using different definitions for the "same" risk or need may not arrive at the same Z code. Some screening tools allow identification of Z codes that may be too high-level to capture the granularity of the problem. In that case, additional, standardized questions may be necessary to arrive at appropriate granular Z codes to determine appropriate interventions and track the effectiveness of their outcomes. Sometimes, a question-and-

[33] https://www.ama-assn.org/practice-management/cpt/social-determinants-health-and-medical-coding-what-know.

answer pair on a screener may be insufficient to identify any appropriate ICD-10 Z code. For example, answering "Yes" to the question "98978-0 At any time in the past 12 months, were you homeless or living in shelter [including now]?" (Children's Health Watch Housing Stability Vital Signs screener) is insufficient to differentiate between Z59.812 Housing instability, housed, homelessness in past 12 months, Z59.00 Homelessness unspecified, Z59.01 Sheltered homelessness, or Z59.02 Unsheltered homelessness. Additionally, some screening tools may be able to identify when a specific social risk or need exists but are not able to fully rule it out. Screening tools that identify true negatives as well as true positives would be useful to allow resources to fully focus on those who most need them.

While the AMA supports data collection efforts to improve the reporting of SDOH to advance the ability to recognize severity of illness, complexity of service, and/or utilization of resources, we believe it is premature to mandate reporting of SDOH ICD-10 Z codes on all claims. There are several administrative factors that must be considered first to standardize the data and improve the reliability and validity of the coded data, including in support of efforts to advance health equity. The data collected must be high quality to ensure that social needs are more accurately identified and managed to, ultimately, improve health outcomes and reduce data collection burden.

Finally, a consistent approach is needed for unanswered screening questions. Unanswered questions may result in misinterpretation that a specific risk is absent when it really indicates that the risk is unknown.

CMS Question:

How can payers promote exchange of social risk and social needs data? Are there promising practices used by MA organizations, state Medicaid agencies, Medicaid managed care plans, commercial health plans or other payers that can potentially be further leveraged in other settings?

AMA Response:

The role of CMS, as the nation's largest payer with regulatory authority, is critical in promoting the exchange of social risk and social needs data. Before promoting the exchange of social risk and needs data, there first need to be financial incentives to collect the data as well as evidence that the data has sufficient value to justify, and reimburse for, its collection. There also need to be evidence-based, cost-effective interventions that can be directed at the identified social risks and needs. Community-based organizations should also be financially incentivized to participate in electronic data exchange. Additionally, payers could participate in collecting social risk data by screening their members for social risks and needs to identify high-risk members, anticipate their needs, and potentially initiate preventive measures (e.g., transportation to dialysis to avoid complications of fluid overload). While this may not necessarily result in increased payment, it may result in cost savings for some members. Where appropriate and with consent, payer-identified risks and needs could then be shared and exchanged with physicians.

CMS Question:

What specific strategies, tactics or policies would help CMS and other Federal agencies facilitate greater standardization in the capture, recording, and exchange of social risk factor data? Are there best practices (related to contracting language, requirements in Federal programs, etc.) that could be adopted, and by which agency?

AMA Response:

Only allow screening tools that have been psychometrically tested, including sensitivity and specificity, against gold standard tools. Any drivers and domains included in a measure should align with data standards such as the HL7 Gravity Project and USCDI. The Gravity Project's consensus-based terminology work, FHIR SDOH Clinical Care Implementation Guide, and submissions to the USCDI are significant steps towards standardization and use of social risk data.

CMS Question:

Which gaps remain that are not being addressed by existing efforts?

AMA Response:

As stated in prior responses, there are still significant gaps in:

- gold standard, uniform, screeners to cover the various domains of social risk and need,
- standardized definitions and codes and terminology to unambiguously represent social risk and need data, and
- standardized exchange standards.

CMS Question:

What privacy issues should be considered when formulating policy for collecting and exchanging social risk and social needs data? Are there certain data elements that patients may wish to exercise more control over than others?

AMA Response:

Privacy is a significant concern for social risk and needs data, especially since this data may be collected or exchanged outside the traditional walls of health care. Formalized collection and coding of much of this data is new. Concerns, such as whether these social risks and needs could be "preexisting conditions" when applying for health or life insurance, need to be understood by all parties, particularly those to whom the data pertains. CMS, the Office for Civil Rights, and ONC's Office of the Chief Privacy Officer need to address the appropriate sharing of social risk and need data between HIPAA-covered entities (providers and payers), and entities which may not be HIPAA-covered (and community and social service organizations).

Data elements over which more control should be exercised may be partially dependent on the opinion of the individual to whom the data pertains (e.g., stigma associated with data may vary by individual). For example, if not properly controlled and protected, data reported on interpersonal violence may put the individual at increased risk of violence. Furthermore, social data that is stigmatized (e.g., past incarceration) or subject to legal action (e.g., immigration status) may be particularly sensitive to privacy concerns.

CMS Question:

Please identify potential existing, emerging, or possible new policy levers that CMS could use to better incentivize use and interoperability of social risk factor data.

AMA Response:

CMS has recently finalized two social screening measures in the Hospital Inpatient Quality Reporting (IQR) program and Merit-based Incentive Payment System with plans to propose them across its other quality programs. The AMA supports the intent of the measures to begin to address the social drivers that can also impact an individual's health outcomes and appreciates the urgency; however, we are concerned that CMS has finalized and implemented the measures prematurely which will impede progress on the issue. **We are worried that too much emphasis is being placed on asking patients about their social needs and SDOH and not enough emphasis on addressing those needs.** Too many organizations are leaving patients to "navigate to nowhere," which may make things worse. We need a coordinated effort across the health care ecosystem including how to handle interventions.

We also continue to have significant concerns about how the measures are designed and the lack of adequate specification and testing. **As currently specified, the measures may produce results that are not valid**. For example, the Screening for Social Drivers of Health measure's numerator definition allows a hospital to screen a patient on "one or all" of the five factors and the positivity rate will be based on this same approach (one factor or up to five). There is a significant risk that comparisons will be made where one hospital only focuses on screening on one health-related social need while others focus on all five factors.
In addition, we believe that there is a flaw in the proposed measure calculation in the positivity screen rate. The first measure on screening allows hospitals to select whether they will report on one or all of the five items using any tool, but this subsequent measure assumes that hospitals will screen on all five. As a result, it remains unclear whether there will be sufficient denominator sizes to enable reliable and valid comparisons. The measures also currently do not exclude patients whose length of stay is only one or two days, which makes it far more difficult for a hospital to administer this screening in addition to all of the other important clinical activities that may take place during an admission.

Furthermore, for applicable domains, quality measures should only include tools that have been psychometrically tested, including sensitivity and specificity, against gold stand tools. Therefore, the drivers and domains included in the measure should align with data standards such as the HL7 Gravity Project and USCDI. The lack of standardization of the tool or factors assessed, adequate denominator exclusions, or testing for reliability and validity goes against fundamental measure development principles outlined by the National Quality Forum and the CMS Blueprint. CMS would be better served to focus on the typical measure development process for these measures rather than the trial-and-error data submission and reporting approach currently proposed.

Ideally, a gold standard screening instrument across all domains should be developed that implements the standards Gravity has recommended. This could be a compilation of multiple standardized and validated tools. Efforts related to social risks and needs must also begin to consider and address broadband access, so we are not creating a digital divide when it comes to access to telehealth and digital tools. In addition, prior to holding physicians accountable for screening patients and the associated data collection, there needs to be an education effort explaining the importance of the information, best practices for collecting the data and intentions for use, as well as education related to privacy and security.

CMS Question:

Please identify opportunities and approaches that would help CMS facilitate and inform effective infrastructure investments to address gaps and challenges for advancing the interoperability of social risk factor data.

AMA Response:

In general, CMS should only include tools that have been psychometrically tested, including sensitivity and specificity, against gold standard tools. The drivers and domains included in a measure, or any requirements should align with data standards such as the HL7 Gravity Project and USCDI. A high priority should be to establish 1) very clear definitions of the prioritized high-level domains, and 2) a screening tool that can readily differentiate whether a given high-level issue (e.g., food insecurity, housing insecurity, transportation insecurity, "utility insecurity") is absent or present. This will allow us to minimize time and resources directed towards those who do not have social needs and focus time and resources on those with social needs. The goal should be to identify 1) a minimum set of questions—to be used on the general population, and 2) a further specified set of questions to refine the exact need more clearly—to be used only for those who screen positive at the high-level.

D. Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health

Improving PA for Maternal Health

The AMA appreciates CMS' commitment to improving maternal health outcomes. Pregnancy and childbirth are complex processes that require careful monitoring and timely interventions to ensure health and safety. Each stage of pregnancy is critically important, and each intervention is time sensitive.[34] Delayed or denied access to necessary care can result in serious adverse outcomes, including pre-term birth, preeclampsia, hemorrhage, and maternal mortality.

Each year in the United States, about 700 women die during or soon after pregnancy, while 50,000 have serious short- or long-term health consequences.[35] Delays in care can contribute to equity issues by disproportionately impacting pregnant women who may face barriers to accessing timely care. For example, pregnant women who have limited financial resources or live in underserved areas may be at an increased risk of experiencing delays in care. Pregnant women who face barriers to accessing care may also be more likely to experience adverse outcomes such as preterm delivery, low birth weight, or maternal mortality. These outcomes are more common among historically minoritized groups and can be exacerbated by delays in care. For example, Black women are three times more likely to die from pregnancy-related complications than white women.[36] **Given our mutual goal to enact meaningful reforms that are health equity centered, taking an aggressive stance on PA reform to help improve maternal outcomes is paramount.** The time-sensitive nature of pregnancy means that any delay in obtaining necessary care can have devastating consequences for maternal health. As such, **the AMA supports the development of regulations that provide access to prenatal care for all women.**[37]

---

[34] National Library of Medicine, Mother to Baby| Fact Sheet. Last accessed March 2, 2023; https://www.ncbi.nlm.nih.gov/books/NBK582659/.

[35] CDC, Pregnancy Related Deaths. Last accessed March 6, 2023; https://www.cdc.gov/hearher/pregnancy-related-deaths/index.html#:~:text=Most%20pregnancy%2Drelated%20deaths%20are,there%20are%20considerable%20racial%20disparities.

[36] CDC, Working Together to Reduce Black Maternal Mortality. Published April 6, 2022; https://www.cdc.gov/healthequity/features/maternal-mortality/index.html.

[37] AMA Policy. Available at https://policysearch.ama-assn.org/policyfinder/detail/AMA%20Policy%20Access%20to%20Prenatal%20Care%20H-420.978?uri=%2FAMADoc%2FHOD.xml-0-3721.xml

PA Processing

Cases of hypertensive disorders in pregnancy are on the rise. They are the leading cause of maternal death and require urgent attention;[38] as such, they provide a clear example of how PA-related care delays can negatively impact maternal outcomes. For instance, preeclampsia, if left untreated, reduces blood flow to the placenta, which can lead to a range of serious health problems, including slow fetal growth, preterm birth, and even stillbirth. In severe cases, preeclampsia can lead to seizures, organ damage, and placental abruption, which can be life-threatening to the mother and baby. Women who develop preeclampsia during pregnancy are at an increased risk of developing cardiovascular disease later in life.[39] Therefore, PA during pregnancy should be removed since PA increases wait time before proper care can be provided, and timely intervention is essential to prevent and/or reduce unwanted maternal health outcomes from conditions such as hypertensive disorders.

The AMA's PA physician survey 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.[40] Moreover, there is mounting evidence that PA requirements impede access to maternal health care services. For instance, the suspension of PA from state Medicaid programs during COVID made maternal health services more accessible.[41] Therefore, as demonstrated by the Medicaid programs during COVID, reforming PA is necessary to provide quality medical care during pregnancy without delays that could result in adverse perinatal outcomes.[42]

Accordingly, in the context of utilization management, **we strongly urge CMS to treat services related to pregnancy care as urgent and mandate that the PA processing timeframe for a final determination for this care be 24 hours.[43]**

Continuity of Care

In line with the Medicare Advantage NPRM (87 Fed. Reg. 79452) put forth by CMS, we urge CMS to consider a continuity of care provision for PAs related to pregnancy. Continuity of patient care is vitally important for patients undergoing an active course of treatment when there is a formulary or treatment coverage change and/or a change of health plan. Too often, disruptions in care caused by repetitive PA requirements result in adverse outcomes for patients. **Therefore, we encourage CMS to adopt a continuity of care provision that would protect pregnant women from these harms by preventing disruptions in ongoing care, treatment delays, and unanticipated medical costs. Furthermore, we urge CMS to require any and all PA approvals to remain valid for the duration of the pregnancy, regardless of a plan change.**

---

[38] CDC, Hypertensive Disorders in Pregnancy and Mortality at Delivery Hospitalization — United States, 2017–2019, *Weekly* 71(17);585–591; (April 29, 2022) https://www.cdc.gov/mmwr/volumes/71/wr/mm7117a1.htm.

[39] ACOG, Preeclampsia and High Blood Pressure During Pregnancy. Last accessed March 3, 2023; https://www.acog.org/womens-health/faqs/preeclampsia-and-high-blood-pressure-during-pregnancy

[40] 2022 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[41] Urban Institute, Maternal Health Inequities during the COVID-19 Pandemic (May 2021). Available at: https://www.urban.org/sites/default/files/publication/104306/maternal-health-inequities-during-the-covid-19-pandemic.pdf.

[42] Jain et al., 2020. *Prior Authorization and its impact on access to obstetric ultrasound.* https://www.sciencedirect.com/science/article/pii/S0002937820300260?via%3Dihub#bib5.

[43] AMA Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

Moreover, payers should be required to share active and pending PA decisions and related clinical documentation and forms when a pregnant patient enrolls with a new impacted payer and requests exchange of these data. This ensures continuity of care for women living in underserved areas for whom frequent trips to and from their physician's office present logistical challenges. This is also in line with the Administration's goals of promoting health equity, as minoritized populations are at a disproportionate risk of negative maternal health outcomes.

Benefits

The AMA supports ensuring the full range of comprehensive benefits, including mental health services, throughout the pregnancy spectrum. This includes postpartum care for up to 12 months. The CDC reports higher rates of depression in women of color and lower rates of treatment.[44] Depression in pregnancy is associated with poor maternal outcomes including maternal death. Postpartum depression occurs in nearly 15 percent of births. In addition to affecting the mother's health, it can interfere with her ability to connect with and care for her baby and may cause the baby to have problems with sleeping, eating, and behavior as he or she grows.[45] **It is therefore critical to include postpartum care in all reforms related to maternal health PA policy.** Given that Medicaid and CHIP allow for coverage for 12 months after pregnancy,[46] **we urge CMS to require PA approvals for postpartum care to extend 12 months after pregnancy, regardless of a plan change.**

The AMA strongly supports preserving access to comprehensive evidence-based reproductive health care services and opposes any effort to undermine the basic medical principle that clinical assessments, such as viability of the pregnancy and safety of the pregnant person, are determinations to be made only by health care professionals with their patients. Considering the crisis to abortion access following the United States Supreme Court's decision in the *Dobbs v. Jackson Women's Health Organization* case, we strongly urge you to consider how PA can impede access to abortion services.

The AMA recognizes that health care, including reproductive health services like abortion, is a human right.[47] Ectopic pregnancies are the leading cause of maternal mortality in the first trimester, and miscarriages due to complications and ectopic pregnancies are not rare. Every day, physicians are making intense, time-sensitive decisions where delays threaten lives. New state laws restricting or banning abortion are making these situations dangerous, and potentially deadly, for patients. States that ban or severely restrict abortion will not end abortion; they will end safe abortion—risking devastating consequences and even jeopardizing patient lives. Timely access to abortion is more critical than ever. A lengthy PA delay could prevent a patient from accessing abortion services within the legally authorized window. As such, **the AMA recommends that CMS lift PA requirements for abortion care/medical management related to pregnancy termination.**

Perinatal care is time sensitive and time limited. By expediting the review timeline for pregnancy-related PAs to urgent (i.e., 24-hour processing); adding a continuity of care component for the duration of the

---

[44] CDC, Tends in Postpartum Depressive Symptoms - 27 States, 2004, 2008, 2012; *Weekly* 66(6);153-159 (February 17, 2017) https://www.cdc.gov/mmwr/volumes/66/wr/mm6606a1.htm?s_cid=mm6606a1_w.

[45] https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml.

[46] https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-more-half-all-states-have-expanded-access-12-months-medicaid.

[47] AMA Policy. Available at: https://policysearch.ama-assn.org/policyfinder/detail/Preserving%20Access%20to%20Reproductive%20Health%20Services%20D-5.999?uri=%2FAMADoc%2Fdirectives.xml-D-5.999.xml.

pregnancy and post-partum care, regardless of a plan change; and eliminating PA requirements for abortion and medical management related pregnancy termination, we will help improve maternal health outcomes and can reduce some of the existing disparities.

Advancing Interoperability for Maternal Health

Standardization is the first step in forming robust research datasets and is especially important for studies on maternal health. The AMA supports the collection of data related to maternal health. Yet, the current lack of data availability and standardization, limited research on data collection practices, and piecemeal implementation of sources and tools should be addressed. While progress has been made, there remain opportunities to improve the collection, linkage, and analysis of data collected at the point of care.

Data must also be of high quality to improve maternal health outcomes and support research on the effectiveness of maternal health care services and interventions. These data are necessary to develop strategies and evidence-based practices to prevent disease conditions that contribute to poor obstetric outcomes, maternal morbidity, and maternal mortality.

Maternal health and child health are inextricably linked, but relevant data are often held in separate, unconnected health records. Models are being developed to support data exchange for predictive analysis, risk assessment, and retrospective maternal health research. **CMS should work with data model developers, including HL7's Longitudinal Maternal & Infant Health Information for Research, to identify risk factors for maternal mortality and poor maternal and infant health outcomes.** Data standards must facilitate data linkages between individuals and their infants' health.

However, advancing this data exchange may require federal involvement beyond CMS' current efforts. **For example, federal policies should support the development and implementation of a maternal mortality surveillance system.** Such a system would accelerate research and help develop strategies toward evidence-based practices to prevent disease conditions that contribute to poor obstetric outcomes, maternal morbidity, and maternal mortality in racial and ethnic minorities.

Standards are also needed to support physician collection of patient-identified race and ethnicity information to better identify inequities. Better EHR data in clinical settings and standardized across health systems is essential for meaningful and unbiased research.

Data Standardization, Harmonization, and Gaps

It is essential that maternal mortality and maternal morbidity have a standard definition across all federal, state, local, and private organizations. This way, data that is collected at the local, state, federal, and even international level can be integrated, and a more complete picture of maternal health can be discovered. Currently there is not a set definition for maternal morbidity, severe maternal morbidity, or maternal mortality/death. See chart below for examples:

Organization	Maternal Morbidity Definition	Severe Maternal Morbidity (SMM) Definition	Maternal Mortality/Death Definition
U.S. Centers for Disease Control and Prevention (CDC) Pregnancy Mortality Surveillance System (PMSS)		The unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.[48]	The death of a woman while pregnant or within 1 year of the end of a pregnancy regardless of the outcome, duration, or site of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.[49]
CDC's National Center for Health Statistics' National Vital Statistics System (NVSS)		Serious complications of delivery that result in short- or long-term consequences to a patient's health.[50]	A death while pregnant or within 42 days of the end of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.[51]
National Institutes of Health (NIH)[52]	Any short- or long-term health problems that result from being pregnant and giving birth.	Life-threatening health problems that are present at delivery.	The death of a woman from complications of pregnancy or childbirth that occur during the pregnancy or within 6 weeks after the pregnancy ends.
World Health Organization	Any health condition attributed to or complicating pregnancy, childbirth or following pregnancy that has a negative impact on the woman's well-being or functioning.[53]	A maternal near miss – a woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy.[54]	The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from unintentional or incidental causes.[55]

[48] https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html.
[49] https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf.
[50] https://www.cdc.gov/nchs/data/nhsr/nhsr166.pdf.
[51] https://www.cdc.gov/nchs/maternal-mortality/evaluation.htm.
[52] https://www.nichd.nih.gov/health/topics/maternal-morbidity-mortality.
[53] https://www.who.int/publications/i/item/9789241508483.
[54] https://apps.who.int/iris/bitstream/handle/10665/270546/PMC2755324.pdf;sequence=1.
[55] https://www.who.int/publications/i/item/9789241516488.

Nebraska Department of Health and Human Services		Significant negative health consequences of labor and delivery. SMM includes unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.	A pregnancy-associated death is the death of a person within one year of the end of a pregnancy from any cause. Pregnancy-associated deaths represent the broadest category of maternal deaths and can be broken down further into two main categories: pregnancy-related deaths and deaths unrelated to pregnancy. A pregnancy-related death is a maternal death due to a pregnancy complication. More specifically, these deaths occur during pregnancy or within a year of the end of a pregnancy and are due to a chain of events initiated by the pregnancy or the aggravation of an unrelated condition by the physiologic effects of pregnancy.[56]
Minnesota Department of Health		"A near miss," like injuries or incidents related to pregnancy or childbirth that did not result in death.	A death during or within one year of pregnancy, from a pregnancy complication, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy.[57]
New Jersey Department of Health[58]		Unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.	Deaths from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes) during pregnancy and childbirth or within 365 days of termination of pregnancy, irrespective of the duration and site of the pregnancy.

Even within the CDC, different divisions have different definitions for maternal mortality/death as shown in the chart above. Without one standard definition, it is difficult for data from different sources to be compiled and universally applied. As such, it is very important that the federal government decide on the timeframe for maternal mortality/death since there are a number of different times used, including one year, 42 days, and six weeks post-delivery.

For example, NVSS defines a maternal death as a death while pregnant or within 42 days of the end of a pregnancy. NVSS gathers information to determine the national maternal mortality rate by using death records and the International Classification of Diseases (ICD-10) codes.[59] However, PMSS uses "a time frame that includes deaths during pregnancy through 1 year after the end of pregnancy; this timeline allows evaluation of all deaths which might be pregnancy related. In PMSS, deaths are reviewed by

[56] https://dhhs.ne.gov/Pages/Maternal-Mortality-Review-Committee-(MMRC).aspx.
[57] https://www.health.state.mn.us/docs/people/womeninfants/maternalmort/maternalmortreport.pdf.
[58] https://www.nj.gov/health/fhs/maternalchild/documents/New%20Jersey%20Maternal%20Mortality%20Report%202016-2018.pdf.
[59] https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm.

medical epidemiologists who perform an in-depth review of vital records and other data as available (e.g., medical records, autopsy reports) for each death to determine the pregnancy-related mortality ratio."[60] **This results in two CDC units that produce maternal mortality statistics using very different timeframes and data.**

Therefore, it would likely create stronger data if one definition was determined. The AMA believes that the postpartum period lasts for one year post delivery. Since PMSS and Maternal Mortality Review Committees (MMRC) include maternal deaths that occur one year post-delivery to ensure a complete picture of maternal mortality,[61] **the AMA believes that the definition of maternal mortality should include a timeframe of one year post-delivery.**

Moreover, as noted above in the chart, some entities do not have a definition, or do not have an easily identifiable definition, for maternal morbidity. As such, it is important to ensure that there is a set definition for this term since it is commonly used within the maternal health space and, if properly defined, could provide better early indicators for individuals that need additional maternal care.

However, the CDC has linked the definition and identification of SMM to a list of 21 indicators and corresponding ICD codes. These indicators are:[62]

1. Acute myocardial infraction
2. Aneurysm
3. Acute renal failure
4. Adult respiratory distress syndrome
5. Amniotic fluid embolism
6. Cardiac arrest/ventricular fibrillation
7. Conversion of cardiac rhythm
8. Disseminated intravascular coagulation
9. Eclampsia
10. Heart failure/arrest during surgery or procedure
11. Puerperal cerebrovascular disorders
12. Pulmonary edema/ Acute heart failure
13. Severe anesthesia complications
14. Sepsis
15. Shock
16. Sickle cell disease with crisis
17. Air and thrombotic embolism
18. Blood products transfusion
19. Hysterectomy
20. Temporary tracheostomy
21. Ventilation

Nevertheless, the current indicators need to be expanded since research has found that these indicators have not captured somewhere between 14 and 22 percent of new postpartum cases.[63] This lack of accuracy seems to be due to the fact that one in seven SMM events occur post hospitalization, and the current SMM definition does not cover post hospitalization events.[64] As such, it is important to ensure that CMS includes post hospitalization data and "near miss" events

[60] https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm.
[61] https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm.
[62] https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/severe-morbidity-ICD.htm.
[63] https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/severe-maternal-morbidity-united-states-primer.
[64] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2775739.

in its definition of SMM, and connects these events to indicators, so that there is increased standardization and decreased gaps in this maternal health data.[65]

However, linking the definition of SMM to indicators and ICD codes "has the advantage of being easily applied to hospital discharge data either locally or in national datasets."[66] As such, despite the need to expand the indicators associated with SMM, **the AMA believes that defining maternal health events to include indicators linked to ICD codes is a positive step and something that should be expanded into the definitions for maternal morbidity and maternal mortality.**

ICD codes currently include numerous codes that indicate a death or morbidity due to pregnancy.[67] However, there is not a universally used set of indicators linked to these ICD codes to help with the identification, classification, and data collection surrounding maternal mortality and morbidity in the same way that there is for SMM. As such, the federal government, including CMS, should work to create a set of detailed underlying cause categories that are mutually exclusive and identify all conditions that are epidemiologically or clinically important in maternal mortality and morbidity and link those categories to ICD codes. In the case of maternal mortality, this increased standardization, based on indicators, will likely be extremely beneficial because it will help to increase the accuracy with which death certificates are filled out and thus increase data collection precision.

To strengthen the collection of maternal mortality and maternal morbidity data even further, CMS could consider adding maternal morbidity, SMM, and maternal mortality information into the USCDI. Especially as the "Birthing Friendly" hospital designation is considered, this data could be very valuable. As such, as CMS works to consider how maternal health data can be better harmonized, they should work to ensure that there is one standard definition for the terms within maternal health and that those definitions are linked to indicators and ICD codes.

Data Standardization and the United States Core Data for Interoperability (USCDI)

The AMA views the USCDI as an important component to drive improvements in maternal health, particularly in the establishment of data standardization across certified health IT systems. As CMS considers policies to leverage the USCDI, **we urge CMS to set a goal of standardizing data capture for comparative analysis over time to improve health outcomes.** In order to achieve this, close coordination with medical experts and specialists will be necessary. For instance, organizations such as the American College of Obstetricians and Gynecologists have issued clinical guidance and a data process strategy to combat maternal mortality and morbidity, which should be considered and utilized.[68] Moreover, the AMA is working with several medical professional organizations to develop principles for the collection of race and ethnicity information in clinical and administrative data. As a guide to support the optimal use of the USCDI, and to achieve our shared goal of improving maternal health outcomes, the AMA recommends data collection standards be:

- informed by research, including real-world testing of technical standards and standardized definitions of race and ethnicity terms to ensure that the data collected accurately reflect diverse

[65] https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/severe-maternal-morbidity-united-states-primer.
[66] https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/severe-maternal-morbidity-united-states-primer.
[67] https://www.medicaid.gov/medicaid/data-and-systems/downloads/macbis/mih_reference_codes.xlsx.
[68] https://www.acog.org/advocacy/policy-priorities/maternal-mortality-prevention.

populations and highlight, rather than obscure, critical distinctions that may exist within broad racial or ethnic categories:

- carefully crafted in conjunction with clinician and patient input to protect patient privacy and provide non-discrimination protections; and
- lead to the dissemination of best practices to guide respectful and non-coercive collection of accurate, standardized data relevant to maternal health outcomes.[69]

Data governance and privacy

As more data are collected, data protection and security must also be considered. Prior to initiating a data collection effort or expanding the type of data collected, **CMS must first evaluate if the necessary technical, governance, and legal protections are in place to maintain an individual's privacy and trust.** Without guardrails in place, the misuse of data could further disparities and decrease individuals' confidence in government data collection efforts. Individuals are increasingly aware that companies gather and use their personal information, including information relating to maternal health services. For example, women who use digital health tools to track their menstrual cycles have started deleting these apps, concerned that their information is not private and secure.[70] As a result of this perceived lack of data privacy, women and other individuals who no longer believe their information is secure may hesitate to engage with the broader health care system.

An effective data governance infrastructure is needed to ensure maternal health data are consistent, trustworthy, and not misused. From the outset, data governance should address the questions "why are we collecting this data" and "what else will it be used for." If these critical questions are not addressed, and as individuals become more aware of the fact that entities can track and share their activity, they will be less likely to share information, even with their physicians. In efforts to promote maternal health care, **CMS must consider what steps it can take to reassure individuals that their personal information, including maternal and infant health information, remains private and secure.**

Moreover, research shows that individuals are most comfortable with physicians and hospitals having their data but are least comfortable with their data leaking outside the provider space.[71] **Trust is a fundamental aspect of the patient-physician relationship.** Even well-informed and knowledgeable patients rely on their physicians to keep personal information confidential and act in their best interests.[72] In a recent survey of 1000 patients, nearly 75 percent said they are concerned about protecting the privacy of their health data. Six in 10 patients are worried about health data being used by companies to discriminate against them or their loved ones or to exclude them from opportunities to find housing, gain employment and receive benefits. The survey also identified that over 50 percent of patients are "very" or "extremely" concerned that unnecessary access to their data could result in negative repercussions related to insurance coverage, employment, or opportunities for health care.[73]

CMS' efforts to increase maternity health information exchange should ensure patient data are protected, safe, and secure. The NPRM states at several points that any data published or referenced in

[69] https://policysearch.ama-assn.org/policyfinder/detail/informed%20by%20research,%20including%20real-world%20testing%20of%20technical%20standards%20and%20standardized%20definitions?uri=%2FAMADoc%2FHOD.xml-H-185.917.xml.
[70] https://www.nytimes.com/2022/07/13/technology/personaltech/abortion-privacy-roe-surveillance.html.
[71] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.
[72] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500897/pdf/jgi_204.pdf.
[73] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.

connection with these proposals will be aggregated and deidentified.[74] The AMA strongly supports stringent protection of all data pertaining to any individual which CMS collects, or that will be collected at the direction of the Agency in connection with the proposed rule. Maintaining the privacy of individuals' health information, particularly those in a vulnerable demographic such as pregnant people, parents, and their children, is of critical importance in advancing the equitable objectives of CMS and maintaining trust in the health care delivery system.

Patients recognize the value of information exchanged among their providers but also worry about the consequences of their information being misused by businesses or other entities, including payers. **Data privacy and data information exchange are not mutually exclusive. CMS' data collection efforts must be grounded by patient data protection and policies must guard against data misuse. Therefore, we urge CMS to encourage both data privacy and data information exchange with equal emphasis.**

[74] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program, 87 Fed. Reg. 76238, at 76249 (last paragraph) and 76369 (first paragraph) (proposed December 13, 2022).