TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

March 28, 2022

Chief Clerk
Texas Department of Insurance
Austin, Texas

Via email: ChiefClerk@tdi.texas.gov

Re: Proposed amendments to 28 TAC §19.1803 and §19.1820, concerning Texas standard prior authorization request forms and the Texas standard prior authorization request form for prescription drug benefits, as published in the Texas Register at 47 TexReg 884-888 on February 25, 2022.

Dear Chief Clerk:

The Texas Medical Association (TMA) appreciates the opportunity to submit these comments on the Texas Department of Insurance's (TDI)'s proposed amendments to 28 TAC §19.1803 and §19.1820, concerning the Texas standard prior authorization request form for prescription drug benefits, as published in the Texas Register at 47 TexReg 884-888 on February 25, 2022.

TMA is a private voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its vision is to "Improve the health of all Texans." Its more than 56,000 members practice in all fields of medical specialization. It is located in Austin and has 119 component county medical societies around the state.

As TDI may know, TMA strongly supported the legislation underlying this rule proposal, as the use of prior authorization processes: (1) directly impacts patient access to coverage for care; and (2) imposes significant administrative burdens on physician practices. Having TDI prescribe a standard prior authorization form for prescription drug benefits is critical to making prior authorization processes more uniform, lessening the burden associated with their completion, and improving patient safety and access to care.

We appreciate the efforts of the Advisory Committee and TDI in reviewing the form for potential updates, and we offer the following specific comments on the proposed amendments to 28 TAC §19.1803 and §19.1820 (and the corresponding proposed amendments reflected in Rev. 10/2021 form).

1. **Proposed §19.1820(a)**

First, TMA notes that in §19.1820(a), TDI proposes amending the rule to adopt by reference the revised Texas Standard Prior Authorization Request Form for Prescription Drug Benefits, Rev. 10/2021. TMA has

some concerns with the language of the revised form. Please see TMA's specific comments and recommendations related to the form under the section of this letter entitled "Texas Standard Prior Authorization Request Form (Rev. 10/2021)."

Additionally, in §19.1820(a), TDI proposes striking language that currently makes the standard form and instruction sheet available from TDI by mail (along with language that includes a corresponding TDI mailing address). While it is likely that most physicians will access the form online, we recommend retaining the current TDI mailing address information in the rule for ease of access, particularly for any physician who may encounter technical issues in downloading or otherwise accessing the form online. Given the numerous prior authorization request requirements currently imposed by health plan issuers, it is important for TDI to facilitate access to the standard form through as many methods as possible.

2. **Proposed §19.1820(a)(3)**

Next, in §19.1820(a)(3), the current TDI rule requires the form to have "a place to request an expedited or urgent review if the prescribing provider of the prescribing provider's designee certifies that applying the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function."

TDI proposes amending (a)(3)'s current language to instead require the form to provide a space for:

> (3) identification of whether the review requested is an expedited/urgent review or a non-expedited/non-urgent review with a signature line for the prescribing provider or the prescribing provider's designee to certify:
> (A) in the case of a request for an expedited/urgent review, that applying the standard review time frame may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function;
> (B) in the case of a request for a non-expedited/non-urgent review, that applying the standard review time is medically appropriate.

TMA **opposes** this proposed change to the rule (and the corresponding changes in the form), as we believe the added certification and signature requirement concerning the medical appropriateness of the standard review time is unnecessary, creates additional administrative burden, and could be perceived as improperly shifting responsibility regarding delays in prior authorization reviews from health plans to physicians.

While it makes sense for a physician or other appropriate prescribing provider to certify **an exception** to the standard review time and the potential need for an expedited/urgent review (as is currently required under the standard form), it does not make sense for a physician to have to make an additional certification of (and provide a signature certifying) the medical appropriateness of the **standard** review time.

Such an additional certification is unnecessary, because a form without a certified expedited/urgent review request presumably automatically defaults to processing under the standard review timeframes (without the need for an additional checked box or signature). Thus, the second check-the-box (and signature certification) requirement adds no needed direction to a plan or company processing a prior authorization request.

Instead, it merely presents an additional administrative burden for the physician or prescribing provider. And, if the physician or prescribing provider forgets to check the box and signs for the non-expedited/non-urgent review, it could unnecessarily delay processing of the entire form, as the health plan or utilization review agent would need to go back to the physician or prescribing provider to seek completion of those additional required fields. This proposed change, therefore, has the potential to delay medically necessary care and is at odds with the underlying goals of the legislation, which were "[t]o save time and streamline the prior authorization process…."[1]

Further, TMA is concerned that the second check-the-box and signature requirement concerning the medical appropriateness of the standard review time presents an improper forced choice to a physician or other prescribing provider who is seeking to use the form. To illustrate this point, there may be a circumstance in which a physician does not believe that the review request meets the potential harm threshold/standard for an expedited/urgent review (which requires certification that "the standard time frame may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function"). But the physician or prescribing provider may also not believe that it is medically appropriate for the plan to take the full standard review time to complete the prior authorization review.

The physician should not have to "certify" that "applying the standard review time frame ***is*** medically appropriate" in this circumstance. (emphasis added). Making such a certification may be inconsistent with the physician's best medical judgment and potentially could be used against the physician if there is a delay in medically necessary care resulting from the plan's prior authorization processing time.

Ultimately, the forced choice certification and signature requirement proposed in the rule could make a physician: (1) feel uncomfortable using the form altogether, which would severely undercut the utility of the form; or (2) more inclined to seek an urgent review to avoid any potential liability associated with signing off on the medical appropriateness of a standard review timeframe. Neither of these is a desired result or is consistent with the intent of the underlying legislation. TMA, therefore, opposes the new language in the rule and form for this reason, in addition to the previously mentioned potential for the language to delay access to care and to impose an additional (and unnecessary) administrative burden on physician practices.

3. **§19.1820(a)(6)(G)**

Next §19.1820(a)(6)(G) of the rule currently states that the form provides space for the following information for a prescription drug:

> (G) whether the medication is:
> (i) a new therapy; or
> (ii) continuation of therapy, and if so, the approximate date therapy was initiated.

[1] *See* SB 644 (83rd Texas Legislature, Regular Session) author/sponsor's statement of intent in Senate Bill Analysis for SB 644; *available at*: BILL ANALYSIS (texas.gov)

The proposed rule would amend this language to "add a requirement that the prescribing provider or the prescribing provider's designee state, in the case of a request for continuation of therapy, whether the patient is complying with the drug therapy regimen and whether the drug therapy regimen is effective."[2]

The rationale for the proposed inclusion of these two new requirements (regarding patient compliance and drug regimen effectiveness) is not expressly stated in the rule preamble. However, in the "public benefit and cost note" in the preamble, TDI appears to hint that the rationale may be for the two new requirements to be completed in lieu of (or as a tradeoff for not) completing Sections VIII and IX of the form. More specifically, TDI states, in relevant part, the following:

> Lower costs for prescribers will result from the elimination of the required completion of certain elements in the form related to continuation of therapy. While some issuers expressed concern that the new fast-track continuation of therapy part of the form could make it harder for issuers to verify requests for continuation, lower costs for issuers could result from the addition of statements in the form for the prescribing provider or the prescribing provider's designee to designate whether the patient is complying with the drug therapy regiment and whether the drug therapy regimen is effective. This additional information could eliminate the need for the issuer to expend time and resources in obtaining that information after a continuation of therapy. Further the changes to the form do not prevent issuers from having their own form available for use.[3]

TMA strongly supports a reduction in the required completion of certain form fields related to continuation of therapy (i.e., Sections VIII and IX of the form). As TDI knows, the burdens of prior authorization have been growing, rather than decreasing over recent years. A 2020 TMA survey revealed that Texas physicians saw a drastic increase in prior authorizations over the past five years. In fact, 87% say this burden increased and nearly half (48%) of physicians had to hire staff solely to process prior authorization requests. Thus, **any** streamlining in the prior authorization process will have a positive impact on physician practices. But, streamlining by not requiring completion of Sections VIII and IX of the form when there is no material change will likely have a **dramatic impact** on physician practices (given the high volume of prior authorizations physicians currently complete for continuing drug therapies). Making such a change in the form would allow physicians to dedicate more of their time to direct patient care (rather than completion of redundant provisions in forms). Such an amendment to the form also is clearly consistent with intent of the underlying legislation "[t]o save time and streamline the prior authorization process…."[4]. Thus, TMA applauds TDI for proposing language in the form that states: "NOTE: For a request for prior authorization of continuation of therapy, it is not necessary to complete Sections VIII or IX unless there has been a material change in the information previously provided."

TMA contends, however, that if there is no material change in the information previously provided in Sections VIII or IX of the form (i.e., the Sections concerning patient clinical information and justification, respectively), those sections should not have to be completed -- period. TMA does not believe that TDI

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[2] 47 TexReg 884.
[3] 47 TexReg 885.
[4] *See* SB 644 (83-R) author/sponsor's statement of intent in Senate Bill Analysis for SB 644; *available at*: BILL ANALYSIS (texas.gov)

needs to add the two new proposed requirements (regarding drug effectiveness and patient compliance) to justify the removal of the requirements to complete Sections VIII and IX for continuing therapies when there is no material change to the information previously provided in those sections.

Presumably, a physician would not seek another prior authorization to continue a therapy if the physician believes the drug therapy regimen is ineffective for the patient. And the health plan should have information available regarding the patient's compliance with the drug (without requiring a physician's statement to that effect). Further, even if a patient is not fully compliant (for various reasons), it may still be medically necessary and appropriate to prescribe the drug regimen for which the prior authorization is being sought. There may be justifiable and/or temporary reasons for a patient's lack of compliance with an appropriately prescribed drug regimen. Thus, these two newly proposed requirements provide an unnecessary additional burden to physicians in completing the form.

TMA, therefore, recommends that TDI:

- **adopt a change in the form (*with a corresponding change in the rules*) to provide that "For prior authorization of continuation of therapy, it is not necessary to complete the fields in Sections VIII or IX of the form unless there has been a material change in the information previously provided;"**
- **not adopt the two new required statements (concerning patient compliance and drug regimen effectiveness) in proposed §19.1820(a)(6)(G)(ii)((II) and (III) or their corresponding language in the form.**

Should TDI, however, believe that the two components of §19.1820(a)(6)(G)(ii)(II) and (III) are critical as trade-offs to being relieved from completing Sections VIII and IX of the form for continuing therapies, then TMA recommends that TDI make certain modifications to the proposed language of these provisions. As currently drafted, the proposed language would inappropriately require the physician to make absolute representations concerning patient compliance and drug effectiveness, which the physician may not know with 100% certainty.

For example, a physician may have relevant patient compliance information (such as information that a patient is filling their prescriptions as reported by the pharmacy or as reported by the patient directly in follow-up appointments), but that information does not guarantee that the patient is actually taking the medication (i.e., "is complying"). Similarly, the practice of medicine is always evolving, thus what is believed to be effective or ineffective at one point in time (based upon the available information) may change with additional information acquired at a later date.

Taking these concerns into consideration, TMA recommends that, if TDI moves forward with the concept for the language in §19.1820(a)(6)(G)(ii)(II) and (III), it modifies the language to include the following knowledge qualifiers (similar to the language found in §19.1820(a)(7) and in the current standard form in other places):

(G) to the best of the prescribing provider's knowledge, whether the medication is:
(i) a new therapy; or

(ii) a continuation of therapy, and if so, to the best of the prescribing provider's knowledge:
(I) the approximate date therapy was initiated;
(II) whether the patient is complying with the drug therapy regimen; and
(III) whether the drug therapy regiment is effective.

These small, but very important, amendments would better align the rule with other provisions in the rule (e.g., §19.1820(a)(7)**)** and are likely to make physicians more comfortable responding to these fields as part of the tradeoff for not responding to Sections VIII and IX of the form for continuing drug therapies. TMA also recommends that corresponding changes (i.e., inserting knowledge qualifiers) be made to the form itself, if TDI moves forward with his approach in the rules.

Finally, it is important to note that TMA would strongly oppose the two additional requirements in §19.1820(a)(6)(G)(ii)(II) and (III) (even with the aforementioned modifications) ***if they were stand-alone new additions without any corresponding benefit in relief from completing the fields in Sections VIII and IX of the form adopted at the same time*** (as, on their own,) the requirements in §19.1820(a)(6)(G)(ii)(II) and (III) would: (1) increase, rather than decrease the administrative burdens of physicians completing the standard prior authorization form; (2) depart from the typical required elements included on prior authorization forms; and (3) not appropriately recognize that it may be medically necessary and appropriate to provide a drug therapy regimen to a patient who is not fully compliant.

4. **§19.1820(c)**

Next, if TDI adopts any revisions to the standard prior authorization request form for prescription drug benefits, TMA would support amending the rules in §19.1820(c) to require an issuer to accept both the old form and the newly revised form for a defined time after the effective date. This type of transition amendment would help to reduce the disruptive impact that an abrupt change in forms might otherwise have on patients and physicians. It will understandably take some time for physicians to become aware of the new form (even with anticipated educational efforts by TMA to promote awareness). TMA, however, recommends that TDI provide 120 days, rather than 90 days as an appropriate transition period during which both the new and old forms may be used by physicians and other prescribing providers.

5. **Texas Standard Prior Authorization Request Form** (**Rev. 10/2021)**

a. Section II of Rev. 10/2021

TMA recommends that TDI **not** adopt the proposed changes in Section II of Rev. 10/2021, which include a new check-the-box requirement and signature certification for non-expedited /non-urgent reviews. TMA hereby incorporates by reference all the reasons stated in Section 2 of this comment letter (concerning Proposed §19.1820(a)(3)) as the basis for our recommendation on this Section of the form.

b. Section V of Rev. 10/2021

Next, TMA s**trongly recommends** that TDI adopt the following proposed language in Section V. of Rev. 10/2021: "NOTE: For a request for prior authorization of continuation of therapy, it is not necessary to complete Sections VIII or IX unless there has been a material change in the information previously provided." TMA hereby incorporates by reference all the reasons stated in Section 3 of this comment letter (concerning Proposed §19.1820(a)(6)(G)) as the basis for our recommendation on this critical component of the form.

Finally, TMA recommends that TDI follow TMA's recommendations stated in Section 3 of this comment letter (concerning Proposed §19.1820(a)(6)(G)) and hereby incorporated by reference) with regard to the proposed patient compliance and drug regimen effectiveness amendments to Section V of the form.

Conclusion

Once again, the Texas Medical Association thanks you for the opportunity to provide these comments. If you should have any questions or need any additional information, please to contact me or following staff of the TMA: Kelly Walla, Associate Vice President and Deputy General Counsel; or Clayton Stewart, Vice President and Chief Lobbyist at TMA's main number 512-370-1300.

Respectfully,

E. Linda Villarreal, MD
President