TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244

Submitted Via *Federal Register*

Dear Administrator Brooks-LaSure,

The Texas Medical Association (TMA), which represents our more than 57,000 physician and medical student members, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule on 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 as posted to the *Federal Register* on Dec. 13, 2022.

In addition to improving patient access to medical treatment, TMA sincerely thanks CMS for proposing this rule since it recognizes the ongoing and increasing burden of prior authorization on physicians and other health care providers. The regulatory changes set forth in the proposal are a needed and critical step forward in improving the prior authorization process. TMA urges CMS to evaluate prior authorization burdens further and make additional proposals to ensure patients receive needed care.

Overarching Comments

TMA commends CMS for issuing this proposed regulation since it will, when finalized, improve patients' timely access to prescribed services and medications while easing prior authorization burdens imposed on physicians. The prior authorization process has needed reformation for a long time, and this is a key step to ensuring Medicare Advantage and Medicaid beneficiaries have access to care that is medically necessary. **TMA calls on CMS to propose regulations that apply such improvements to the prior authorizations for all health plans under the agency's purview.**

TMA appreciates that CMS' proposals support:

- Making information about prior authorization requests and decisions available to patients;
- That payers provide a specific reason for denied prior authorization decisions, and call on CMS to ensure the denial is understandable with clear and actionable next steps;
- That payers publicly post on their websites aggregated prior authorization data;
- Consideration of a gold-carding program to reduce prior authorization requirements for physicians who demonstrate a consistent pattern of compliance; and
- Consideration that Certified Electronic Health Record Technology (CEHRT) vendors be required to

update their technology to support adopted electronic prior authorization standards.

TMA recommends that CMS establish an oversight and enforcement process to ensure impacted payers comply with regulatory requirements and provide a process allowing patients and physicians to report noncompliant payers.

It is unfortunate that CMS does not propose policies related to retrospective review. TMA recommends that CMS adopt a policy to restrict the practice of retrospective review to revoke a previously approved item or service. With very few and extreme exceptions, payers' use of retrospective review processes to revoke previously approved items or services is inappropriate. This behavior leaves the physician uncompensated for services previously approved by the payer.

TMA recommends that CMS establish a workgroup consisting of physicians, hospitals, health insurers, EHR vendors, and claims clearinghouse vendors to monitor and evaluate issues or concerns as the regulations are implemented.

As articulated in a Feb. 13 letter to CMS and fully supported by the TMA, national and state medical associations urge CMS to further strengthen its prior authorization reform efforts by extending its proposed clinical validity and transparency of coverage criteria policies into the area of prescription drugs.

TMA has comprehensive policy regarding prior authorization, and we ask CMS to consider it carefully as the agency finalizes this proposal and future prior authorization policies.

TMA supports policy and legislation that (1) third-party payers, benefit managers, and utilization review entities may not implement prior authorization mechanisms unless these payers compensate physician practices for work required independent of any payment for patient care; specifically, medical practices must be compensated for the burden of added staff and resources required to navigate payer-initiated prior authorizations for medications, studies, or procedures; (2) third-party payers, benefit managers, and utilization review entities should disclose all prior authorization requirements and restrictions on their websites in both the subscriber section and the physician section with neither location requiring a log-in or password; (3) third-party payers, benefit managers and utilization review entities should confirm patient eligibility, payment determinations, medical policies, and subscriber-specific exclusions as part of the prior authorization process; and (4) third-party payers, benefit managers, and utilization review entities should make detailed statistics regarding prior authorization approval and denial rates available on their website.

TMA supports policy and legislation that third-party payers, benefit managers, and any other party conducting utilization management be required to accept and respond to (1) standard electronic prior authorization (ePA) transactions for pharmacy benefits that use a nationally recognized format, such as the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard; and (2) standard electronic transactions for review and response to prior authorization requests for medical service benefits that use a nationally recognized format, such as the ASC X12N 278 Health Care Service Review Request.

TMA supports that (1) the criteria for prior approval for patient referrals, tests, surgeries, procedures, and medications be available to all physicians at the time of the request for such action; (2) the types of patient referrals, tests, surgeries, procedures, and medications that typically require prior authorization be kept to a minimum, and such criteria be available to the physician and staff in a transparent manner; and (3) prior approval for patient referrals, tests, surgeries, procedures, and medications be handled in a timely fashion, appropriate to facilitate treatment of the illness for which the test or intervention is being sought.

Specific Comments

Patient Access API: Blue Button 2.0 (FR 76243-44)
CMS proposes to use Blue Button 2.0 to make claims data for Medicare Parts A, B, and D available electronically via an application programming interface (API) to Medicare beneficiaries.

TMA Response
TMA appreciates the importance of increasing patients' secure access to their private medical information. TMA supports the work and advancements of Blue Button 2.0 in making information available to Medicare patients. Since Medicare beneficiaries may have secondary payers and would thus use an application other than Blue Button 2.0 to compile data from multiple payers, TMA encourages CMS to ensure patients can use the application of their choice to access Medicare claims data. Additionally, Blue Button 2.0 should be configured so that information from payers other than Medicare may be gathered and utilized by Blue Button 2.0.

Patient Access API: Prior Authorization Information (FR 76244)
CMS proposes requiring impacted payers make information about prior authorization requests and decisions available to patients via the patient's health application no later than one business day after the payer receives the prior authorization request or if there is a status change. Under this proposal, payers are further required to make their prior authorization decisions available to patients for one year.

TMA Response
TMA agrees with CMS that patients having secure access to their private medical and prior authorization information enables patients to take a more active role in their own health care. TMA encourages CMS to finalize the payer requirements that give patients access to their prior authorization information within one business day. Further, the explanations provided to the patient should be at a sixth-grade level as measured by using a reading ease test such as the Flesch-Kincaid readability test. Patients and physicians should have a mechanism to alert the payer of any incorrect information that is displayed regarding prior authorization decisions. TMA further agrees that the prior authorization information should remain available to patients for at least one year.

Regarding patient access to APIs, TMA asks CMS to consider how health plan API requirements align with 21st Century Cures Act requirements regarding information sharing.

CMS Request for Comment (FR 76245)
CMS requests comment on how they could or should apply these requirements to Medicare fee-for-service and its existing prior authorization requirements and standards.

CMS also requests comments on whether they should consider policies to require impacted payers to include information about prior authorizations for drugs when the payer covers drugs.

TMA Response
Just as is the case for Medicare Advantage (Part C) patients, TMA members continue to express serious concerns with traditional Medicare (Parts A and B) and Medicare Prescription Drug Benefit (Part D) beneficiary access to medically necessary procedures as a direct result of prior authorization. TMA therefore calls on CMS to expand this regulation's proposed policies that address and limit prior authorization throughout all Medicare programs. CMS should suspend the prior authorization requirements generally or for a particular service at any time by issuing a notification on the CMS website.

TMA emphatically asks CMS to make the workflows as standardized as possible for all prior authorizations.

Interaction with HIPAA Right of Access Provisions (FR 76246-48)
CMS discusses requiring all impacted payers to provide individuals' electronic protected health information (ePHI) via an industry standard FHIR API.

CMS requests comment on whether it can leverage and build other Department of Health and Human Services (HHS) health exchange initiatives, such as the Trusted Exchange Framework and Common Agreement (TEFCA) and how health applications may interact.

TMA Response
TMA urges CMS to require payers to adopt the industry standard Fast Healthcare Interoperability Resource (FHIR) API allowing patients to seamlessly have information across payers in the event of changing payers, managing family records when family members may have different coverage, and in instances when individuals have primary and secondary coverage with different payers. Impacted payers should receive significant penalties for noncompliance.

Regarding other HHS health exchange initiatives, health applications used by patients could connect with Qualified Health Information Networks (QHINs) or certified sub-participants to share data with patients. This could be designed so that the application providers access patient data from the QHIN or sub-participant and are not keepers of the data. The health application provider then competes on visual display, organization, and service to the patient. This model keeps the data in a HIPAA-protected manner and would prevent health application providers from wrongfully accessing and using patient data.

Furthermore, TMA supports the requirement that health plans implement information exchange over APIs to support coordinated care when patients transition between plans. As part of this, health plans should recognize and honor prior authorization approvals from a patient's previous health plan. Doing so would both support continuity of care and protect patients from disruptions in ongoing therapy.

Proposed Requirements for Payers: Provider Access Application Programming Interface (API) for Individual Patient Information (FR 76255)
CMS proposes to require that impacted payers implement and maintain a provider access API to enable current patients' information to be exchanged from payers to providers that are in that payer's network, at the provider's request.

TMA Response
TMA agrees that it will be helpful for physicians to access patient claim and encounter information from the payer at the point of care to inform clinical decisions. TMA appreciates that CMS correctly places the patient opt-out requirements and process on the payers.

Any associated costs with implementing the proposals should not fall to physicians. If CMS moves forward with this proposal, TMA urges CMS to not burden physicians by requiring extra effort during the patient visit. These technologies should be designed and implemented in a way that delivers the information at the point of care in an easy-to-access and easy-to-view format. The power of information is limited by the ability to effectively deliver that information to the user. TMA encourages CMS to test the models proposed to ensure the efficacy of the systems and the information delivered. Further, CMS should be more involved with tracking, developing, and testing API standards used by health plans and HIT vendors.

Improving the Prior Authorization Process/Electronic Options for Prior Authorization (FR 76288)
CMS states that though payers are required to use the X12 278 version 5010 HIPAA transaction standard for electronic prior authorization transactions, however, there has not been a high adoption rate by covered entities, such as physicians. CMS quotes the Council for Affordable Quality Healthcare in saying the biggest barrier to using the X12 278 version 5010 HIPAA transaction standard is because of "lack of vendor support for provider

systems, inconsistent use of data content from the transaction, and lack of an attachment standard to submit required medical documentation." CMS proposes that impacted payers implement the HL7 FHIR API to work in combination with the HIPAA transaction standard to conduct the prior authorization process.

TMA Comment
TMA urges CMS and ONC to require that EHR vendors support adopted electronic prior authorization transaction standards. Physicians are not software developers and cannot program their own systems to accept the transactions payers require. Vendor support must complement the payer requirements, and this can be accomplished through the ONC's EHR vendor certification program.

Prior Authorization Requirements Documentation and Decision (PARDD) API (FR 76289)
CMS seeks comment on allowing payers to have a phased-in approach allowing payers to implement their prior authorization rules through the PARDD API in 25%, 50% and 25% increments meeting targets in 2026, 2027, and 2028 respectively.

TMA Comment
The amount of complexity that a phased-in approach adds to physician practices is untenable and TMA appreciates CMS acknowledging this in the proposed rule. TMA calls on CMS to finalize a reasonable date and require payers to have 100% of its prior authorization rules implemented. Non-compliant payers should be penalized.

Requirements for Prior Authorization Decision Timeframes and Communications (FR 76294)
CMS proposes up to 14 calendar days for payers to make a decision for standard or non-urgent requests and as expeditiously as the patient's health plan requires, but no later than 72 hours for expedited or urgent requests.

TMA Comment
TMA recommends CMS require payers to have appropriate personnel reasonably available at a toll-free telephone number to provide a verification under these proposals 24 hours a day, seven days a week, including between 6 am and 6 pm Central Time, Monday through Friday on each day that is not a legal holiday, and between 9 am and noon Central Time on Saturday, Sunday, and legal holidays. Plans must have a telephone system capable of accepting or recording incoming phone calls for verifications during any period in which personnel are not available due to circumstances beyond the plan's reasonable control. Plans must respond to each of those calls as soon as possible but not later than two hours after or before the second calendar day after the date the call is received.

Public Reporting of Prior Authorization Metrics (FR 76304)
CMS proposes requiring impacted payers to publicly report certain aggregated metrics about prior authorization on their websites.

TMA Comment
TMA recommends CMS require payers include these aggregated metrics about prior authorization:

- List of all items and services that require prior authorization.
- Percentage of standard prior authorization requests: approved/denied, approved after appeal, and where review was extended and request was approved.
- Percent of expedited prior authorization requests approved.
- Percent of expedited requests denied.
- Average and median time between submission of a request and determination by the plan, for standard prior authorizations.
- Average and median time elapsed between submission of request and decision by plan for expedited prior authorization.

TMA also urges CMS to require plans to report the information on a centralized website, such as a CMS site, to make it more accessible by patients and physicians.

"Gold Carding" Programs for Prior Authorization (FR 76307)
CMS seeks comment on implementing a gold-carding program to relax or reduce prior authorization requirements for providers that have demonstrated a consisted pattern of compliance.

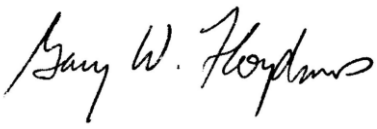
TMA Comment
TMA was the key driver behind the Texas gold-card law that passed during Texas' 87th legislative session in 2021. Texas' law provides a preauthorization exemption for a particular health care service if the insurer or HMO subject to Texas' gold-carding law approved at least 90% of the preauthorization requests submitted by the physician or provider for that service during a defined evaluation period. TMA encourages CMS to adopt a similar program for all payers it regulates.

Electronic Prior Authorization for the Merit-Based Incentive Payment System (MIPS) (FR 76311)
CMS proposes adding a new measure titled "Electronic Prior Authorization" to the MIPS Promoting Interoperability performance category beginning with the 2026 performance year.

TMA Comment
To relieve ongoing administrative burdens, TMA is concerned with the proposal to add this new MIPS measure since it would link a physician's success in MIPS with the practice's HIT capabilities. CMS should first ensure that any new MIPS measures, and this one specifically, are supported by the technology of all impacted users. While we encourage CMS to finalize the proposed prior authorization policies immediately, for quality measurement purposes, CMS should reconsider adding any new measure.

TMA appreciates the opportunity to comment on the proposal as CMS seeks to improve interoperability and the prior authorization process. Any questions may be directed to Shannon Vogel, associate vice president of health information technology, by emailing shannon.vogel@texmed.org or calling (512) 370-1411.

Sincerely,



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