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Submitted electronically via regulations.gov

March 10, 2023

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P7
500 Security Boulevard
Baltimore, MD 21244-1850

RE: Advancing Interoperability and Improving Prior Authorization Processes [CMS-0057-P]

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking entitled "Medicare and Medicaid Programs; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, etc.," 87 *Fed. Reg.* 76238 (December 13, 2022).

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers. Learn more at aamc.org.

The AAMC applauds CMS for its efforts to advance interoperability, support the access, exchange, and use of electronic health information to improve patient care and reduce burden. We support improvements to make the prior authorization process more streamlined across all payers. **Specifically, the AAMC supports initiatives that standardize data and processes around ordering services and related prior authorization, and that automate ordering and prior authorization processes through adoption of standardized templates and data elements.** We have previously commented on the burden of the prior authorization process and

the need for improvements to promote safe, timely and affordable access to care for patients through reducing administrative burden. We also previously commented to CMS that efforts to address prior authorization processes must include Medicare Advantage (MA) plans[1] and have supported legislative efforts to reform prior authorization.[2] The AAMC is pleased that CMS listened to stakeholder feedback and incorporating MA organizations into these proposals.

We commend CMS for the efforts in this rule to address burdensome prior authorization processes. Providers strive to deliver quality health care in an efficient manner. However, the frequent phone calls, faxes, electronic health record (EHR) connectivity with payer systems, and different forms that physicians and their staff must complete to obtain prior authorizations hinder efficient care. Rules and criteria for prior authorization must be transparent and available to the physician at the point of care. In addition, if a service or medication is denied, both the patient and the physician should be given a specific reason for the denial, information about rights to appeal the decision, and other alternatives that may be covered (e.g., different medications). **Medically necessary care should not be denied because a physician and/or patient cannot jump through complicated opaque hoops.**

However, automation alone is not sufficient to solve all prior authorization-related issues. We thank CMS for proposing public reporting from regulated payers on their use of various technological tools, primarily application programming interfaces (APIs), to support automated and improved prior authorization processing and interoperability. We believe this is a step to better understand decision making by payers that limits patient access to care and worsens health outcomes. With that data, CMS should use future rulemaking to continue to address prior authorization-related issues and hold payers accountable for decisions that fail to allow care that physicians judge to be necessary and appropriate.

Finally, the AAMC shares CMS's commitment to ensuring that patients and clinicians have increased ability to access electronic health information to make informed health decisions through appropriate, secure, and seamless exchange of electronic health information. This includes the use of various technological tools to improve patient and provider access to information held by payers and greater exchange of information on health-related social needs to reduce inequities and improve the health of all. The focus of efforts to improve interoperability should be on what is needed for high quality clinical management of patients receiving care from providers as they move through the health care system and their communities.

Comments to specific proposals follow.

[1] AAMC Comments to CMS Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information (Jan. 2021).
[2] AAMC Washington Highlights, AAMC-Supported Prior Authorization Reform Bill Passes House (Sep. 2022).

IMPROVING PRIOR AUTHORIZATION PROCESSES

CMS Should Require Payers to Implement an Application Programming Interface (API) for Prior Authorization Requirements, Documentation, and Decision (PARDD) that Includes Prescription Drugs

CMS proposes to require regulated payers to implement and maintain a Fast Healthcare Interoperability Resources (FHIR) PARDD API to support and streamline the prior authorization process beginning January 1, 2026. The PARDD API would allow providers to query the payer's system to see if prior authorization is required and the necessary documentation, and it would automate compilation of data required to populate the HIPAA-compliant prior authorization transaction and allow payers to provide the status of the request, including whether it has been approved or denied. (p. 76289) **The AAMC supports streamlining the prior authorization process** as we have outlined in our recent comment letter.[3]

We strongly believe that prescription drug information should also be included in the PARDD API. Insurers limit the use of certain prescription drugs by requiring prior authorization and step therapy (e.g., trial and failure). **Excluding prescription drug information from the PARDD API omits an important component of care, and a large segment of prior authorizations that providers and patients experience.** Moreover, excluding prior authorization requirements for prescription drugs may confuse patients who may not understand why there is a separate process for prescription drugs.

Prior authorization and step therapy requirements are routinely used by insurers to steer patients to less expensive medications.[4] Research on the use of step therapy protocols among some of the largest U.S. commercial health plans showed that plans applied step therapy in 38.9 percent of drug coverage policies.[5] Without including prescription drugs in the PARDD API, CMS will not be able to capture the extent to which these requirements harm patients and increase the administrative burden on providers. Prior authorization denials delay needed care or force patients to forego care or disrupt adherence to prescription drug regimens. For example, low-income Medicare beneficiaries may not fill a prescription due to formulary restrictions such as prior authorization and step therapy imposed by a Medicare Part D plan.[6]

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[3] AAMC Comments to CMS on CY2024 Policy and Technical Changes to the Medicare Advantage Program, (Feb. 13, 2023).
[4] *See*, for example, SP Pourali, et al., Out-of-pocket costs of specialty medications for psoriasis and psoriatic arthritis treatment in the Medicare population, JAMA Dermatol, 157:1239-1241 (2021), finding that 90 percent of Part D plans required prior authorization for the use of biologics in the management of psoriasis and psoriatic arthritis.
[5] KL Lenahan et al., Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans, Health Affairs, Vol. 40, No. 11 (Nov. 2021).
[6] SB Dusetzina et al., Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions, Health Affairs, Vol. 41, No. 4 (Apr. 2022).

Payers Must Improve Information Provided Regarding the Status of Prior Authorization Requests and Reason for Denial of Such Requests

CMS proposes that impacted payers must provide a specific reason for denied prior authorization decisions regardless of method used to send the prior authorization request. Responses about a prior authorization request decision sent through the PARDD API from payer to provider must include information regarding whether the payer approves (and for how long) or denies the prior authorization request, or requests more information from the provider to support the request. For Medicaid managed care plans and CHIP managed care entities, CMS proposes that responses to providers transmitted via the PARDD API would satisfy notice requirements under 42 CFR § 438.210(c). CMS proposes to apply the same policies regarding prior authorization processes that it applies for Medicare Advantage (MA) plans and Medicaid managed care plans to applicable integrated Eligible Special Needs Plans. These proposals would not change the content requirements for written denial notices to patients (plan enrollees). **The AAMC supports these proposals to help streamline notice to providers and to improve information available to providers regarding prior authorization decisions.**

Decision Timeframes and Communications

CMS proposes to require that Medicare Advantage organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities provide notice of prior authorization decisions as expeditiously as a patient's health condition requires. Under no circumstances would this be later than 72 hours after receiving a request for "expedited" decisions, and no later than 7 calendar days after receiving a request for "standard" decisions. (p. 76296) CMS does not propose to include these timeline requirements to qualified health plans on the federally facilitated exchanges due to existing standards regarding internal claims and appeals at 45 CFR § 147.136(b)(3). (p. 76297)

The AAMC believes coverage decision timeliness is critical for patient care, and that in the case of decisions that could jeopardize a patient's timely access to necessary medical care, decisions must be made more quickly than within 72 hours of receipt of the request in a critical care situation. **We urge CMS to consider more timely requirements for impacted payers: 24 hours of receipt of a request for urgent items or services and 48 hours for non-urgent care decisions. Additionally, we urge CMS to restrict the use of prior authorization in instances when a patient seeks treatment for substance use disorder (SUD).** Prior authorization requirements impose a unique barrier for individuals seeking SUD treatment by delaying the initiation of care at the critical moment when an individual has potentially taken the first step to accept treatment. Delays due to prior authorization place patients at risk of continued substance use, medical complications, overdose, and death. Finally, we recommend that CMS make necessary changes to the regulations for QHPs on FFEs to create a more uniform timeliness standard for payers in all CMS regulated programs.

Utilization Management Tools Add to Clinician Burden and Burnout

The American Medical Association surveyed more than 1,000 practicing physicians regarding their experience with prior authorization; 88 percent reported that prior authorization interferes

with continuity of care.[7] More than 80 percent reported that in the last five years they have seen an increase in the number of prior authorizations for medical services and prescription drugs, with almost 20 percent of prescription drugs requiring prior authorization.

Further, clinicians increasingly cite the use of electronic health records as a cause of burnout. To meet billing rules the medical record has become bloated, thereby impeding physicians' ability to easily access the information they need to deliver high quality care. Adding to this burden is the requirement for clinicians to navigate coverage requirements for an array of insurance plans and a lack of standardized transmissions for this information, including the submission of prior authorization requests. **We support CMS' proposals to minimize burden on providers.** Also, the Agency should evaluate the process and clinical workflow factors contributing to the burden associated with utilization management tools to investigate ways to reduce their onerous effects. CMS should evaluate the expanded use of prior authorization across all programs to better understand the impact of prior authorization requirements on patients' timely access to medically necessary care and prescription drugs.

Finally, the AAMC is concerned that its members who provide specialized and sub-specialized care will be unreasonably subjected to prior authorization requirements. Tertiary and quaternary institutions and their associated providers who provide specialized care tailored to patients who will benefit from such care, and which can be more costly, may be unjustly targeted for increased prior authorization requests. We ask CMS to ensure that providers that furnish this specialized care are not subject to a disproportionate burden of prior authorization requests.

Public Reporting of Prior Authorization Metrics Increases Transparency of the Breadth of Utilization Management Tools Across Impacted Payers

CMS proposes to require impacted payers to publicly report aggregated prior authorization metrics on the payer's website or via a publicly accessible hyperlink. (p. 76304) CMS proposes that this reporting be at the organizational level for MA organizations, at the state level for Medicaid and CHIP FFS programs, the plan level for Medicaid and CHIP managed care, and at the issuer level for QHP issuers on the federally facilitated exchanges. Impacted payers would be required to publicly report all of the following metrics at least annually: (1) list of items and services that require prior authorization; (2) percentage of standard prior authorization requests that were approved, aggregated for all items and services; (3) percentage of standard prior authorization requests that were denied; (4) percentage of prior authorization requests that were approved after appeal; (5) percentage of prior authorization requests for which the timeframe for review was extended and the request was approved; (6) percentage of expedited prior authorization requests that were approved; (7) percentage of expedited prior authorization requests that were denied; and (8) average and median elapsed time between the submission of a request and a determination by the payer for standard prior authorizations.

The AAMC supports transparency on payers' use of prior authorization. We urge CMS to require MA organizations to submit data on the contract level to better understand how different plans employ prior authorization requirements. As CMS notes, MA organizations generally have multiple plans within the same service area, and those plans may not require prior authorization

[7] American Medical Association (AMA), 2021 AMA prior authorization (PA) physician survey (2022).

on that same items and services. This contrasts with Medicaid and CHIP managed care plans, where CMS states that reporting on the plan level is proposed so that "beneficiaries could compare and states could evaluate plans within the state." (p. 76304) Increasing transparency about the use of prior authorization will enable patients to make an informed decision about their care, but only if the information available allows them to do so.

Request for Comment on "Gold-Carding" Programs for Prior Authorization

The proposed rule notes that some payers relax or reduce prior authorization requirements for some providers who have demonstrated a consistent pattern of compliance, often referred to as "gold-carding." CMS believes that the use of gold-carding programs could help alleviate the burden associated with prior authorization. (p. 76307). The AAMC supports ways to decrease the burden of prior authorization requests on providers. If evidence indicates that gold-carding programs reduce burden, we support expansion and encourage CMS to require regulated payers to develop programs.

However, it is unclear which contracted providers typically receive the gold-carding designation. If gold-carding is primarily used for routine and widely accepted treatments and procedures, then it likely excludes specialized and sub-specialized care that often is tailored specifically to the patient and can be more costly. In other words, institutions that provide tertiary and quaternary care and their associated providers care will continue to be unreasonably subjected to prior authorization requirements. We ask CMS to further explore what type of procedures and treatments are typically included in gold-carding programs and share its findings publicly. If it is determined that specialty and sub-specialty care continue to be subjected to a preponderance of prior authorization requests, then plans should be required to expand the gold-carding to include other types of care, including specialized care. The AAMC is willing to assist in developing gold-carding standards for physicians who provide specialized services.

ELECTRONIC PRIOR AUTHORIZATION FOR THE MIPS PROMOTING INTEROPERABILITY CATEGORY AND THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM

CMS proposes a new measure related to electronic prior authorization for MIPS eligible clinicians under the Promoting Interoperability (PI) performance category of MIPS, and for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program (PIP) beginning with the CY 2026 performance period for clinicians and CY 2026 electronic health record (EHR) reporting period for hospitals. (p.76312) The measure, entitled the Electronic Prior Authorization, is designed to address concerns over low provider utilization of APIs established by payers for electronic prior authorization.

The Electronic Prior Authorization measure, as proposed, would require the healthcare provider to use data from their certified electronic health record technology (CEHRT), such as patient demographics and medical information, to justify the prior authorization request via the PARDD API. The PARDD API would automate compilation of necessary data to populate the HIPAA-compliant prior authorization request. The measure would require reporting a numerator and denominator. The denominator is the number of unique prior authorizations requested for medical items and services ordered by the MIPS eligible clinician and the numerator is the

number of prior authorizations that are requested electronically from a PARDD API using data from CEHRT. The denominator would include requests made using fax, mail, or portal to a payer that offers an API that meets the PARDD API requirements, even if that payer specifically requires a mailed or faxed request, but would exclude requests made to a payer that does not offer an API. Prior authorizations for prescription drugs would be excluded from both the numerator and the denominator. If a MIPS eligible clinician, eligible hospital, or CAH fails to report the measure or claim an exclusion with respect to a performance period or reporting period, they would not satisfy the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program reporting requirements, respectively, for that performance or reporting period.

While we share CMS's goal to improve interoperability and care coordination, we do not support this approach. **The AAMC recommends that CMS use an attestation-based approach (yes/no method) rather than requiring numerator/denominator measurement for reporting this measure.** It would be overly burdensome for providers to track and report the prior authorization requests made using fax, mail, or portal to a payer for inclusion in the denominator. EHRs do not have the capability to track the manual prior authorizations so staff would need to gather this information on prior authorizations and put it into a report. While we support interoperability, we believe that this measure is not necessary to incentivize providers to use electronic prior authorization. Providers will want to use the PARDD API if it delivers on the benefits of improving patient care and reducing burden. **We recognize it would be helpful to CMS to identify how many prior authorizations are submitted manually verses electronically; however, we recommend that the payers provide that information to CMS instead of providers.**

PATIENT ACCESS API

The expansion of prior authorization requirements by insurers has led to delays in care and in some cases caused beneficiaries to forego medically necessary care or prescription drugs. We support providing patients with access to information on the prior authorization process, including denials. We strongly believe, however, that prescription drug information should be included in the Patients Access API. Excluding prescription drug information from the Patients Access API omits an important component of patients' care.

Further, patients are not the only ones to suffer from onerous prior authorization requirements. The administrative burden of prior authorization contributes to physician burnout. We support ways to decrease burden on both the provider and patient and ensure that patients receive medically necessary care. Educating and informing patients about the prior authorization process is a positive step to decrease the burden of prior authorization for all involved. **We support proposals that seek to empower patients with information about their care and the prior authorization process using the Patient Access API.**

Prescription Drug Claims and Prior Authorization Information Must Be Included in the Patient Access API

The proposed rule outlines the claims and prior authorization information that will be available to patients via the Patient Access API. Equipping patients with information about how the prior authorization process works, and ultimately the decision that is made, is valuable. **However, not including prescription drugs information in the Patients Access API leaves out a large segment of patient care**.

Provide Patients' Access to Prior Authorization Requests That Have Expired

The proposed rule states that patients would have access to information about prior authorization via the Patient Access API for as long as the authorization is active and at least 1 year after the last status change. It goes on to say that requiring payers to share a patient's full prior authorization history could be a significant amount of information that may no longer be clinically relevant. (p. 76245). We agree that the amount of information could be "significant" given the extensive use of prior authorization and the vast amount of information that providers are required to submit with each prior authorization. But removing this information after the expiration of the prior authorization or 1 year after status change dismisses the importance of this historical documentation. Insurers have been known to change their prior authorization requirements and formularies mid-year. That means that any history of "try and fail" for either medical interventions or prescription drugs is "lost" to the patient under this proposal. This benefits neither the patient nor provider. Further, patients that change insurers year to year could be required to submit the same prior authorization information to the new insurer.

The AAMC urges CMS to reconsider the timeframe during which prior authorization information is available. Additionally, CMS should allow patients to download the prior authorization history so they can share this information with a new payer and other providers to potentially utilize the same information in other circumstances. In particular, this would be valuable to patients who have "tried and failed" treatments and medications in the past by being able to show future providers and insurers this information and hopefully not have to undertake additional step therapy for medication or treatments. This would also align with CMS' goal to enable patients to participate more in their care, reduce burden and add an additional layer of accountability for payers to make timely prior authorization decisions to mitigate delays in care. (p. 76245).

Apply the Patient Access API Requirements to Medicare Fee-For-Service

CMS asks whether it should apply the same Patient Access API requirements to the existing prior authorization requirements and standards within the Medicare fee-for-service (FFS) program. (p. 76245). In the Calendar Year 2020 Outpatient Prospective Payment System (OPPS) final rule, [8] CMS finalized its proposal to implement prior authorization requirements for certain outpatient items and services in Medicare FFS. CMS has since expanded the OPPS prior

[8] Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; etc., 84 Fed. Reg. 61446 (Nov. 11, 2019).

authorization requirements to additional items and services. **The AAMC supports applying the proposals to the Medicare FFS claims information and prior authorizations to align requirements across different programs and for all patients to benefit from greater access to information about their health care claims and services.**

PROVIDER ACCESS API

CMS proposes to require regulated payers to implement and maintain a Provider Access API to enable exchange of information of current patients from payers to providers at the provider's request. CMS believes this would be valuable for providers to have more timely data available at the point of care and reduce burden on patients to recall information regarding prior care received. (p. 76255) Information exchange via the Provider Access API would be subject to the same HIPAA Privacy Rule as disclosures for treatment purposes, as well as disclosures required by law. **The AAMC supports this approach to improving interoperability of important health care, with two suggested changes**.

Require Payers to Implement a Provider Access API for Current Patient Information Based on Treatment Relationship, Not Network Limits

Unlike the now rescinded 2020 proposed rule, CMS proposes to limit this requirement for payers to sharing information only with providers that are in the health plan's network who request information. CMS recognizes "this could make it more difficult for an out-of-network provider to create a comprehensive care record for a patient," but that there "could be" privacy, security, and program integrity concerns with sharing information with out-of-network providers." (p. 76256) Instead, CMS states its encouragement for "payers to share information via API with out-of-network or unenrolled providers who have a verified treatment relationship with the patient, to the extent permitted by law." (p. 76256)

CMS should require provider access and information sharing based on active treatment relationships. The AAMC is concerned that limiting the requirement to sharing information via API only with in-network providers frustrates the value of the Provider Access API. Teaching hospitals and their associated physicians and other providers play a unique role in providing health care to their communities and are sometimes excluded from insurer networks because their rates may be higher than non-teaching hospitals due to the complexity of their patients and the highly specialized services. Our members deliver highly specialized care, including subspecialty care, that is often unavailable at other institutions. In many communities, these services, such as trauma centers, burn units, and neonatal services, are only available at teaching hospitals. In addition, academic medical centers have highly trained subspecialty physicians – such as subspecialists in pediatric and oncology medicine – on their staff who are called upon for care by the wider health care community. Further, the patients cared for by these providers may be medically complex and often cannot access needed care elsewhere. For example, it is possible that a patient will seek care at a teaching hospital and will be treated by teaching physicians, both of which may have been excluded from the network. It is as important that out-of-network providers from which patients receive care can receive information via the Provider Access API as seamlessly as in-network providers. **Patients seeking care outside of their plan's network**

of providers should not have to shoulder greater responsibility for sharing information regarding their care than those patients within network.

Payers Should Include Beneficiary Cost Sharing Information with Current Providers

CMS proposes to limit the information shared with providers to claims and encounter information, without provider remittances and enrollee cost-sharing, as a complement to clinical data shared to support treatment and care coordination. **The AAMC asks CMS to include patient cost sharing information, as that information is critical to addressing conversations about affordability concerns that impact shared decision making and treatment adherence.** One study has found that including cost in care conversations can reduce patient uncertainty and increase patient knowledge and involvement.[9] Without insight into patient cost sharing, providers are blind to the actual cost limitations patients face.

PAYER-TO-PAYER DATA EXCHANGE

CMS proposes requirements on impacted payers to implement and maintain a payer-to-payer data exchange using a FHIR API (p. 76269) with a patient opt-in policy (p. 76271) and a January 2026 compliance deadline. The proposed data requirements for this Payer-to-Payer API are consistent with those for the Patient Access and Provider Access API proposals. (p. 76270) CMS notes that research shows that more complete patient records improve coordinated care and support informed decision making. (p. 76268) **In general, the AAMC supports this additional approach to improving interoperability and data exchange to support patient care**.

CMS Should Consider Future Rulemaking to Improve Continuity of Care for Patients by Honoring Prior Authorizations from Previous Payers

CMS does not propose to require payers to review, consider, or honor active prior authorization decisions by a patient's former payer. Instead, CMS states that under the proposed Payer-to-Payer API, payers would have access to prior authorization information as part of the patient's longitudinal record received from the prior payer. (p. 76270) The new payer could then consult this information to make its own decision under a new request under its own rules and potentially reduce burden on patients and providers over time. CMS seeks comment for potential future rulemaking to adopt policies to require impacted payers to honor prior authorizations from a prior payer. (p. 76271) **The AAMC strongly supports future policymaking to improve continuity of care for patients by honoring prior authorizations from a previous payer.** Rather than approach policymaking on a condition-specific model for honoring prior authorizations by a previous payer, we urge CMS to consider a timeframe approach. For instance, CMS could set a requirement that the new payer honor all prior authorizations from a previous payer that involve ongoing care and that have been reviewed by the previous payer in the prior 12 months to the transition of coverage to the new payer. Policy should ensure continuity of patient care for patients under active treatment to ensure a patient's condition

[9] NR Espinoza Suarez, MD et al, Impact of Cost Conversation on Decision-Making Outcomes, Mayo Clin Proc Innov Qual Outcomes, 5(4): 802-810 (Aug. 2021).

remains stable and not force a patient a to "re-set" their care due to a change in payer or health plan.

REQUESTS FOR INFORMATION

Accelerating the Adoption of Standards Related to Social Risk Factor Data

Best Practices Regarding Frequency of Collection of Social Risk and Social Needs Data

Evidence is still emerging on determining the best practices for the frequency of social needs screening. This is understandable as we begin to best understand the data collected and balance the benefit and burden of frequent screening on patients and providers alike. Research of quarterly screening of MA plan beneficiaries attempted to better understand fluctuations of self-reported social needs from quarter-to-quarter and found prevalence of social needs consistent over time and similar to previous assessments, but that marked fluctuations were observed at the individual level.[10] Similarly, the Social Interventions Research and Evaluation Network (SIREN) reported on the state of science in screening in healthcare settings and found some evidence of frequency trends but not such to establish a best practice.[11] Alternatively, the Health Information Technology, Evaluation, and Quality Center has a helpful guide of strategies based on questions a health care provider or organization can ask itself to inform the development of a workflow.[12] At this stage, we believe more evidence should be collected with the goal of establishing best practices regarding the frequency of screening patients. CMS policies to encourage collection of social risk and social needs data should remain flexible to support provider-led approaches to screening.

Best Practices Regarding Workforce Training on Collection of Social Risk and Social Needs Data

Similar to the best practices regarding frequency of screening, evidence is still emerging regarding best practices for workforce training on the collection of social risk and social needs data. The SIREN report on the screening in healthcare found that "health professional education and training about screening and referral programs improved physician trainees' comfort, confidence and behaviors related to social screening."[13] However, studies evaluated in the report identified four categories of important implementation concerns among providers: (1) insufficient time and workflow disruption, (2) provider discomfort with screening (often linked to a lack of training), (3) patient discomfort/negative impacts on provider-patient relationship, and (4) insufficient knowledge or resources to adequately address identified needs.[14] Interestingly, 25 studies examined the impacts of provider-focused education on providers'

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[10] N. Haff et. al., Frequency of Quarterly Self-reported Health-Related Social Needs Among Older Adults, 2020, JAMA Open Network (Jun. 2022).
[11] EH De Marchis et. al., State of the Science of Screenings in Healthcare Settings, Social Interventions Research & Evaluation Network (2022), using the "Adoption" category to identify research available on assess uptake of screening and frequency with which health care team members conducted screening.
[12] HITEQ, Strategies for Determining the Frequency of Social Need Screening (Apr. 2022).
[13] SIREN, *supra* note 11, at p. 31.
[14] *Ibid*, at p. 32.

perceptions of screenings, and indicated "that many, though not all, provider concerns appear to decrease following program exposure" though the concern with inability to address patient needs persisted post-program exposure. [15] This important research can help inform barriers to screening and training interventions to address those barriers. We recommend that CMS continue to seek information on workforce training efforts to inform the future development of best practices for training.

Challenges in Representing and Exchanging Social Risk and Social Needs Data from Commonly Used Screening Tools

A recent paper from the American Health Information Management Association (AHIMA) and the NORC at the University of Chicago found that most survey respondents who collect social risk and social needs data primarily capture data from common screening tools electronically via an electronic health record (EHR).[16] This represents a positive step towards the ability to electronically represent and exchange the data captured from screening instruments. The AAMC has previously commented[17] regarding efforts to expand the existing Z-codes as a potential mechanism to represent and exchange social risk and social needs data from screening tools used by health care providers. One benefit of the use of Z-codes to exchange social risk and social needs data is that they are easily incorporated into health care claims submissions, thus creating administrative data from information represented in the EHR that are commonly exchanged between providers and payers to inform payment and quality measurement.

The National Committee for Quality Assurance, the Joint Commission, and the National Quality Forum (NQF) recently jointly called for the Office of the National Coordinator for Health IT to recommend FHIR US Core 6.0.0 for inclusion in the Standards Version Advancement Process and future inclusion in the US Core Data for Interoperability (USCDI) specifically because it includes the US Core Observation Screening Assessment Profile.[18] They argue that one benefit of the Screening Assessment Profile is that it balances flexibility of screening tool with specificity of standardized findings from a given valid and reliable screening instrument. In In previously submitted comments to CMS, the AAMC recommended that CMS not mandate a given screening tool at this time, to ensure that health care providers are able to select a validated instrument that accurately identifies the social needs of individuals in the contexts of the communities the provider serves.[19] With this in mind, we see value in exploring the potential of the FHIR US Core 6.0.0 through accelerated testing to begin to better support the exchange of data collected from commonly used screening tools as a complimentary pathway to the use of ICD-10-CM Z-codes.

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[15] *Ibid*, at p. 33.
[16] AHIMA and NORC, Social Determinants of Health Data: Survey Results on the Collection, Integration, and Use (Feb. 2023).
[17] AAMC Comments on Proposal to Expand ICD-10-CM Codes for Social Determinants of Health (May 2019).
[18] NQF, Joint Statement on Digital Health Exchange of Social Determinants of Health Assessments (Feb. 2023).
[19] AAMC Comments to CMS on Medicare Inpatient Prospective Payment System Fiscal Year 2022 Proposed Rule, page 33 (Jun. 2021).

Barriers to Exchanging Social Risk and Social Needs Data Across Providers

The AHIMA NORC paper identified a key barrier to exchanging social risk and social needs data across providers, both health care providers who are likely to identify health-related social needs through screening at the point-of-care and community-based organizations (CBOs) that are most likely to have the expertise and resources to address the identified needs.[20] We believe that other CMS initiatives to improve interoperability and data exchange across health care providers via interoperable EHR use can address the first exchange barrier. The second barrier, between health care providers and CBOs, is in part due to the lack of technical resources for interoperable platforms to appropriately exchange social risk and social needs data outside of the EHR, as CBOs are unlikely to adopt EHR platforms for their work. We agree with the recommendation that the federal government should provide funding, technical resources, reasonable privacy regulations or guidance, and infrastructure to support coordination and connectivity at the state and local level between health care providers and CBOs and social services providers.

A non-technical barrier to exchange of social risk and social needs data is trustworthiness. Last year, the AAMC Center for Health Justice conducted polling to explore the connections between the public's trust in institutions and willingness to share personal health information.[21] A critical finding of that polling was that, at a baseline, many adults are not aware of the opportunities that can come from sharing information about themselves and whether it can have a positive impact on their personal health or the health of others. This means that work must be done with communities to develop ways to best engage in local conversations about the benefits and risks of data collection, the most valuable and useful kinds of data to collect, meaningful informed consent, and identifying ideal partners. This requires a commitment to trustworthiness and to transparent communication around data collection that centers on the communities providing their information.

How Payers Can Promote Exchange of Social Risk and Social Needs Data

ICD-10 Z-codes have great potential for improving the collection and exchange of social risk and social needs data, as they are currently available for inclusion on claims and are well understood in the context of diagnosis coding. That said, there are practical hurdles to their utilization. One, many providers simply do not know about them, and those that do have expressed confusion as to who on the care team is able to document them. Two, at this point in time, Z-codes do not influence reimbursement rates and are not incorporated into the risk adjustment models despite growing evidence of their salience.[22] The first would be best resolved through an effort to map standardized data collected from screening tools directly to the Z-codes within the EHR and by

[20] AHIMA and NORC, Social Determinants of Health Data, page 13, finding "The lack of interoperability or communication across organizations that identify needs (e.g., hospitals, health systems, and physician offices) and those most likely to have the expertise and resources to address these needs (e.g., CBOs) may limit the ability to measure the impact of the intervention."
[21] A. Dev et. al., For the Common Good: Data, Trust, and Community Health (Mar. 2022).
[22] W Bensken et al, "The Use of Clinically Documented Social Determinants of Health (SDOH) and their Association with Poor Health Outcomes: Findings from ICD-10 Z-codes in the Nationwide Readmission Database (NRD)" AcademyHealth's Annual Research Meeting 2020, Virtual, (Aug. 2020).

provider education regarding their existence and documentation requirements. The second could be addressed by health care payers promoting the collection and exchange of social risk data by incorporating such data into reimbursement models.

If payers wish to promote the collection and exchange of social risk and social needs data, they should appropriately pay providers for care addressing social needs of their patients or work to improve risk adjustment models to capture social risk factors that, unaccounted for, may artificially reduce payment. More granular and specific ICD-10 Z-codes for capturing social risk factors also potentially benefit the transformation of our health care system away from fee-for-service payment towards paying for value and outcomes. Collecting additional Z-code data can inform changes to payment models (or risk adjustment models), where their inclusion will ensure that more providers utilize them, leading to more robust adjustment and/or stratification by social risk factors, as appropriate, for measuring value and quality. To this end, we support the final technical guidance issued by the NQF, with funding from CMS, entitled "Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk Within Healthcare Performance Measurement."[23] We believe this should inform best practices for risk adjustment models and stratification to promote the exchange and use of social risk and social needs data to improve health outcomes and reduce inequities.

Electronic Exchange of Behavioral Health Information

Federal Regulations or Payment Rules That Have Created Barriers to Technical Integration of Health IT Systems Within Behavioral Health Practices and Policy Issues to Consider for Facilitating Secure Electronic Exchange of Sensitive Health Information

There are two main issues that inhibit the exchange of behavioral health information: federal and state privacy regulations that often require sensitive behavioral health information to be kept separate from other health information and technological capability to appropriately segment data within the EHR. On the federal level, the Substance Abuse and Mental Health Services Administration (SAMHSA) recently released a notice of proposed rulemaking to better align confidentiality rules for substance use disorder patient records with HIPAA rules.[24] Final regulations from SAMHSA will likely improve inconsistencies in federal law that might pose barriers to exchanging behavioral health information, but will not address the challenges posed by a patchwork of state healthcare data privacy protections. Additionally, due to the sensitive

[23] NQF, Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk Within Healthcare Performance Measurement (Dec. 2022), articulating the core principles for risk adjustment; setting forth a five-step process to developing and testing risk models; defining seven risk-adjustment, best practices standards; describing a set of social and functional risk factors for consideration; discussing key considerations for identifying and selecting risk factors within data sources; articulating guidance for stratification analyses, and providing a path forward for the field to advance equity while ensuring a transparent, consistent, and fair approach to quality measurement.

[24] AAMC Washington Highlights, AAMC Comments on Revisions to Confidentiality of Substance Use Disorder Records (Feb. 2023).

nature of mental and behavioral clinical notes, federal polices limit individual right of access to psychotherapy notes under HIPAA and SAMHSA sought feedback on potential layers of protection for SUD counseling notes similar to that of psychotherapy notes. In effect, such extra layer of protection technically could be achieved by EHR capabilities to appropriately segment data for privacy. It is our understanding that there is no federal standard for data segmentation for privacy (DS4P) that is required for CEHRT, and thus the landscape of technological capability is not yet ready to support appropriate electronic exchange of behavioral health information in line with federal (and presumably) state privacy requirements. We urge CMS to work with partners across the Department of Health and Human Services to identify regulatory approaches and technical capabilities and standards to meet the policy goal of greater electronic exchange of behavioral health information while balancing privacy and confidentiality concerns of patients.

Advancing Interoperability and Improving Prior Authorization for Maternal Health

Special Considerations for Prior Authorization Processing for Maternal Health Care - Timeframes

CMS notes that inefficient prior authorization processing might have specific impact on maternal health and that care delays can place patients at risk for adverse perinatal outcomes. (p. 76327) CMS asks whether there should be special considerations for the prior authorization process for maternal health care, including timeframes for decisions. The American College of Obstetrics and Gynecology encourages CMS to identify services that should never require prior authorization and implementation of quick response times for requests,[25] and notes the particular use of prior authorization for genetic testing.[26] Preventing pregnancy-related deaths requires a broad set of tools, including improved access to care during pregnancy and for a full year postpartum.[27] **The AAMC urges CMS to prohibit prior authorization for maternal care, including all prenatal care and for a postpartum period of one year.** All pregnant patients deserve equitable access to the best prenatal and maternal care options, regardless of payer or insurance coverage.

Special Considerations for Prior Authorization Processing for Maternal Health Care – Carry Over Across Payers During Pregnancy and Post-Partum Period

[25] American College of Obstetrics and Gynecology (ACOG), Policy Priorities – Administrative Burden: Prior Authorization (last viewed Feb. 27, 2023), stating "ACOG supports the establishment of gold-carding programs, which set forth parameters in which compliant physicians are relieved of many prior authorization requirements, across all payers. ACOG supports the implementation of quick response time requirements for submitted prior authorizations."
[26] ACOG, Access to Genetic Testing - Position Statement (Jan. 2018), stating "ACOG opposes changes in preauthorization policies and procedures that shift burdens to physician practices while potentially impeding women from undergoing timely indicated genetic testing."
[27] Centers for Disease Control and Prevention, Pregnancy-related deaths (May 2019), finding that roughly one third of deaths occur during pregnancy and another third occur in the period of 1 week to 1 year after delivery.

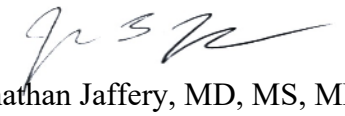
CMS also asks whether prior authorizations should carry over from one payer to another when a patient changes payers for the duration of a pregnancy, to support continuity of care. The AAMC recommends requiring payers to honor prior authorizations from a previous payer during pregnancy and for a post-partum period to ensure that payer changes do not delay access to care and treatment.

CONCLUSION

The AAMC thanks CMS for the opportunity to provide input on this important effort to advance interoperability of health care data and improve electronic prior authorization processes. We would be happy to work with you on any of the issues discussed above or other topics that involve the academic medicine community.

Please contact my colleagues Mary Mullaney (mmullaney@aamc.org) and Phoebe Ramsey (pramsey@aamc.org) with any questions about these comments.

Sincerely,



Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO