TEXAS MEDICAL ASSOCIATION
Physicians Caring for Texans

January 4, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Administrator Verma:

On behalf of our more than 53,000 Texas physician and medical student members, the Texas Medical Association (TMA) writes in response to the proposed rule titled, "Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information" as announced by the Centers for Medicare & Medicaid Services (CMS) on Dec. 10, 2020.

Extending the Comment Period

The rule proposes a comprehensive set of regulatory requirements that, if implemented appropriately, could improve care delivery. In addition, the rule includes numerous requests for information on a wide range of topics, each of which will require careful consideration. Prior to issuing a final rule, it will be critical for CMS to receive comprehensive, thoughtful, and detailed feedback from impacted stakeholders.

While TMA appreciates the opportunity to discuss proposed solutions that address the administrative burdens associated with prior authorization, we strongly urge CMS to provide 60 days, as is the case for most significant proposed rules, for stakeholders to comment.

Expanding the Proposals to Include Medicare Advantage

This proposed rule would place new requirements on Medicaid and Children's Health Insurance Program (CHIP) managed care plans, state Medicaid and CHIP fee-for-service programs, and qualified health plan (QHP) issuers on the federally facilitated exchanges (FFEs).

To promote standardization, TMA urges CMS to expand the proposals to include Medicare Advantage plans as well. Doing so would improve the electronic exchange of health information among payers, physicians, and patients. Having different approaches to prior authorization (PA) and patient electronic access wastes resources by forcing electronic health record (EHR) developers to create multiple software programs, and it increases expenses as these costs and the burden of use are passed on to physicians and health care organizations.

Patient Access Application Programming Interface (API)

Summary

CMS proposes, starting Jan. 1, 2023, to require impacted payers to include, as part of the already-established Patient Access API, information about the patient's pending and active prior

authorization decisions to ensure patients have a better understanding of the PA process and its impact on their care. The regulation also would require impacted payers to establish, implement, and maintain a process for third-party application developers to attest to certain privacy policy provisions prior to retrieving data via the payer's Patient Access API. CMS also proposes to require impacted payers to report quarterly to CMS metrics about patient use of the Patient Access API to assess the impact the API is having on patients.

CMS also proposes to require impacted payers to build and maintain by Jan. 1, 2023, a Provider Access API for payer-to-physician/provider sharing of claims and encounter (but not cost) data, a subset of clinical data as defined in the U.S. Core Data for Interoperability, version 1, and pending and active prior authorization decisions for both individual patient requests and groups of patients. CMS also proposes the use of the HL7 Fast Healthcare Interoperability Resources (FHIR)- Bulk Data Access (Flat FHIR) specification to facilitate the exchange of data for more than one patient at a time.

TMA Response
TMA believes that if CMS moves forward with regulations mandating that covered payers build and maintain FHIR-based APIs for physician/provider-payer data sharing, then payers should implement an EHR-integrated, FHIR-enabled Document Requirement Lookup Service API. Additionally, payers should increase the transparency of prior authorization metrics. This will have significant potential to streamline information exchange between health care organizations/clinicians and payers. These proposals will require substantially revised business workflows based on new standards.

TMA agrees that CMS correctly places much responsibility on the payer community to provide information to patients. There is concern that payers, through coercive contracts, will place additional responsibility on network physicians. **Any associated costs with implementing the proposals should not fall to physicians, and CMS should prohibit payers from using these proposals to place additional contractual demands on 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 -view format. The power of information is limited by the ability to effectively deliver that information to the user.

<u>Provider Access APIs</u>

Summary
CMS states "while we have no data, we anticipate that putting patient data in the hands of the provider at the point of care would reduce provider burden and improve patient care."

TMA Response
TMA calls for CMS to test concepts before finalizing regulations that require vendors, payers, and physicians to retool systems to accommodate changes. Even though this proposed regulation applies to a narrow scope of plans, EHR vendors must make modifications for all payers as the systems are developed to track patient information equally regardless of payer. Decisions to make changes that have this sort of significant impact should be evidence-based.

Additional Proposed Requirements for the Provider Access APIs, (c) Provider Resources

Summary
CMS proposes that payers make educational resources available to physicians and providers that describe in nontechnical, simple, and easy-to-understand language how a physician can request patient data using the payer's Provider Access APIs.

TMA Response
TMA agrees with this proposal and further suggests that payers provide patient-facing materials to physician offices. At the point of care, patients will have questions about how to access their information provided via payer applications and whether the applications are secure. Patients trust their physician and have more interactions with their physician than with the payer. Additionally, payers should have service representatives available to answer questions from physicians and patients about accessing information via the payer APIs.

Standardization of educational materials across payers is strongly encouraged. If physicians are required to have different processes and materials for each payer, this simply adds to the burden and complexity of running a physician office/health care organization.

Prior Authorization

Summary
CMS proposes to require that impacted payers include a specific reason for a denial of a prior authorization request, regardless of the method used to send the PA decision, to facilitate better communication and understanding between the physician or provider and payer. The agency proposes to require impacted payers (not including QHP issuers on the FFEs) to send PA decisions within 72 hours for urgent requests and seven calendar days for standard requests.

The agency proposes to require impacted payers to publicly report prior authorization data, such as their percent of PA requests approved, denied, and ultimately approved after appeal, and their average time between submission and determination, to improve transparency into the PA process, which will help patients understand the approval process.

TMA Response
TMA strongly supports efforts to reduce excess prior authorizations within Medicaid and CHIP and to make the PA process more transparent. Texas Medicaid has already begun implementing many of the best practices outlined within the proposed rules.

In 2019, the Texas Legislature adopted legislation to significantly improve Medicaid managed care organization (MCO) oversight and accountability, including simplifying and streamlining prior authorization requirements, strengthening grievance and appeal mechanisms, and establishing an external review organization. Lawmakers adopted these reforms at the behest of organized medicine, hospitals, and consumer advocacy organizations.

In particular, the reforms established the following protections:

- Required the state Medicaid agency, the Texas Health and Human Services Commission (HHSC), to establish a standard definition of grievance across all Medicaid divisions,

standardize grievance reporting and tracking, develop an expedited process for resolution of grievance related to access to care, and ensure a "no-wrong-door" policy for patients or physicians to submit a grievance.

- Directed HHSC to provide guidance and education to MCOs regarding federal requirements that services be continued while a patient appeals an MCO decision or if the case is sent to a Medicaid fair hearing or other review.
- Required MCOs to provide:

    - Explicit clinical rationale for PA denial;
    - A clear, specific list and description of the documentation needed to fulfill a PA request and the timeframes for finalizing PA decisions; and
    - A reasonable opportunity for the physician requesting PA to speak to a medical director within the same or similar specialty and with experience treating the same patient population on whose behalf the PA was submitted.

- Required MCOs to maintain on their websites a current catalogue of PA requirements and to annually review all PA requirements to ensure each is up to date, is evidence-based, and distinguishes between categories of patients.
- Established an external medical review process, similar though not identical to commercial independent review organizations, allowing Medicaid patients to request an independent review of an MCO's decision to reduce or deny a medical service based on medical necessity or an HHSC denial of eligibility based on functional or medical need.
- Specified that HHSC must determine a plan for collecting additional data to improve STAR KIDS, as necessary, based on the External Quality Review Organization's initial findings about the program, which could also include conducting annual recipient surveys for children in the Medically Dependent Children Program or focus groups.
- Directed HHSC to establish with input from physicians, hospitals, advocates, and others a Medicaid-specific process and timeframe wherein MCOs will review and issue determinations for PA requests lacking sufficient documentation, not to exceed federal timeframes.

The legislation also specified that MCOs must issue a decision on a prior authorization request for a nonhospitalized patient within three business days of receipt of the request, but that HHSC must establish a separate timeframe and process, with input from physicians, consumer advocates, and other stakeholders, wherein MCOs will review and issue determinations for PA requests lacking sufficient documentation, not to exceed federal timeframes.

TMA strongly supported the latter flexibility to allow physicians and providers a reasonable timeframe to submit missing documentation without having the entire prior authorization be denied. Unlike the average commercial MCO enrollee, many Medicaid patients have complex medical and long-term care needs. When PA is needed for highly specialized services, such as private-duty nursing, durable medical equipment, and so forth, physicians indicated it would be useful to have more time to submit missing documentation rather than start the PA process anew. The process developed by HHSC balances the need for quick resolution and opportunity for appeal without creating a new hassle if a PA is denied simply for missing information.

As drafted, it appears Texas' new process will be compliant with the proposed rules. TMA supports retaining this flexibility.

We continue to support other reforms to further ameliorate prior authorization-related hassles:

- Heightening enforcement and penalties when a health benefit plan issuer or its agent (1) knowingly violates the prudent layperson standard for emergency care; (2) deters enrollees from seeking care consistent with the prudent layperson standard for emergency care; or (3) engages in a pattern of wrongful denials of claims for emergency care, including denials related to application of the prudent layperson standard.
- Requiring health benefit plan issuers and benefit managers that require PAs to have staff available to process approvals 24 hours a day, every day of the year, including holidays and weekends.
- Prohibiting PA for generic drugs (except for safety-related reasons, such as a medication contraindication) and essential health benefits (EHB) covered under the Affordable Care Act. Since nongrandfathered health benefit plan issuers are required to cover all EHB services, PA is an unnecessary barrier to patient care and a misuse of physician time better dedicated to patient care.
- "Support[ing] continuity of care for medical services and prescription medications for patients on appropriate, chronic, stable therapy through minimizing repetitive [PA] requirements."[1]
- Requiring health benefit plan issuers to "gold card" certain physicians from PA processes (i.e., creating an automatic approval or exemption, on a physician-by-physician basis, that waives PA requirements if a specific procedure/service is ultimately approved for that physician the vast majority – i.e., 80% – of the time).
- Requiring CMS to perform audits of health plan compliance with statutory PA timelines for approvals and denials.
- Strengthening policies to better prevent payment denials once patient care has been approved.

Requests for Information

A. Methods for Enabling Patients and Providers to Control Sharing of Health Information

TMA General Response
As CMS considers enabling patients, physicians, and providers to effectively share health information, please be certain to address these areas in rulemaking:

- Any new regulations should carefully consider alignment with the current information-blocking and patient access requirements.
- Health information exchanges (HIEs) should be considered as stakeholders with patient-facing capabilities as some are moving into this space.
- EHR vendors need to be required to demonstrate data segmentation capabilities, which will likely lead to new certification criteria.
- CMS needs to ensure that special populations are considered, such as children (especially those with divorced parents sharing custody), the elderly (especially those with guardians), and people with special needs (especially those with guardians).

[1] Consensus Statement on Improving the Prior Authorization Process by the American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, American Medical Association, and Medical Group Management Association.

- CMS needs to realize that allowing patients to segment and withhold data may lead to improper care and could impede care coordination, especially if patients choose which physicians or providers can receive information.
- CMS should test any new concepts and be sure those concepts can scale down to a solo practice before requiring the health care system to adopt new processes that may not work in all settings.

Specific Responses to CMS Questions

(1) CMS asked, "What role should patients and providers play in data segmentation decisions? Should patients assume this responsibility and are there mechanisms currently in place or available that could support the documenting of these preferences? Would providing opportunities to express these preferences negatively impact patients who are unable or choose not to state their preferences? For instance, would a patient who did *not* fully understand how, or, or the pros and cons of, sharing some data but not other data be at a disadvantage in some way? How can patients be engaged in these decisions and acquire adequate understanding of how their data are being shared without burdening them?"

TMA response
TMA believes patients who are capable of making rational decisions that do not harm others should be able to help manage data segmentation decisions. This should be done without physician burden, or there should be a mechanism through which physicians can be paid for helping patients make decisions.

Unfortunately, we know very little about how patients make these decisions, and much more research is needed. Rather than creating regulations that lock in untested approaches, CMS should fund evaluation projects with physicians and health information technology (HIT) vendors that discover the answers to these questions.

(2) CMS asked, "Are there specific situations, use cases, or considerations that should limit how the impacted entity responds to a data segmentation request to either restrict uses and disclosures of some of the data, or to obtain access to some of the data from a patient or provider? Are there unintended consequences of such data segmentation requests or options? If so, how can they be addressed?"

TMA response
Adolescent privacy and maternal/family information placed in a newborn's chart are two well-known examples that require disclosure restrictions. The unintended consequences of inappropriate release of information may be devastating. Similarly, if patients are able to hide their infectious disease status from clinicians, the consequences could be devastating to these patients, their contacts, and the clinicians caring for them. This field is still in its infancy, and regulations are premature. **More research is needed. CMS should spend its resources on research rather than attempting to create regulations based on opinions.**

(3) CMS asked, "Would requiring the ability to segment the data by, for instance, conducting data tagging, place additional burden on clinical providers? Please describe the nature of any additional burden. What are possible solutions to consider to address these concerns?"

TMA response
Carefully controlled research is the best way to find the answer to these questions. Certainly having to tag individual data elements would be onerous and near-impossible if clinicians had to do this for each element. But providing patients with an app that (a) manages each element of tagging, (b) provides patients with education into the pros and cons of their choices, and (c) alerts the patients' primary care physician that a patient is attempting to selectively restrict data so the physician can have a discussion with the patient might be a way to approach this in the future. For example, if an elderly, competent patient wanted to hide the fact that she had trichomoniasis from her adult-child guardian, an app could be constructed that (a) selectively removed this from the problem list, notes, medications, and medical history; (b) provided education on the pros and cons of hiding this; and (c) alerted the primary care physician of the patient's desire to selectively hide some data. But we are far away from being able to do this in terms of the EHR/HIT technology and the shared appreciation of where it should and shouldn't be done (e.g., COVID-19 infection being hidden from an adult-child guardian). **The industry is far away from the ability to control release to and from HIEs. Much more research and thinking about consequences is needed before any significant regulations can be considered.**

B. Electronic Exchange of Behavioral Health Information
CMS asked "What levers could CMS consider using to facilitate greater electronic health data exchange from and to behavioral health providers? What costs, resources, and/or burdens are associated with these options?"

TMA Response
TMA urges CMS to consider the sensitivity of behavioral health information during future rulemaking. Organizations must delicately balance on a case-by-case situation how much information should be shared without potentially causing harm when patients access their information. It may be challenging to develop APIs for the sharing of behavioral health information that protect the patient. Physicians should be able to consider special situations and act accordingly in the best interest of the patient.

The failure of the original meaningful use program to fund behavioral health clinicians and to think about the need to have them electronically connected to other clinicians is an example of how regulation-driven EHR adoption is fundamentally flawed. **For the future, CMS should research what market-based approaches would encourage behavioral health clinicians to adopt workflow-friendly EHRs and incentivize clinicians of all types to exchange behavioral health information to the limits allowed by law and necessary for efficient and safe patient care.**

D. Reducing Burden and Improving Electronic Information Exchange of Prior Authorizations
CMS posed several questions about approaches that CMS could consider that help support clinician use of electronic prior authorization solutions such as the Prior Authorization Support API.

TMA Response
TMA believes the idea of using APIs, portals, and decision support has merit. It has potential to lessen the burden on physicians as long *as payers do not add to the number of medications, services, and supplies that require prior authorization.*

The burden of developing prior authorization interfaces/apps should fall to payers without additional expense to the physician users. Additionally, the interfaces/apps and processes should be

standardized in such a way that there is no variance by payer, whether public, private, or self-funded. Lack of standardization is a very significant burden on physicians. Note that standardization may require extra effort of the EHR vendors, which may require additional certification criteria.

TMA stresses that electronic prior authorization should not come at extra expense or effort to physicians and should not be used as an excuse to add additional medications, services, and supplies that need prior authorization.

E. Reducing the Use of Fax Machines
CMS posed several questions about the impact and recommendations for reducing the use of fax machines when exchanging health care information.

TMA Response
Phones, faxes, and other "non-electronic" technology are a part of our lives outside of health care and will be so probably forever. **CMS should not be focused on the usage of faxes.** It seems analogous to focusing on the use of handwriting when things can be typed – typing is better, true, but the bigger issue is that physicians and patients will use workflows best suited for what they need to do.

Additionally, electronic faxing – the e-fax – is actually an efficient means of sharing information between physicians and other clinicians. EHRs and other HIT products are able to incorporate e-faxes, and with character recognition and other tools they sometimes are able to create discrete data from them.

The reduction in the use of faxes should be a by-product of improved technology, not a focus.

Many practices and facilities rely on paper forms to gather data due to the varying levels of sophistication of products and devices that can integrate with EHRs for digital data collection.

Additionally, universal interoperability between EHRs and other HIT products is still nonexistent. **Until standards are in place and used by all HIT developers and patients, the use of faxes should be considered a necessary technology. Prohibiting or penalizing the use of fax machines will significantly impede care coordination and can lead to patient harm.**

Physicians spend an inordinate amount of time and money trying to share information across disparate systems. Physicians must not be held up by inefficient technology that places them in an untenable position between health IT developers and federal regulations.

F. Accelerating the Adoption of Standards Related to Social Risk Data
CMS asked questions regarding the collection and exchange of social risk and social needs data.

TMA response
In making health care electronic, we replicated the paper approach that all data are collected and stored locally. Unfortunately, for some types of data this is not the right approach. Social risks/needs are one of these types, as the social risks/needs collected by each organization are going to be different because they vary through time. So the risks/needs collected by one organization will

be inconsistent with those collected by another, and sharing becomes an impossible reconciliation project.

The best way to collect and maintain accurate social risk/need data is for each patient to have a single source of truth that can be shared with EHRs/HIT products as needed for clinical decision support. Updating should not be in the local EHR/HIT, but rather at the single source of truth. How this is accomplished needs additional research – in some cases individual patients could manage their source of truth, and in other cases, a service that provided this for patients would be needed.

CMS should consider incentivizing health information exchanges and other vendors to provide these single sources of truth products and to educate patients and clinicians on how to use them effectively.

Alternatives Considered (page 82658 of the *Federal Register*)
In this section, CMS explains why it does not support using health information exchanges as an approach to the Patient Access API enhancements.

TMA Response
TMA *strongly* disagrees with CMS' decision to exclude HIEs as an approach to the Patient Access API enhancements. Just because all patients don't have access to an HIE does not mean NONE of them should.

HIEs that are opening their systems to individual patients could work with payers to consume, organize, and normalize patient data, allowing dissemination to patients and their physicians in a way that reduces burden to all.

CMS has made significant investments in health information exchanges and should work with The Sequoia Project, the Office of the National Coordinators' Recognized Coordinating Entity that was established to advance nationwide health information exchange. TMA believes it is extremely short-sighted for CMS to undermine the viability of HIEs by eliminating the opportunity to provide value to patients and physicians.

In closing, TMA appreciates the opportunity to comment on the proposed regulations and requests for information. If you have any questions, please do not hesitate to contact Helen Kent Davis, associate VP for governmental affairs, at helen.davis@texmed.org or Shannon Vogel, associate VP for health information technology, at shannon.vogel@texmed.org.

Sincerely,

Diana L. Fite, MD
President
Texas Medical Association