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May 9, 2022

Texas Department of Insurance
333 Guadalupe
Austin, TX 78701

RE: Proposed Rules for 28 TAC §19.1730 - 19.1733 & 28 TAC §12.601 relating to the Prior Authorization Exemptions

Dear Ms. Brown,

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country, including our member society in Texas, formed to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our nationwide coalition serves practicing rheumatologists in charge of patient care for these illnesses.

CSRO was encouraged by the passage of HB 3459, and the ensuing draft rulemaking published by your office. We offer the following comments on the draft rule for your consideration.

§19.1731. Preauthorization Exemption (b) & (c)

TDI's proposed rule requires payers to "evaluate all preauthorization requests submitted… during the most recent evaluation period that were finalized" in determining whether a provider should be issued a preauthorization exemption. For providers with an existing preauthorization exemption, TDI's proposed rule requires that a random sample of "at least five and no more than 20 claims submitted during the most recent evaluation period."

CSRO believes there is lack of clarity within HB 3459 and the proposed rule on how preauthorization requests that are denied, but ultimately overturned on appeal, should be categorized by a payer with respect to the pool of claims used to make the determination of whether to grant or rescind an exemption. Similarly, there is a lack of clarity on how exception requests related to services with preauthorization requirements should be categorized for the purposes of this determination.

Paragraph (b) of this section indicates that requests pending appeal should not be included in the pool used to make the aforementioned determination. This ***suggests*** that appeals and exception requests which have been adjudicated should be included in the pool used by the payer, but this is not explicitly stated in either HB 3459 or the proposed rule. **CSRO encourages the department to explicitly require inclusion of finalized appeal and**

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exception requests within the pool analyzed by payers to issue exemption determinations.

Inclusion is crucial to ensure that preauthorization requirements that are incorrectly applied do not form the basis of a denial or recission of a preauthorization exemption, the purpose of which is to reduce the burden of unnecessary preauthorization requirements. Otherwise, payers may be further incentivized to issue an upfront denial of care in order to avoid having to issue preauthorization exemptions.

§19.1730. Definitions
(6) Particular health care service

The Texas Department of Insurance's proposed rule defines a particular health care service to include prescription drugs subject to prior authorization. This clarification of HB 3459 is consistent with the legislation's intent, and CSRO encourages the department to finalize this definition.

(8) Preauthorization & (9) Preauthorization exemption

TDI's proposed rules aligns the definition of preauthorization with the definition provided by HB 3459. Accordingly, the proposed rule indicates that a preauthorization requirement constitutes a "determination by a health maintenance organization, insurer… that health care services proposed to be provided to a patient are medically necessary and appropriate.[1]" Providers granted a "Preauthorization exemption" are thus not subject to determinations by a payer that a particular health care service is medically necessary and appropriate.

While this is sensible on face value, and CSRO does not recommend amending the definitions themselves, conceptual and operational overlap between the term "preauthorization" and other utilization management techniques, such as step therapy, may cause confusion regarding how preauthorization exemptions may be applied among providers and payers alike.

Step therapy protocols require enrollees to use a prescription drug or sequence of prescription drugs prior to providing coverage for a drug recommended by the enrollee's physician.[2] This required sequence of drugs is largely based on the financial preference of the payer, but also implicitly serves as a test of the medical necessity and appropriateness of non-preferred therapies vs. preferred ones. Requirements to obtain preauthorization for prescription drugs are a common means by which payers enforce the step therapy protocol's sequencing requirements.

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[1] Sec. 4201.651. DEFINITIONS. (a)
[2] https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1369.htm#1369.0546

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As such, providers are likely to face situations where they are afforded an exemption to the operational means through which a payer enforces additional layers of utilization management screening, but not necessarily the additional layers of utilization management screening themselves. A provider may logically conclude that their exemption from the determination by a payer "that health care services proposed to be provided to a patient are medically necessary and appropriate" extends to a step therapy protocol which also provides this test for services that are of like use, but different financial preference for the payer. If this is not the case, and the payers continue to enforce step therapy protocols when a preauthorization exemption exists, providers may end up on the hook for the provision of these services due to lack of clarity on the interaction between preauthorization exemptions and these techniques. This would induce a chilling effect on use of preauthorization exemptions for services with additional layers of medical necessity or utilization management screening that undermines the intent of providing the exemption. **To avoid this outcome, CSRO urges TDI to clarify how a preauthorization exemption interacts with step therapy requirements and other like utilization management techniques in its final rule.**

If TDI determines that a preauthorization exemption does not extend to utilization management techniques that share the purpose of preauthorization as defined in the proposed rule and state law, it begs the question of the underlying purpose of issuing exemptions for large swaths of prescriptions drugs or other restricted services. Seemingly, a payer could circumvent a preauthorization exemption through the use of a substantially similar utilization management program layered within or on top of preauthorization requirements that is textually but not functionally distinct. **CSRO encourages TDI to provide clarity on how preauthorization can be substantively distinguished from utilization management techniques of like character, and how it will enforce the law against attempts to re-characterize preauthorization programs.**

Thank you for your consideration of these comments. If you require additional information, please do not hesitate to contact us.

Respectfully,

Madelaine Feldman, MD, FACR
President, CSRO