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Submitted via www.regulations.gov

January 4, 2021

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9123-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information [CMS-9123-P]

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to respond to the proposed rule entitled "Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications," 85 *Fed. Reg 82586* (December 18, 2020).

The AAMC is a not-for-profit association dedicated to transforming health through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 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 their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

This proposed rule builds upon the CMS Interoperability and Patient Access final rule issued in May 2020 and seeks to further improve health information exchange and to increase data sharing and reduce overall payer, provider, and patient burden through changes to prior authorization processing. The AAMC continues to oppose prior authorization due to concerns that its use as a utilization management tool by payers often causes delays in patients' ability to receive timely, medically necessary care and imposes additional administrative burden on providers. Additionally, there is some literature that suggests prior authorization may negatively impact the treatment of underserved patients which requires serious review.[1], [2] While we oppose prior authorization, the AAMC supports improvements to prior authorization

[1] Lu et al., "Unintended Impacts of Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness," Medical Care. Volume 48, Issue 1 (January 2010).
[2] Association of Black Cardiologists, Inc. "Identifying How Prior Authorization Impacts Treatment of Underserves and Minority Patients," (Winter 2019) Available at: http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf

processes to reduce burden on patients and providers. In general, we are supportive of the approach proposed by CMS in this rule to that end. However, we urge CMS to consider other requirements for payers to improve and standardize their prior authorization processes rather than considering future requirements for providers.

Due to the condensed comment period, a mere 22 days between when the rule was put on public display and the date comments are due, the AAMC has limited the scope of our comments to those which are most salient. The AAMC recommends that CMS continue to engage stakeholders on topics included in this proposed rule and related RFIs to ensure more opportunities to provide meaningful feedback.

DOCUMENTATION AND PRIOR AUTHORIZATION BURDEN REDUCTION THROUGH APPLICATION PROGRAMMING INTERFACES (APIS); STANDARDIZATION AND TRANSPARENCY ARE KEY

The AAMC supports improvements to make the prior authorization process more streamlined across all payers. **Specifically, we support 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 regulatory 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. 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 provided a specific reason for the denial 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.**

CMS Should Include Medicare Advantage Organizations as Impacted Payers

CMS uses the term "impacted payer" to refer to payers subject to this proposed rule, including issuers of qualified health plans (QHPs) in federally-facilitated exchanges (FFEs), Medicaid and Children's Health Insurance Program (CHIP) fee-for-service (FFS) programs, Medicaid managed care plans, and CHIP managed care entities. Medicare Advantage (MA) organizations, while subject to the related May 2020 Interoperability and Patient Access final rule, are not included in the impacted payer group for this proposed rule. Instead, CMS will consider their inclusion for future rulemaking, and notes that nothing precludes MA organizations or any other payer from implementing the policies proposed. **Adopting a standardized, straight forward form of requirements and process for prior authorization for *all payers* would reduce burden**. **CMS should at a minimum also include MA organizations as payers that must comply with the proposed prior authorization practices, considering the continued growth of Medicare beneficiaries enrolling in MA plans.** In addition, we would be happy to participate in an all payers discussion to develop a single common form.

Document Requirement Lookup Services (DRLS) API

CMS proposes to require impacted payers to implement and maintain a Fast Health Information Resource (FHIR)-based DRLS API that conforms with specified technical standards and is populated with the payer's list of covered items and services, excluding prescription drugs and/or covered outpatient drugs, for which prior authorization is required. The DRLS API must also be populated with the payer's documentation requirements for submitting a prior authorization request, including a description of the required documentation. The DRLS API is intended to make the prior authorization process and requirements more accessible and transparent to providers at the point of care. CMS proposes a January 1, 2023 implementation date for impacted payers. CMS asks whether it should consider future requirements on providers or other incentives to encourage providers to use the DRLS API.

The AAMC supports the DRLS API requirement for payers as one mechanism to ease the burden of prior authorization on providers. If implemented, providers could use the API to query the requirements for specific items and services, identify documentation requirements, and could potentially use the API to complete electronic forms and templates to link elsewhere to submit the documentation. CMS should ensure that EHR system vendors are able to easily develop functions within their EHR systems to maximize this potential. **The AAMC believes that if the full potential of the DRLS API is maximized within the EHR, the reduced burden on providers could be incentive enough to use the payer's DRLS API in their workflows**. **CMS should not impose additional requirements on providers.**

Prior Authorization Support (PAS) API

CMS proposes to require impacted payers implement a PAS API to facilitate a HIPAA-compliant prior authorization request and response, including any forms or medical record documentation required by the payer for items or services for which the provider seeks authorization. Where a prior authorization request is denied, impacted payers must include a specific reason for the denial, regardless of the method used to send the decision. **The AAMC supports the requirement for a new PAS API and agrees with CMS that it could reduce burden and improve the electronic data exchange between payers and providers so long as providers' EHRs (or practice management systems) connect with the PAS API.** CMS should coordinate with the Office of the National Coordinator for Health Information Technology (ONC) to include this function and standard in the ONC's certification programs.

Timeliness of Prior Authorization Decisions by Payers

CMS proposes to require 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, as defined by Medicaid regulations. CMS does not propose to include these timeline requirements to QHPs on FFEs due to existing standards regarding internal claims and appeals at 45 CFR § 147.136(b)(3). **The AAMC believes timeliness of prior authorization decisions is critical for patient care, and that in the case of decisions that could jeopardize a patient's timely access to necessary medical care, expedited decisions must be**

made more quickly than within 72 hours of receipt of the request. Additionally, we urge CMS to make necessary changes to the regulations for QHPs on FFEs to create a broader more uniform timeliness standard for payers in all programs.

RFI: REDUCING BURDEN AND IMPROVING ELECTRONIC INFORMATION EXCHANGE OF PRIOR AUTHORIZATIONS; NEW COPS ARE NOT NEEDED

CMS Should Not Propose New Medicare Conditions of Participation (CoPs) to Require the Electronic Request or Receipt of Prior Authorization Decisions

CMS seeks information on whether hospital Conditions of Participation (CoPs) are a way to achieve adoption and use of electronic prior authorization requests. The AAMC supports efforts to improve the prior authorization process, including through the adoption and use of standardized electronic prior authorization requests. **However, the AAMC does not support changing the Medicare conditions of participation to require electronic processing**. As CMS states on its website, the CoPs are "health and safety standards [that] are the foundation for improving quality and protecting the health and safety of beneficiaries."[3] While electronic processing will reduce burden and may provide patients with care more expeditiously, it is not a health or safety standard. The conditions of participation are not the right vehicle to encourage electronic prior authorization requests given the significant unintended consequences if the CoPs are not met, particularly since there are still numerous operational challenges that need to be resolved, including the applicability of standards and requirements across all payers. We believe that if CMS works to achieve a seamless process with straight forward requirements then the electronic process will be adopted by all as the preferred process. Attention should be paid to ease of use that reduces burden rather than determining ways to force adoption. We recommend CMS consider other approaches to achieving this goal, such as setting forth requirements related to the adoption of electronic prior authorization processing in the Promoting Interoperability Program and encouraging payers to adopt broad standardization for prior authorization requirements.

RFI: ACCELERATING THE ADOPTION OF STANDARDS RELATED TO SOCIAL RISK DATA

The AAMC appreciates the opportunity to comment on questions relating to the standardization of social risk data. Over the past decade – and especially during the current transition towards patient-centered care and value-based payment (VBP) – the health care community has reached a consensus on the conceptual and empirical impacts of social risk factors (SRFs) on health outcomes and healthcare delivery and payment. As consensus has grown on the importance of patients' SRFs, so too did the realization that a key challenge going forward is identifying and collecting the appropriate SRF data to meaningfully mitigate their impacts on VBP programs and, crucially, to develop specific interventions to improve patient, population, and community health. From data collection to data use, broad consensus is needed to determine which social risk data should be collected and at which levels (that is, patient, hospital and community) and how (based upon patient-engaged health services research) best to obtain valid data.

Better data about specific SRFs would support providers in developing targeted interventions to improve the delivery of care, advance providers' (and their institutions') understanding of the

[3] CMS Website – Conditions for Coverage (CfCs) & Conditions of Participation (CoPs).

patients and communities they serve, and help determine how best to invest resources (like community benefit dollars) to counteract the SRFs that matter most.

Data Collection and Screening Tools

There is a great need to develop a standardized, core set of SRF measures to support national policy and quality initiatives, while maintaining flexibility for additional SRF screening tools that capture additional SRF data that are most relevant in a given community, based on that community's assets and ability to act and implement appropriate interventions. Screening tools must be based on evidence-based research that the tool meaningfully engages patients to share information about their social needs and is based upon recognized standards of data privacy and confidentiality.

The Gravity Project, led by the University of California San Francisco and the Social Interventions Research & Evaluation Network (SIREN), is one such project that is seeking to build consensus around the use of EHRs to effectively collect and use SRFs data elements. We recommend that CMS review and build off of this consensus effort to ensure any resulting standards are both translatable (from screening tool to coding for claims) yet flexible (to ensure appropriate for each community's particular needs). If flexibility is prioritized over translatability, the result will be data that are highly relevant for local interventions but useless for national-level policy development and quality measurement. Conversely, if translatability is prioritized over flexibility, the result will be standardized data that might not capture all information a local community – and its health care and public health partners – needs for focused interventions and implementation strategies. We are continuing our research in this area and would welcome the opportunity to work with CMS, who should take the lead on how best to strike that balance.

Translating Screening Tools in Z-Codes on Claims

The AAMC has previously commented[4] regarding efforts to expand the existing Z-codes in the ICD-10-CM code set as complementary to the work by the Gravity Project and standards-setting. While base Z-codes are currently available for inclusion on claims, they often lack requisite specificity for identifying interventions. Moreover, 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, they are not directly reimbursable and are not incorporated into the risk adjustment models despite growing evidence[5] of their salience. 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 provider education in regard to 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 (which we discuss in detail below).

[4] AAMC Comments on Proposal to Expand ICD-10-CM Codes for Social Determinants of Health, May 9, 2019.
[5] Bensken W, Alberti PM, Koroukian SM "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, (August 2020).

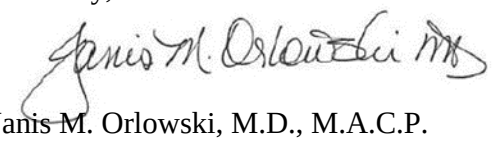
Role of Health Care Payers to Promote Exchange of Social Risk and Social Needs Data

Simply put, if payers wish to promote the collection and exchange of social risk and social needs data, they should work to improve risk adjustment models and/or appropriately pay providers for care addressing social needs of their patients. More granular and specific ICD-10 Z-codes for capturing SRFs also benefits risk adjustment as we seek to transform 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 risk adjustment models, where their inclusion will ensure that more providers utilize them, leading to more robust adjustment for social risk factors for appropriate measures of value and quality. To this end, we support the efforts by CMS and the National Quality Forum and its recently formed technical expert panel[6] on Best Practices for Developing and Testing Risk Adjustment Models to oversee the development of technical guidance on social and functional status-related risk adjustment in quality measurement, that we hope will inform best practices for risk adjustment models.

CONCLUSION

We hope this is not the only opportunity to provide comment on the interoperability of prior authorization processing and remain committed to work with CMS on any of the issues discussed above or related topics that impact the academic health center community. If you have questions regarding our comments, please feel free to contact me or Phoebe Ramsey, pramsey@aamc.org.

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer, AAMC

cc: Phoebe Ramsey, J.D., AAMC
Gayle Lee, J.D., AAMC

[6] National Quality Forum "Risk Adjustment Guidance Project"